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NUCLEAR LEGISLATION: ANALYTICAL STUDY

Regulatory and Institutional Framework for Nuclear Activities

NUCLEAR ENERGY AGENCY
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Pursuant to Article 1 of the Convention signed in Paris on 14th December 1960, and which came into force on 30th September 1961, the Organisation for Economic Co-operation and Development (OECD) shall promote policies designed:

- to achieve the highest sustainable economic growth and employment and a rising standard of living in Member countries, while maintaining financial stability, and thus to contribute to the development of the world economy;
- to contribute to sound economic expansion in Member as well as non-member countries in the process of economic development; and
- to contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations.

The original Member countries of the OECD are Austria, Belgium, Canada, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The following countries became Members subsequently through accession at the dates indicated hereafter: Japan (28th April 1964), Finland (28th January 1969), Australia (7th June 1971), New Zealand (29th May 1973), Mexico (18th May 1994), the Czech Republic (21st December 1995), Hungary (7th May 1996), Poland (22nd November 1996) and the Republic of Korea (12th December 1996). The Commission of the European Communities takes part in the work of the OECD (Article 13 of the OECD Convention).

NUCLEAR ENERGY AGENCY

The OECD Nuclear Energy Agency (NEA) was established on 1st February 1958 under the name of the OEEC European Nuclear Energy Agency. It received its present designation on 20th April 1972, when Japan became its first non-European full Member. NEA membership today consists of 27 OECD Member countries: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, Norway, Portugal, Republic of Korea, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The Commission of the European Communities also takes part in the work of the Agency.

The mission of the NEA is:

- to assist its Member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purposes, as well as
- to provide authoritative assessments and to forge common understandings on key issues, as input to government decisions on nuclear energy policy and to broader OECD policy analyses in areas such as energy and sustainable development.

Specific areas of competence of the NEA include safety and regulation of nuclear activities, radioactive waste management, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information. The NEA Data Bank provides nuclear data and computer program services for participating countries.

In these and related tasks, the NEA works in close collaboration with the International Atomic Energy Agency in Vienna, with which it has a Co-operation Agreement, as well as with other international organisations in the nuclear field.

AUSTRALIA

I. GENERAL REGULATORY REGIME

1. Introduction

Australia's basic nuclear legislation consists of five Acts passed by the Federal Government, three in 1986-1987, the fourth (a major piece of amending legislation) in 1992 and the fifth in 1998. The first two Acts were prompted by the need for domestic legislation to implement Australia's international obligations. The third arose from a long-standing recognition that the Atomic Energy Act 1953 was inappropriate as the legislative basis for the activities of Australia's national nuclear organisation. The three principal Acts are:

- the South Pacific Nuclear Free Zone Treaty Act [No. 140 of 1986];
- the Nuclear Non-Proliferation (Safeguards) Act [No. 8 of 1987];
- the Australian Nuclear Science and Technology Organization Act [No. 3 of 1987].

In 1992, the government recognised that the Australian Nuclear Science and Technology Organization Act required some changes. As a result, several amendments were made to the Act by the Australian Nuclear Science and Technology Organization Amendment Act 1992 [No. 83 of 1992].

In 1998, a set of legislation consisting of three Acts in the field of radiation protection and nuclear safety was passed. The first of these Acts, Australian Radiation Protection and Nuclear Safety Act [No. 133 of 1998], which is a framework Act, establishes a regime to regulate the operation of nuclear installations and the management of radiation sources, where these activities are undertaken by Commonwealth entities. Act No. 134, Australian Radiation Protection and Nuclear Safety (Licenses Charges) Act, requires holders of both facility and sources licences to pay an annual charge, to be prescribed by regulation. Lastly, Act No. 135, Australian Radiation Protection and Nuclear Safety (Consequential Amendments) Act, repeals those provisions of the 1987 Australian Nuclear Science and Technology Organization Act which concern the Nuclear Safety Bureau, and the 1978 Environment Protection Act.

Each of these Acts will be discussed in more detail below but, briefly, their scope is as follows.

The South Pacific Nuclear Free Zone Treaty Act implements Australia's obligations under the Treaty. The manufacture, possession and testing of nuclear weapons in Australia is prohibited, as is research and development relating to the production of nuclear weapons.

The Nuclear Non-Proliferation (Safeguards) Act provides a legislative basis for Australia's safeguards system, implementing its obligations under both the Nuclear Non-Proliferation Treaty and the Convention on the Physical Protection of Nuclear Material.

The Australian Nuclear Science and Technology Organization Act transformed the Australian Atomic Energy Commission into the Australian Nuclear Science and Technology Organization (ANSTO). The change represented a move away from work on power generation and the nuclear fuel cycle, the basis of the Australian Atomic Energy Commission's charter, to focus instead on the development and utilisation of nuclear and associated technologies, concentrating in particular on radiation and radioisotope applications in medicine, industry, science and agriculture. ANSTO operates one nuclear reactor to further its research in these areas.

The Australian Radiation Protection and Nuclear Safety Act provided for the appointment of the Chief Executive Officer (CEO) of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), who is entrusted to perform functions and exercise powers under the Act. The Nuclear Safety Bureau, which had been responsible for monitoring and reviewing the safety of ANSTO's nuclear plant under the ANSTO Act, was abolished. The CEO regulates, through a licensing system, nuclear installations from the time at which plans are drawn up for their construction through all stages of operation until decommissioning, as well as the use of radiation sources. The Act also established the Radiation Health and Safety Advisory Council and two supporting Committees. The Council's tasks include advising the CEO on matters relating to nuclear safety and radiation protection.

In addition, the Atomic Energy Act [No. 31 of 1953] is still partly relevant. Although substantial parts of it were repealed in 1987 when ANSTO replaced the Australian Atomic Energy Commission, a few provisions remain which are significant in the context of the regulatory regime governing uranium mining in the Northern Territory.

Another relevant federal Act, discussed below, the Environment Protection (Sea Dumping) Act 1981 [Act No. 101 of 1981].

Because Australia is a federal system, with a division of power between the national (Commonwealth) government and the six state governments, the Commonwealth Government does not have the capacity to legislate on all aspects relevant to nuclear activities. For this reason it will be necessary to discuss state laws in some areas, for example, radiation protection and transport. In addition to the states, Australia has two internal Territories (the Northern Territory and the Australian Capital Territory) whose constitutional position is different from that of the states. Essentially, the Territories have fewer legislative powers than the states and are subject to Commonwealth intervention in areas where the states are not. The legislative framework that exists in relation to the mining of uranium in the Northern Territory, is an illustration of this situation: the law governing the operations of the Northern Territory's uranium mines is a combination of Commonwealth and territory law.

2. Mining Regime

Mining is an area over which the Commonwealth Government has no direct power under Australia's Constitution. However, it can exercise indirect control over uranium mining because it does have constitutional power over Australia's international trade and commerce [Constitution, Article 51(i)], and therefore has the power to regulate or prohibit exports and imports. The Customs (Prohibited Exports) Regulations, made under the Customs Act [No. 6 of 1901], forbid the export of uranium and other source material, including thorium bearing ores such as monazite, except with a permit from the Minister for Resources and Energy. In this way, the Commonwealth Government is able, in practice, to control the decisions of state governments and of mining companies as to the establishment of uranium mines.

The regulatory system covering uranium mining in the Northern Territory is complicated by the constitutional position of this Territory. Under the Australian Constitution, the Commonwealth Government has plenary legislative power over the Territories [Article 122]. In 1978, the national Parliament passed the Northern Territory (Self-Government) Act [Act No. 58 of 1978], which enabled the Northern Territory to elect its own legislature, and conferred general powers on that legislature. In respect of certain subject matters, however, such as Aboriginal affairs and uranium mining, the Commonwealth Government has retained control, though not necessarily to the total exclusion of a role for the Territory's own legislature.

The specific effects of this in relation to uranium mining in the Northern Territory are as follows:

- The Commonwealth has retained ownership of all uranium found in the Territory [Atomic Energy Act No. 31 of 1953, Section 35].

- All discoveries of uranium and thorium in Australia must be reported to the Commonwealth authorities within one month [Atomic Energy Act, Section 36].

- The Ranger uranium mine venture is authorised by the Commonwealth Minister for Resources and Energy [Atomic Energy Act, Section 41].

In addition, the Commonwealth has passed environmental protection legislation to cover the region containing both the Ranger and the Nabarlek uranium deposits. This Act, the Environment Protection (Alligator Rivers Region) Act 1978 [Act No. 28 of 1978], provides for the appointment of a Supervising Scientist, who is to report and provide advice to the Commonwealth Minister for the Environment on the environmental effects of uranium mining in the region [Section 5].

However, the Northern Territory legislature is not entirely excluded from the field of uranium mining. The Northern Territory Mining Act [No. 15 of 1980] establishes a system of licences and leases for mineral exploration and mining, "minerals" being defined broadly enough to include uranium [Section 4(1)]. However, since the Commonwealth has retained ownership of uranium in the Northern Territory, the Northern Territory provides that an authorisation in relation to uranium mining can only be issued at the direction of the relevant Commonwealth Minister [Section 175]. The Northern Territory also has its own environmental legislation, specifically aimed at the uranium mining activities carried on in the Territory. The Uranium Mining (Environment Control) Act [No. 46 of 1979] applies to the whole of the region containing the Ranger and Nabarlek deposits. It stipulates that the owner or manager of any uranium mine within the region must appoint a qualified environment protection officer [Section 5]; mining and incidental activities can only be carried out if authorised by the Territory's Minister [Sections 8, 9, 10 and 12]; and the Minister may require the mine owner to rehabilitate land which has been affected by mining operations [Section 11]. The Act provides for inspectors to enforce compliance with the Act and with the conditions of ministerial authorisations [Section 19]. Contravention of the Act, of an authorisation or of an inspector's direction is a criminal offence [Section 27].

Uranium mining activities at Roxby Downs in South Australia are regulated primarily by South Australian legislation, the Roxby Downs (Indenture Ratification) Act 1982 (as amended). This Act ratifies the Olympic Dam and Stuart Shelf Indenture, a detailed agreement between the operator and the Government of South Australia. The Act deals with matters such as protection of the rights of the project, streamlining of some administrative procedures, approval of radiation protection codes, environmental protection requirements and enforcement of conditions. The Indenture overrides some general South Australian legislation, such as the Mining Act, by granting a special mining lease for the

Olympic Dam. Commonwealth regulation and involvement is minimal, with interaction generally restricted to participation in consultative arrangements. These were restructured in 1997 and now consist of two consultative committees, the Olympic Dam Environment Consultative Committee (ODECC) and the Community Consultative Forum (CCF). ODECC, consisting of representatives of the state, the Commonwealth and the operator of the mine, exchanges information on environmental and related matters affecting the Olympic Dam project. The CCF includes Aboriginal, pastoralist, environmentalist and Roxby Downs township representatives, and provides the mechanism for a regular flow of information to the public on the project's environmental performance.

In contrast to the situation in the Northern Territory and South Australia, two states have legislated to prohibit prospecting for and mining of uranium. Victoria passed its Nuclear Activities (Prohibitions) Act in 1983 [Act No. 9923] and New South Wales passed the Uranium Mining and Nuclear Facilities (Prohibitions) Act in 1986 [Act No. 194 of 1986]. Thus, even if the federal government changed its policy and relaxed its export restrictions, uranium mining would not be permitted within Victoria and New South Wales.

3. Radioactive Substances and Equipment

The regulation of radioactive substances and equipment used in the medical and industrial contexts is largely a matter for the states. Each state, the Northern Territory and the Australian Capital Territory has legislation establishing a permit or licensing system to cover the sale, use, possession, disposal, etc., of radiation apparatus and radioactive substances (for further details on this subject, see, *infra*, Section 6 "Radiation Protection").

4. Nuclear Installations

The Radiation Protection and Nuclear Safety Act [No. 133 of 1998] prohibits the construction or operation of nuclear fuel fabrication plants, nuclear power plants, uranium enrichment plants and reprocessing facilities. Australia, however, has one research reactor and radioactive waste management facilities. Under the Act, the Chief Executive Officer (CEO) of the Australian Radiation Protection and Nuclear Safety Agency is the major authority in the regulation of the safety of nuclear installations.

The CEO is empowered to issue facility licences which authorise controlled persons to prepare a site for, construct, have possession or control of, operate, decommission, dispose of, or abandon, nuclear installations. A "controlled person" means, under the Act, a Commonwealth entity or a person who has a contractual relationship with Commonwealth entity [Section 32]. The facility licence is issued subject to the condition that any licensee allow the CEO, or a person authorised by it, to enter and inspect the site and the facility, and comply with any requirements specified in the regulations in relation to such an inspection. The licence is also subject to the conditions prescribed by the regulations or imposed by the CEO at the time of issue or amendment [Section 35]. Licences remain in force until cancelled by the CEO or surrendered by licensees [Section 37]. Several cases in which the CEO may suspend or cancel a licence, including for breach of a condition of the license, are prescribed in the Act [Section 38]. Licence decisions made by the CEO can be reviewed by the Minister or the Administrative Appeals Tribunal at the request of applicants or licensees [Section 40].

The CEO may appoint an inspector who may enter any premises and exercise powers, with the consent of the occupiers of the premises or under a warrant issued by the magistrate in order to ensure compliance with this Act and the regulations [Sections 62 and 63]. An inspector may exercise powers

by searching premises, inspecting, examining, taking measurements of, or conducting tests concerning anything on the premises which relates to controlled material, apparatus or facility [Section 67].

In 1999, implementing Regulations of the Radiation Protection and Nuclear Safety Act (Statutory Rules No. 37) was proclaimed. They were amended by Statutory Rules No. 97 (for further details, see *supra* under Section 6 "Radiation Protection").

At the international level, Australia is a Party to the following conventions:

- 1994 Convention on Nuclear Safety, ratified on 24 December 1996;
- 1986 Convention on Early Notification of a Nuclear Accident, ratified on 22 September 1987; and
- 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, ratified on 22 September 1987.

5. Trade in Nuclear Materials and Equipment

Australia's trade in the uranium it produces is international, since there is no domestic nuclear power industry. As already mentioned, the Commonwealth Government exercises control over this trade by virtue of its constitutional power in relation to international trade and commerce. Specifically, the Customs (Prohibited Exports) Regulations, made under the Customs Act [No. 6 of 1901], prohibit the export of uranium unless the approval of the Minister for Resources and Energy has been obtained. The Minister's decision is affected by government policy and by the need to comply with Australia's obligations under, for example, the Non-Proliferation Treaty and the South Pacific Nuclear Free Zone Treaty.

6. Radiation Protection

In 1998, the Environment Protection (Nuclear Codes) Act [No. 32 of 1978], which aimed to provide for the protection of people and the environment from possible harmful effects associated with nuclear activities, was repealed. Under the new regime established by the Australian Radiation Protection and Nuclear Safety Act [Act No. 133 of 1998], the Chief Executive Officer (CEO) of the Australian Radiation Protection and Nuclear Safety Agency is the regulatory authority in this field.

The CEO may issue a radiation source licence which authorises controlled persons to deal with a controlled apparatus or material [Section 33 of the Act No. 133]. A "controlled apparatus" is defined as (a) an apparatus that produces ionising radiation when energised or that would, if assembled or repaired, be capable of producing ionising radiation when energised, (b) an apparatus that produces ionising radiation because it contains radioactive material or (c) an apparatus prescribed by the regulations that produces harmful non-ionising radiation when energised. "Controlled material" means any natural or artificial material, whether in solid or liquid form, or in the form of a gas or vapour, which emits ionising radiation spontaneously [Section 13]. The source licence is issued subject to the conditions that the licensee allow the CEO, or a person authorised by CEO, to inspect a controlled apparatus or material, and comply with any requirements specified in the regulations in relation to such an inspection [Section 35]. Sections 35, 37, 38, and 40 of the Act, which were described under Section 4 "Nuclear Installations" *supra*, are also applied to the delivery of source licenses.

As already said *infra* under Section 4 "Nuclear Installations", Radiation Protection and Nuclear Safety Regulations (Statutory Rules No. 37) were adopted in 1999 to implement the Act No. 133. They were amended by Statutory Rules No. 97. These Regulations covers, *inter alia*, facility and sources licences, exemptions and applications for licences. In this respect, they list matters that the CEO must take into account when issuing licences. Furthermore, the Regulations lay down the effective dose limit for occupational exposure, which is set at 20 mSv annually, averaged over five consecutive calendar years, and the effective dose limit for public exposure, set at 1 mSv annually.

The following Codes of Practice have been made under the Environment Protection (Nuclear Code) Act [No. 38 of 1978] and are currently reflected in state and territory law :

- Code of Practice on the Management of Radioactive Waste from the Mining and Milling of Radioactive Ores (1982);

- Code of Practice on Radiation Protection in the Mining and Milling of Radioactive Ores (1987);

- Code of Practice for the Safe Transport of Radioactive Substances (1990).

In addition to the Codes developed under the Environment Protection (Nuclear Codes) Act 1978, there are a number of other codes and standards relating to radiation protection which have been developed by organisations like the National Health and Medical Research Council, the National Occupational Health and Safety Council and Standards Australia (two such instruments were adopted in June 1995, based upon the 1990 Recommendations of the International Commission on Radiological Protection, Publication No. 60). Although states are not obliged to adopt these codes, most states incorporate them into their own radiation protection Acts.[1]

The Northern Territory and the Australian Capital Territory also have their own radiation protection legislation.[2]

Although these Acts are not identical, they have a common approach and their major elements are as follows:

- a permit or licence is required before a person can make, store, transport, sell, possess or use radioactive materials and radiation-emitting equipment;

- the permit will not be issued unless the responsible authority is satisfied that the person is properly trained and is in other respects a "fit and proper person";

- the permit is granted for a limited period and may be made subject to conditions. If a condition is breached, or the permit-holder contravenes the legislation, the permit may be revoked;

1. New South Wales: Radiation Control Act 1990; Queensland: Radioactive Substances 1958; South Australia: Radiation Protection and Control Act 1982; Tasmania: Radiation Control Act 1977; Victoria: Health (Radiation Safety) Act 1983; Western Australia: Radiation Safety Act 1975.

2. Australian Capital Territory: Radiation Act 1983; Northern Territory: Radiation (Safety Control) Act 1979.

- permit-holders must keep records indicating the nature, purpose, usage, manner of storage etc., of radioactive substances and radiation-emitting equipment in their possession;

- specified precautions must be adopted for the protection of workers and persons undergoing medical diagnosis or treatment;

- maximum limits of radiation dosage are prescribed for radiation workers and medical patients;

- controls are imposed on methods of radioactive waste disposal;

- compliance with the regulatory system is achieved through the appointment of inspectors with statutory powers to enter and search premises and to collect information;

- contraventions of the relevant Act or regulations are criminal offences.

With regard to the specific issue of radiation protection in relation to uranium mining, the Northern Territory Mines Safety Control (Radiation Protection) Regulations [S.I. No. 30 of 1981] set safety standards by direct reference to the Code of Practice on Radiation Protection in the Mining and Milling of Radioactive Ores (as amended from time to time). In addition, it sets out its own safety precautions, imposing detailed duties on the owner and the manager of the mine and on the employees at the mine. The owner's responsibilities include ensuring that new employees are instructed in the radiation risks in their work and how to avoid them; that regular inspections of safety facilities are made and recorded; that a radiation safety officer, responsible to the manager, is appointed; and that the health of employees is monitored regularly [Section 4]. Duties are also imposed on the employees; they are obliged to report any defect which may contribute to a radiation hazard, use the protective equipment that is provided to them and submit to health assessments as required by the Code [Section 5]. A person who contravenes any of the Regulations, whether owner, manager or employee, is guilty of an offence and may be fined.

7. Radioactive Waste Management

Management of radioactive waste in Australia is the responsibility of the government in whose jurisdiction it is produced. Australia's radioactive waste comes from two main sources: mining activities and the use of radionuclides in research, medicine and industry.

Waste from uranium mining activities is managed and disposed of near the site of origin at the cost of the mine operator and in accordance with the requirements of the Code of Practice on the Management of Radioactive Wastes from the Mining and Milling of Radioactive Ores (1982). These requirements have been incorporated in the Northern Territory's Mines Safety Control (Radioactive Wastes Management) Regulations and, by reference, in South Australia's Roxby Downs (Indenture Ratification) Act.

Low-level and short-lived intermediate-level radioactive waste resulting from research and the medical and industrial uses of radionuclides is at present held at approximately 50 temporary storage sites throughout Australia. Phase 3 of a Commonwealth study to select a suitable site for near-surface disposal of this waste has been suspended pending consideration of the findings of a Senate select committee inquiry into radioactive waste management in Australia. The 1992 amendments to the ANSTO Act added to ANSTO's functions that of conditioning, managing and storing radioactive materials and waste, but only if the materials or waste had arisen either from ANSTO's own activities

or from the activities of persons specified in the regulations [ANSTO Act, Section 5(1)]. The Act specifically states that ANSTO's premises are not to become a permanent national nuclear waste repository [Section 5(1)(a)]. The Code of Practice for the Near-Surface Disposal of Radioactive Waste in Australia (issued in 1992 by the National Health and Medical Research Council) sets out requirements for siting, design and operation of a new near-surface disposal facility.

One state, Western Australia, has established its own near surface disposal facility for low level radioactive waste. Regulations made under Western Australia's Radiation Safety Act 1975 have incorporated the requirements of the Code of Practice for the Near-Surface Disposal of Radioactive Waste in Australia.

The storage and disposal of radioactive substances and apparatus are also addressed by the Code of Practice for the Disposal of Radioactive Wastes by the User (1985) and by the radiation control Acts and Regulations of the states and territories.[3]

The Commonwealth's Environment Protection (Sea Dumping) Act [No. 101 of 1981] regulates the dumping at sea of radioactive material. Until 1986, the Act prohibited dumping of high level radioactive waste, but allowed dumping under permit of other radioactive wastes and materials. In 1986 amendments were made to the Act following Australia's ratification of the 1972 Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (the London Convention, ratified on 21 August 1985) and of the 1985 South Pacific Nuclear Free Zone Treaty (the Rarotonga Treaty, ratified on 11 December 1986). The result of the amendments is that all dumping of radioactive material in Australia's territorial sea is now prohibited [Section 9(a)].

"Radioactive material" is defined as material that has an activity of more than 35 becquerels per gram [Section 4(1)]. If radioactive material is dumped in contravention of the Act, the owner and the person in charge of the vessel, aircraft or platform from which the dumping occurred are both guilty of an offence, as is the owner of the material dumped [Section 9(a)]. The amendments did not alter the exemptions contained in the original Act. The Act does not apply to the disposal of wastes arising from exploration and exploitation of seabed mineral resources [Section 5], nor does it apply in relation to a vessel, aircraft or platform belonging to the defence forces of Australia or of a foreign country [Section 7].

In September 1995 Australia signed the 1995 Convention to Ban the Importation into Forum Island Countries of Hazardous and Radioactive Wastes and to Control the Transboundary Movement and Management of Hazardous Wastes with the South Pacific Region (Waigani Convention).

8. Non-Proliferation and Physical Protection

Australia ratified the following international instruments:

- the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 23 January 1973;
- the 1985 South Pacific Nuclear Free Zone Treaty on 11 December 1986;

3. New South Wales: Radiation Control Act 1990; Queensland: Radioactive Substances Act 1958; South Australia: Radiation Protection and Control Act 1982; Tasmania: Radiation Control Act 1977; Victoria: Health (Radiation Safety) Act 1983; Western Australia: Radiation Safety Act 1975; Australian Capital Territory: Radiation Act 1983; Northern Territory: Radiation (Safety Control) Act 1979.

- the 1996 Comprehensive Nuclear Test Ban Treaty on 9 July 1998; and

- the 1979 Convention on the Physical Protection of Nuclear Material on 22 September 1987.

Other relevant international instruments are Australia's safeguards agreement of 10 July 1974 with the International Atomic Energy Agency (IAEA), and Australia's bilateral nuclear safeguards agreements with individual countries and Euratom.

The Nuclear Non-Proliferation (Safeguards) Act [No. 8 of 1987] and the South Pacific Nuclear Free Zone Treaty Act [No. 140 of 1986] establish the legal framework that is required at a national level by the Non-Proliferation Treaty and the South Pacific Nuclear Free Zone Treaty. An account of each of these elements now follows.

a) Bilateral Safeguards Agreements

The Commonwealth Government permits exports of nuclear material only to countries with which Australia has concluded a bilateral safeguards agreement. These agreements are designed to guarantee that Australian uranium can be used only in the civil nuclear fuel cycle of the importing state. This state undertakes that:

- Australian obligated nuclear material will not be used in the manufacture of nuclear weapons or other nuclear explosive devices, or in related research or development;

- Australian obligated nuclear material will not be used for any military purpose;

- Australian obligated nuclear material will be covered by IAEA safeguards;

- fallback safeguards will apply if at any stage IAEA safeguards cease to operate;

- the enrichment of Australian uranium beyond 20% U^{235}, the reprocessing of spent fuel from Australian uranium, or the retransfer of Australian uranium to another country will not occur without prior Australian consent;

- physical security to internationally agreed levels to prevent theft of nuclear material will be applied;

- it will participate in consultations with Australia, as and when required, particularly in respect of reprocessing and plutonium use questions.

Each of these bilateral agreements is supplemented by an administrative arrangement which sets out details as to the manner in which the obligations under the agreement are to be performed, including arrangements for accounting for Australian obligated nuclear material as it passes through each phase of the recipient's fuel cycle.

b) International Atomic Energy Agency Safeguards Agreement

In 1974 Australia concluded a safeguards agreement with the IAEA, as required by the Treaty on the Non-Proliferation of Nuclear Weapons. Although the main function of the Agreement is to

establish a system of safeguards to apply to nuclear material within Australia, it also requires Australia to notify the IAEA of intended transfers of material subject to IAEA safeguards out of Australia. On 23 September 1997 Australia signed a Protocol supplementing and strengthening its basic safeguards agreement with the IAEA, based on the Model Protocol developed by the IAEA's Programme 93+2.

c) The South Pacific Nuclear Free Zone Treaty Act

The South Pacific Nuclear Free Zone Treaty Act [No. 140 of 1986] gives effect to all the substantive provisions of the Treaty. Its main provisions are contained in Part II (a series of prohibitions relating to nuclear explosive devices) and in Part IV (dealing with inspections to ensure Australia's compliance with the Treaty).

Part II of the Act prohibits the manufacture, production and acquisition of nuclear explosive devices [Section 8]. Research and development directed towards the manufacture of a nuclear explosive device is forbidden [Section 9], as is the possession of, or control over, such a device [Section 10]. It is an offence to station a nuclear explosive device in Australia [Section 11] or to carry out a test of such a device [Section 12]. Section 14 extends all these offence provisions to acts occurring outside Australia if those acts are committed by a commonwealth, state or territory government or government authority, or if those acts are committed on an Australian ship or aircraft. However, the Act does not seek to affect the visits of foreign ships or aircraft visiting Australia, navigating through Australian waters or flying through Australian airspace [Section 15]. The penalty for any of these offences is, in the case of an individual, a fine of Australian dollars (AUD) 100 000, a gaol term of 20 years, or both, and, in the case of a body corporate, a fine of AUD 500 000 [Section 16].

Part IV of the Act provides for the appointment of special Treaty inspectors to investigate a complaint brought against Australia under the Treaty [Section 19]. While the Treaty inspectors are given certain powers to enter premises with the consent of the owner or occupier, to examine, take samples, make copies of documents, etc. [Section 22], it is envisaged that their inspections will be facilitated by Australian inspectors who have been appointed under the Nuclear Non-Proliferation (Safeguards) Act [No. 8 of 1987]. These Australian inspectors are given extensive powers, for example, to apply to a magistrate for a search warrant [Section 21] and to require information from a person suspected of committing an offence against the Act [Section 24].

d) The Nuclear Non-Proliferation (Safeguards) Act

Until the enactment of the Nuclear Non-Proliferation (Safeguards) Act [No. 8 of 1987], those aspects of the Non-Proliferation Treaty which required domestic implementation through control of the possession, use and transport of nuclear material were dealt with by means of the Customs Act [No. 6 of 1901] and regulations made under it, and by relying on co-operation from holders of nuclear items. The Safeguards Act now regulates the possession, use and transport of nuclear items in Australia. There are express provisions in the Act stating that its objects are to give effect to certain obligations under the Non-Proliferation Treaty and the Physical Protection Convention [Section 3], and that the Act will be administered in accordance with these Treaties [Section 70].

The Act establishes a national system regulating the possession of nuclear material, equipment and technology. In practice, the bodies chiefly affected by this system are uranium mining companies and ANSTO. The Act seeks to subject all nuclear material and associated items within Australia to a system of stringent and detailed controls.

"Nuclear material" is defined in Section 4(1) to mean any source or special fissionable material, as defined in Article XX of the IAEA Statute, but not including ore or ore residue. "Associated item" means associated material, associated equipment or associated technology [Section 4(1)]. Broadly speaking, this means:

- material of a kind specially suited for use in the construction or operation of a nuclear reactor;

- equipment or plant that is specially suited to the production of nuclear weapons or for use in other nuclear activities; and

- information (other than information available to the public) that is applicable primarily to nuclear weapons or to equipment for the enrichment of nuclear material, the reprocessing of irradiated material, or the production of heavy water [Section 4(1)].

The Minister has the power to exempt certain nuclear material and associated items from the Act [Section 11] and this has been done under the Nuclear Non Proliferation (Safeguards) Regulations [S.I. No. 75 of 1987]. The regulations exempt, for example, depleted uranium and heavy water in non-nuclear use; thorium incorporated in electronic components and aircraft parts; source material incorporated in ceramic glazes; source material contained in certain chemical mixtures in which the uranium or thorium content is less than 0.05% of the weight of the mixture [Regulation 3].

The principle underlying the safeguards system is that every possession, use and transportation of nuclear material covered by the Act is prohibited unless it is carried out under a permit granted by the Minister for Foreign Affairs [Sections 13 and 16]. The procedure is described below.

A person may apply for a permit to the Director of Safeguards, who may request more information from the person. The Director then makes a report to the Minister in relation to the application [Section 12]. The Minister may not grant the permit unless the applicant has provided all the information required by the Director, and the Director is satisfied that:

a) appropriate procedures can be applied at the nuclear facility concerned for the implementation of the Australian safeguards system; and

b) adequate physical security can be applied to nuclear material and associated items at the facility [Section 14].

If the Minister grants the permit, it may be made subject to conditions and restrictions [Section 13(2)]. Commonly, the conditions will specify the following matters [Section 13(3)]:

- precisely what material is covered by the permit;

- the period of time for which the permit is valid;

- the procedures which must be followed if the material is to be transported (including notifying the Director or Minister);

- the measures which must be taken to ensure the physical security of the material;

- who is to be allowed access to the material;

- the steps to be followed, and the records to be kept, in order to account for the material;
- the permitted uses of the material;
- the inspections which must be permitted in relation to the material;
- the conditions under which any transfer of the ownership, possession or control of the material may take place;
- in the case of a permit to possess information covered by the Act restrictions on the communication of that information.

Similar procedures apply in relation to a transport permit and an authority allowing the communication of information that comes within the definition of "associated item" [Section 4(1)]. A permit to allow nuclear material to be moved from one specified location to another may be subject to conditions stipulating the means of transport, the route, physical security measures, records to be kept, reports to be made etc. [Section 16]. In the case of communication of information, an authority may be given subject to restrictions as to precisely what information may be passed on, to whom it may be given, and within what time period it may be given [Section 18].

Further control can be exercised over the holders of permits and authorities by means of ministerial orders and directions [Section 73]. Broadly speaking, these may deal with the same matters as those that are dealt with by the conditions which may be attached to a permit or authority (for example, requirements as to physical security measures to be taken, the permitted uses of the nuclear material, etc.).

If the holder of a permit or authority contravenes one of the conditions attaching to it, or a direction under Section 73, or is convicted of an offence against the Act, the permit or authority may be revoked by the Minister [Section 19]. A further deterrent is that any contravention of a condition or a Section 73 order or direction is itself an offence against the Act [Section 25], punishable by a fine or a gaol term or both. The Act also ensures that safeguards can be maintained even if the permit-holder has failed to carry out his or her obligations. In such a situation, the Director may authorise an inspector to do anything necessary to ensure compliance with the condition, order or direction that has been contravened [Section 68]. Any costs incurred by the Commonwealth as a result of the inspector's actions become a debt due to the Commonwealth by the permit-holder [Section 68(4)].

The safeguards system established by these provisions is supported by the creation of a number of offences. The basic offence is that of possessing nuclear material or an associated item without a permit granted under Section 13 or 16. The offence provision [Section 23] is drafted so as to extend to possession outside Australia if the material is on an Australian ship or aircraft or is in the course of a journey which began at a place in Australia. The communication of information covered by the Act without an authority under Section 18 is also made an offence [Section 26]. The Act creates several other related offences, all punishable by a fine, a term of imprisonment or both [Sections 25 and 28-31]. As is usual in Commonwealth law, the fine incurred by a company may be up to five times higher than the amount of the fine incurred by an individual.

Two final points should be noted regarding the permit and authority system. The first is that where the Minister has made an adverse decision (for example, refusing to grant a permit or revoking a permit), the person affected must be given reasons for the decision and has the right to have the decision reviewed by an independent administrative tribunal, which has the power to overturn the Minister's decision [Section 22]. The second point concerns the relationship between the system of

permits and authorities established under this Act, and any state or territory law that regulates radioactive substances, etc. The Commonwealth Act makes it quite clear that its requirements are additional to any that may exist under state law; the granting of a permit under this Act does not excuse the permit-holder from complying with relevant state law [Section 21].

In addition to establishing this system of permits and authorities, the Safeguards Act gave statutory recognition to the Australian Safeguards Office and the Director of Safeguards. The functions of the Director include ensuring the effective operation of the permit system, carrying out Australia's safeguards obligations under its agreement with the IAEA and its bilateral agreements, and monitoring compliance by Australia's partners in those bilateral agreements [Section 43].

Australia's agreement with the IAEA requires Australia to ensure that inspections in Australia can be carried out by the Agency. The Safeguards Act provides both for the appointment of Australian inspectors to ensure compliance with the Act and the Regulations, and also for the recognition by the Minister of inspectors who have been designated by the Agency for the purpose of making Agency inspections [Section 57].

Agency inspectors have powers to examine, take samples, verify the proper functioning of equipment, take measurements, install or operate a containment device or a surveillance device, take extracts from records and other documents, as well as a general power to do anything necessary to carry out an Agency inspection [Section 60]. Their powers are more limited than those of the Australian inspectors; for example they have no powers to enter premises without the consent of the owner. However, the Act provides that one of the functions of a local inspector is to facilitate an inspection by an Agency inspector [Section 59(1)(e)]. The Act envisages situations where a local inspector will obtain a search warrant [Section 59(6)] for the purpose of facilitating an Agency inspection, and the Agency inspector will then accompany the local inspector to the premises or land in question and carry out an Agency inspection [Section 60(3)].

The Safeguards Act contains a Division creating a number of offences relevant to the Physical Protection Convention. It is an offence to steal nuclear material or obtain it by false pretences [Section 33], to demand it by threats [Section 34] or to use or threaten to use it to cause serious personal injury and substantial property damage [Section 36]. These offences are punishable by a maximum fine of AUD 20 000 or imprisonment for a maximum of ten years or both. In addition, a court convicting a person of one of these offences may order the forfeiture of any article used in the offence [Section 39].

One of the regulation-making powers under the Act concerns the making of standards for the physical security to be applied with respect to nuclear material and associated items [Section 74(f)].

Finally, it should be noted that the Australian Radiation Protection and Nuclear Safety Act 1998 does not exclude the implementation of the Nuclear Non-Proliferation (Safeguards) Act. For example, a controlled person may be required by 1998 Act to hold a licence, and by 1987 Act to hold a permit, in respect of the same thing. The controlled person must satisfy the requirements of both Acts in so far as they are capable of being satisfied concurrently [1998 Act, Section 9].

9. Transport

As previously mentioned, the Commonwealth controls the import and export of radioactive substances and requires a permit to be obtained before such substances can either leave or enter Australia [S.I. No. 90 of 1956 (dealing with imports) and S.I. No. 5 of 1958 (dealing with exports)].

In relation to transport within Australia, the Nuclear Non-Proliferation (Safeguards) Act [No. 8 of 1987] provides that conditions may be attached to a permit to possess nuclear material and that they may set out the procedures to be followed if the material is to be transported from one location to another [Section 13(3)(c)]. The Act also provides for a special transport permit, which may have detailed conditions attached to it [Section 16].

The Commonwealth has formulated a Code of Practice for the Safe Transport of Radioactive Substances. Originally formulated in 1982 and revised in 1990, the Code adopts the IAEA Regulations for the Safe Transport of Radioactive Material. Different aspects of the Code are now reflected in various pieces of legislation dealing with different types of transport.

Transport of dangerous goods by sea is covered by the Navigation Act 1912 [No. 4 of 1913] and by regulations made under it.

Transport of dangerous goods by air is covered by the Crimes (Aviation) Act 1991 [No. 139 of 1991] and by regulations made under it.

The regulation of land transport is, generally speaking, a matter for States and Territory governments. The Code of Practice, insofar as it applies to land transport, is implemented by the States and Territories through regulations made under their respective transport Acts. As mentioned previously, requirements imposed by the States regarding the possession and transport of nuclear material operate in addition to those imposed under the Commonwealth's Safeguards Act (provided, of course, that the state requirements are not inconsistent with those of the Commonwealth).

10. Nuclear Third Party Liability

There are no specific provisions in Australian legislation governing nuclear third party liability. Moreover, Australia is not a party to any of the conventions on nuclear third party liability.

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities

a) Minister for Resources and Energy

The Minister for Resources and Energy has the power to allow or disallow the movement of uranium and other source material out of Australia. The Customs (Prohibited Exports) Regulations, made under the Customs Act [No. 6 of 1901], forbid the export of uranium products except with a permit from the Minister [Regulation 11].

The Minister is also responsible for those provisions of the Atomic Energy Act [No. 31 of 1953] which remain in force. All discoveries of uranium and thorium in Australia must be reported to the

Minister within one month [Section 36]. Provision is also made in this Act for the Minister to represent the Commonwealth's continuing interests in the Ranger uranium mining venture in the Northern Territory. Section 41 provides that the Minister may authorise a person to carry on operations in the Ranger Project Area on behalf of or in association with the Commonwealth and the Minister may vary or revoke the authority if satisfied that its conditions are not being met [Section 41(a)]. A person who has been given the authority may not assign his or her interest in the venture to another person without the consent of the Minister [Section 41(b)]. The Minister also has the power to renew the authority for a further period and to impose conditions and restrictions on the new authority [Section 41(c)].

b) Minister for Industry, Science and Tourism

The Australian Nuclear Science and Technology Organization (ANSTO) is accountable to the Minister for Industry, Science and Tourism. The Minister may direct ANSTO to undertake research and development in relation to matters specified by the Minister [Section 5(1)(a)(iii)]. ANSTO may not become involved in commercial ventures without the approval of the Minister. The Minister may also give directions to the Board of Directors of ANSTO with respect to the performance of ANSTO's functions [Section 11], and may convene meetings of the Board [Section 16].

The Board of ANSTO is financially accountable to the Minister. It must prepare estimates of its receipts and expenditure for each financial year and submit them to the Minister [Section 28].

c) Minister for the Environment

The Minister for the Environment has certain powers and functions under the Environment Protection (Alligator Rivers Region) Act [No. 28 of 1978]. The Minister may give directions to the supervising scientist and may request that he provides information in relation to the operation of the Act [Section 7]. The Minister receives advice from the supervising scientist on a range of environmental issues arising from the mining operations in the Alligator Rivers Region [Section 5(e)]. The Minister is obliged to lay before each House of Parliament a copy of the supervising scientist's annual report and any other reports that the supervising scientist has made to the Minister, except for reports made to the Minister in connection with scientific and technical advice on environmental matters outside the Alligator Rivers Region [Section 36].

d) Minister for Foreign Affairs

Under the South Pacific Nuclear Free Zone Treaty Act [No. 140 of 1986], the Minister for Foreign Affairs has the function of declaring a person to be a Treaty inspector for the purposes of the Act. The Minister will only make this declaration if the person has been appointed as a special inspector under the Treaty for the purpose of investigating a complaint brought against Australia pursuant to the Treaty [Section 19].

The Minister is responsible for the administration of the Nuclear Non-Proliferation (Safeguards) Act [No. 8 of 1987] (hereinafter referred to as "the Safeguards Act"). Under the Safeguards Act it is the Minister who grants or refuses to grant a permit for the possession of nuclear material, an associated item or associated technology [Sections 13, 16 and 18]. Similarly, it is the Minister who imposes conditions and restrictions on any permit or authority granted [Sections 13, 16 and 18] and who exercises the power to revoke the permit or authority in certain circumstances [Section 20]. The

Minister has a further power to control the activities of permit-holders, in the shape of orders and directions under Section 73. Under this Section, the Minister may make orders which are to be complied with by all permit-holders, and may also give directions to a particular permit-holder.

All these decisions of the Minister are subject to review by the Administrative Appeals Tribunal [Section 22]. This is an independent tribunal established by legislation for the purpose of reviewing a wide range of administrative decisions. Upon application by a person adversely affected by such a decision, the tribunal is empowered to examine the merits of the decision, as well as its procedural correctness [Administrative Appeals Tribunal Act, No. 91 of 1975]. The Safeguards Act envisages, however, that some ministerial decisions made under it may not be suitable for review by the Administrative Appeals Tribunal. Section 22(5) provides that the Minister can issue a certificate stating that it is in the public interest that responsibility for a particular decision should reside solely with the Minister, and that the Minister's decision should not be reviewable. The Minister is obliged to include in the certificate a statement of the grounds on which the certificate is issued [Section 22(6)], and must table the certificate before each House of Parliament [Section 22(9)].

The Minister has the power to issue directions to the Director of Safeguards and the Director must comply with any such directions in the performance of his or her functions under the Act [Section 44].

The Minister's other responsibilities under the Safeguards Act include the appointment of inspectors for the purposes of the Act, and the declaration of Agency inspectors where these have been designated by the IAEA [Section 57]. The Minister is also required to submit to Parliament the annual report made by the Director of Safeguards [Section 51].

The Minister has the power to delegate any of the functions mentioned above (except the power to certify that a decision is not subject to administrative review) to the Director of Safeguards or to an officer of the Ministry [Section 72].

e) Minister for Health and Aged Care

Australian Radiation Protection and Nuclear Safety Agency is within the portfolio of the Minister for Health and Aged Care, which is responsible for providing protection, promoting the health of all Australians and minimising the incidence and severity of preventable mortality, illness, injury and disability. The Minister must, by notice in writing, give directions to the chief executive officer (CEO) with respect to the performance of the CEO's functions or the exercise of the CEO's powers, if it is in the public interest to do so. This Minister is one of the two ministers responsible for the issue of permits to import radioactive material and substances. The other minister who may exercise this power is the Minister for Customs [Section 4(r), Customs (Prohibited Imports) Regulations].

f) Minister for Finance

The Minister for Finance has various functions under the Australian Nuclear Science and Technology Organization Act [No. 3 of 1987]. Parliament decides each year an amount of money to be provided for the purposes of ANSTO [Section 27(1)] and for the purposes of the Nuclear Safety Bureau [Section 37(q)]. The Minister may give directions as to the times at which, and the amounts in which, that money will be paid to the two organisations [Sections 27(2) and 37(q)(2), respectively].

The Minister for Finance may also lend money to ANSTO on behalf of the Commonwealth [Section 32].

2. Advisory Bodies

a) Advisory Committees

Section 41 of the ANSTO Act [No. 3 of 1987] allows the Minister to establish committees to give advice to the Board of Directors on a particular matter or classes of matter relating to the functions of ANSTO.

b) Australian Ionizing Radiation Advisory Council

The Council advises the Minister for Health on matters relating to ionising radiation. It has provided advice, for example, on the current state of knowledge on the biological effects of ionising radiation, on radiation protection standards and on control procedures for radiation.

c) Radiation Health and Safety Advisory Council

The Radiation Health and Safety Advisory Council was established by the Radiation Protection and Nuclear Safety Act [No. 133 of 1998] as a consultative body on radiation and nuclear safety [Section 19]. The Council examines issues of major concern to the community in relation to radiation protection and nuclear safety and advises the Chief Executive Officer (CEO) of Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) on these issues as well as on the adoption of recommendations, policies and codes [Section 20]. The Radiation Health Committee and the Nuclear Safety Committee were established as advisory committees to the CEO and the Council [Sections 22 and 25]. Both Committees draft national policies, codes and standards in their respective fields and review their effectiveness periodically [Sections 23 and 26].

The membership of the Council and two Committees includes the CEO of ARPANSA, a representative of local governments, a person to represent the interests of the general public and other members. Each member, other than the CEO, is appointed by the Minister [Section 21].

3. Public and Semi-Public Agencies

a) Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)

i) Legal Status

The Chief Executive Officer (CEO) of Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is the statutory officer whose functions are laid down in the Australian Radiation Protection and Nuclear Safety Act [No. 133 of 1998].

ii) Responsibilities

The functions of the CEO fall into the following categories [1998 Act, Section 15]:

- to promote uniformity of radiation protection and nuclear safety policy and practices;
- to provide advice and services concerning radiation protection and nuclear safety;
- to undertake research in relation to radiation protection, nuclear safety and related issues;
- to accredit persons with technical expertise for the purpose of this Act;
- to monitor the operations of ARPANSA, the Radiation Health and Safety Advisory Council, the Radiation Health Committee and the Nuclear Safety Committee and to report on their operations to the relevant minister and to the Parliament.
- to monitor compliance with the provision which deals with the prohibition of construction or operation of nuclear installations or possession of controlled material or controlled apparatus, without a license.

The CEO must comply with the directions which are given by the Minister with respect to the performance of the CEO's functions or the exercise of the CEO's powers [Section 16]. The CEO may give written directions to controlled persons requiring them to take appropriate steps, in order to protect the health and safety of people or to avoid damage to the environment [Section 41].

iii) Structure

The CEO is appointed by the Governor-General for a period up to five years [Section 45]. The CEO's appointment can be terminated only on certain grounds specified in the Act (for example, misbehaviour or incapacity) [Section 51]. The CEO may engage the staff or consultants to assist in the performance of any of its functions [Section 58].

iv) Financing

ARPANSA Reserve was established to make payments for the object of the Australian Radiation Protection and Nuclear Safety Act and otherwise in connection with the performance of the CEO's function. The Reserve consists of money appropriated by Parliament for the purpose and amounts equal to amounts received by the Commonwealth in connection with the performance of the CEO's functions under this Act or regulations [Section 56].

b) Australian Safeguards Office

i) Legal Status

The Australian Safeguards Office is established by Section 54 of the Nuclear Non-Proliferation (Safeguards) Act [No. 8 of 1987], and consists of the Director of Safeguards and staff.

ii) Responsibilities

The statutory functions of the Director are, with the assistance of the staff, to ensure the effective operation of the Australian safeguards system; to carry out Australia's reporting obligations under the IAEA Agreement and bilateral agreements in relation to the Australian safeguards system; to monitor compliance by Australia's bilateral agreement partners; to undertake research and development in relation to nuclear safeguards; and to advise the Minister for Foreign Affairs on matters relating to the operation of the Australian safeguards system. The Director is required to make an annual report to the Minister, which must include details of all nuclear material and associated items of Australian origin transferred from Australia to any foreign jurisdiction, their quantities and their intended end-use [Section 51].

iii) Financing

The Australian Safeguards Office is funded by a combination of money appropriated by the Parliament and by a "cost recovery" mechanism. This mechanism was established by two amending Acts, the Nuclear Non-Proliferation (Safeguards) Amendment Act 1993 [Act No. 33 of 1993] and the Nuclear Safeguards (Producers of Uranium Ore Concentrates) Charge Act 1993 [Act No. 34 of 1993]. The Acts provide for the imposition of a charge on commercial uranium producers in Australia in order to recover some of the costs of the Office's activities.

c) Australian Nuclear Science and Technology Organization (ANSTO)

i) Legal Status

On 27 April 1987 the Australian Atomic Energy Commission became the Australian Nuclear Science and Technology Organization (ANSTO) [Nuclear Science and Technology Organization Act (No. 3 of 1987), Section 4]. ANSTO is a body corporate, with the capacity to sue and be sued [Section 4(2)]. It can enter into contracts, own property and form, or participate in the formation of, companies [Section 6]. Its participation in companies is subject to certain limitations and to the approval of its supervisory Minister.

ii) Responsibilities

The functions of ANSTO fall into the following general categories:

- undertaking research and development in relation to nuclear science and technology and in relation to the production and use of radioisotopes, the use of isotopic techniques and nuclear radiation, for medicine, science, industry, commerce and agriculture;
- conditioning, managing and storing specified radioactive materials and radioactive waste;
- encouraging and facilitating the application and utilisation of the results of such research and development;
- providing and selling goods and services in connection with ANSTO's activities;

- liaising between Australia and other countries, and between other Commonwealth and state authorities in relation to its activities;

- providing advice on aspects of nuclear science and nuclear technology;

- making available to other people, on a commercial basis, ANSTO's knowledge, equipment and facilities;

- publishing scientific and technical reports, periodicals and papers; and

- arranging and encouraging training in matters related to its activities [Section 5].

In undertaking its statutory functions, ANSTO is required to have regard to the government's national science, technology and energy policy objectives and to its commercialisation objectives for public research institutions [Section 5(3)].

iii) Structure

The Organisation consists of a board of directors, and an executive director and staff. The board consists of the executive director and at least two other members. The total maximum number of members is seven [Section 9]. The members, other than the executive director, are appointed by the Governor-General for a term of up to five years, and they can be dismissed from office only by the Governor-General, on the ground of misbehaviour or physical or mental incapacity [Sections 9 and 14].

The board's role is to ensure the proper and efficient performance by ANSTO of its functions, and in doing so, the board is to have regard to the policies of the Commonwealth Government insofar as they are relevant to ANSTO's work [Section 10]. ANSTO's Minister may give directions to the board about the performance of ANSTO's functions, if satisfied that it is in the public interest to do so [Section 11].

The Executive Director of ANSTO is appointed by the board of directors [Section 18] to manage the affairs of the Organisation subject to the directions, and in accordance with the policies, of the board [Section 19].

The Executive Director is empowered to appoint such staff as the board considers necessary for the purposes of the Act [Section 24].

iv) Financing

ANSTO is funded by money appropriated by Parliament for the purposes of the Organisation. The Minister for Finance may give directions as to the amounts in which, and the times at which, the money appropriated is to be paid to ANSTO [Section 27]. The Organisation may also borrow Commonwealth money from the Minister for Finance, on conditions determined by the Minister [Section 32], and may deal with securities, with the approval of the Treasurer [Section 34]. ANSTO may also accept gifts and bequests made to it [Section 38].

d) Supervising Scientist

The Environment Protection (Alligator Rivers Region) Act [No. 28 of 1978] creates the position of Supervising Scientist for the Alligator Rivers Region [Section 4]. This area of the Northern Territory, which includes the Kakadu National Park, contains the Ranger uranium mine, the rehabilitated Nabarlek uranium mine and the Jabiluka and Koongarra uranium deposits. The functions of the Supervising Scientist in relation to the protection of the environment were originally confined to the effects of uranium mining in the region, but the Act was amended in 1987 [Environment Protection (Alligator Rivers Region) Amendment Act 1987 – Act No. 17 of 1987] to extend these functions to all mining operations in an area declared to be a conservation zone. The Supervising Scientist's general functions include the following:

- developing research and information programmes on the environmental effects of mining in the areas concerned;
- developing and promote standards and procedures in relation to mining for the protection of the environment in the areas concerned;
- supervising the implementation of Commonwealth and Northern Territory laws relating to environmental protection of the areas from the adverse effects of mining; and
- advising the Commonwealth Minister for the Environment on all these matters [Sections 5 and 5(a)].

The Supervising Scientist is also a member of the Advisory Committee established under the Act. The other members of the Committee are:

- a chairperson appointed by the Minister for the Environment;
- the Director of the Commonwealth's National Parks and Wildlife Service;
- a member appointed by the Minister for the Environment on the nomination of the Northern Territory government;
- a member appointed by the Minister for the Environment on the nomination of the appropriate Aboriginal Land Council; and
- such other members as are appointed by the Minister for the Environment from time to time.

The Advisory Committee provides a formal forum for consultation on the effects of uranium on the environment in the Alligator Rivers Region and on matters relating to environmental research conducted in the region and referred to it by the Technical Committee.

Associated with the Advisory Committee is the Technical Committee, appointed by the Minister for the Environment. The Technical Committee considers environmental research needs in relation to uranium mining in the region, reviews research programmes, refers matters relating to such programmes to the Advisory Committee, and makes recommendations to the Minister on the nature and extent of research necessary, and on the appropriate organisation to conduct the research.

Finally, the Supervising Scientist is charged with the management of the Environmental Research Institute of the Supervising Scientist. The functions of the Institute are, in general terms, to support the Supervising Scientist in the research and information functions conferred under Sections 5 and 5(a) [Section 24]. It is also permitted to undertake research on matters outside the region on a commercial basis.

AUSTRIA

I. GENERAL REGULATORY REGIME

General Outline

Austria does not operate any nuclear power plants. Thus, its interest in the safety of nuclear facilities relates primarily to environmental, health and safety concerns arising from nuclear power plants in neighbouring countries.

In 1978, legislation prohibiting nuclear power plants on Austrian territory was adopted as a result of a referendum, in November 1978, rejecting the nuclear power plant project Zwentendorf. The events in Chernobyl in 1986 reinforced this parliamentary decision and further strengthened public opposition to nuclear power. Confirming this policy, on 13 August 1999 the Parliament adopted the Federal Constitutional Act for a Nuclear-Free Austria [BGBl 1999 I, p. 1161].

The policy adopted by the Austrian government aims to establish a "Nuclear Power Free Zone Central Europe". In line with this general policy, Austria attaches great importance to international efforts to harmonise and steadily increase nuclear safety levels on a multilateral and global basis. Austria contributes to various programmes aimed at analysing and evaluating the safety of nuclear power plants in the context of both European Union and International Atomic Energy Agency (IAEA) activities, such as the IAEA's extra budgetary programme on VVER and RBMK reactors. It has also embarked on bilateral activities with neighbouring countries to exchange information on nuclear safety related matters, including not only operational information on nuclear installations but also early warning schemes in the case of nuclear incidents or accidents and mutual assistance for the prevention or mitigation of effects from such radiological events.

1. Introduction

In Austria, the development and use of nuclear energy for peaceful purposes have been significantly influenced by the passing, on 15 December 1978, of the Act prohibiting the use of nuclear fission for energy purposes in Austria [BGBl[1] No. 676/1978: "*Bundesgesetz vom 15 Dezember 1978 über das Verbot der Nutzung der Kernspaltung für die Energieversorgung in Österreich"*].

This Act, adopted as a result of the referendum rejecting the start-up of the first Austrian nuclear power plant at Zwentendorf in 1978, is at the origin of the Austrian government's nuclear power policy.

1. BGBl: *Bundesgesetzblatt* = Federal Law Gazette.

The Federal Constitutional Act for a Nuclear-Free Austria of 13 August 1999 [BGBl 1999 I, p. 1161] refers to the 1978 Act and confirms Austria's policy on both civil and military matters in the nuclear field.

Legislation in the nuclear field is directed primarily towards *nuclear safety* and addresses the following areas:

- radiation protection: all rules and measures concerned with the protection of the lives or health of human beings and future generations from damage due to ionising radiation;
- facility safety: all construction and other technical norms and standards designed to afford protection against ionising radiation from nuclear facilities;
- safeguards: accounting and control of nuclear materials designed to prevent their diversion from peaceful utilisation (non-proliferation);
- protection of nuclear materials and installations against interference or encroachment by unauthorised third parties (physical protection).

These matters are covered in various pieces of legislation, involving both federal (*Bund*) and regional (*Land*) authorities.

In addition, there are licensing provisions in specific statutes and the General Administrative Procedures Act of 1991 applies as well.

2. Mining Regime

There is no specific legislation in this field. The Mining Act of 1954 [BGBl No. 73/1954] does not restrict the mining of ores containing uranium or thorium. They may be prospected for and mined by any person in compliance with the general provisions of the Mining Act.

3. Radioactive Substances, Nuclear Fuel and Equipment

The main provisions of the Radiation Protection Act of 11 June 1969 [*Strahlenschutzgesetz*, BGBl No. 227/1969] address the licensing of the construction and operation of installations involved in the handling of radioactive materials or of radiation-emitting equipment [Sections 5-7].

"Handling of radioactive materials" means the extraction, production, storage, carriage, delivery, supply, processing, use or disposal of radioactive materials or any activity resulting in the emission of ionising radiation [Section 2(e)].

"Radiation-emitting equipment" means devices used for the production of ionising radiation or the use of which involves the emission of radiation in so far as the ionising radiation does not result from spontaneous nuclear processes [Section 2(d)].

Under the Radiation Protection Act, any other activities involving radioactive materials or the operation of ionising radiation-emitting devices also require a licence [Section 10].

Specific regulations exempt from licensing activities involving radioactive materials entailing no radiation hazards, the carriage of radioactive materials, provided it complies with the appropriate transport regulations [Section 13], and installations used for military research and experimental purposes.

The design of devices containing radioactive materials or of radiation-emitting equipment may be approved by the authority in accordance with strict legal requirements. Such an approval may simplify the licensing procedures [Sections 19-22].

The possession of radioactive materials or of radiation-emitting equipment which is exempt from licensing under the Radiation Protection Act must be reported [Section 25], unless for example, the radioactive material is below given limits of activity, or the transport of radioactive materials is in compliance with the relevant transport regulations.

4. Nuclear Installations

Apart from the site at Zwentendorf, where a nuclear power plant was built but not put into operation, Austria operates the following four "nuclear facilities" (three research reactors and a central waste processing and interim storage facility):

Atominstitut (Atomic Institute)

The Austrian Universities' Atomic Institute in Vienna operates a TRIGA Mark II research reactor. It has a maximum thermal power output of 250 kW. However, it can also be operated in the "pulse mode" up to a maximum output of 250 MW. In operation since 1962, the reactor has been used exclusively for university research and teaching purposes.

Because of its low thermal output, the reactor's original 57 fuel elements are still in the core. A further 22 fuel elements have been loaded in subsequent years. Over the past 33 years, 8 fuel elements were permanently removed, and a total of 8 fresh fuel elements are in storage.

Österreichisches Forschungszentrum Seibersdorf (Austrian Research Centre)

The ASTRA research reactor at the Austrian Research Centre Seibersdorf, a 10 MW thermal water-cooled and moderated pool type reactor, has been in operation since 1960. The reactor is mainly used for the production of radioisotopes for industrial and medical purposes, irradiation of materials, and irradiation of samples for the analysis of neutron activation. The future of the reactor is currently under review, with the option of possible shut-down.

Reaktorinstitut Graz (Graz Reactor Institute)

The Graz Reactor Institute has been operating a nominal 10 kW Siemens ARGONAUT reactor since 1965. The fuel enrichment levels are 20% and 90%. The reactor is mainly used for training purposes within the framework of Graz Universities' education programme. The available fuel reserves will last until 2005.

Interim Storage Facility for Radioactive Waste

This waste storage facility, together with related waste treatment facilities, is operated by the Seibersdorf Austrian Research Centre to meet the radioactive waste management needs of Austrian industry, hospitals, other medical institutions and research institutes. The storage facility has a design capacity of 15 000 barrels containing 200 litres each. Approximately 50% of this capacity is still available.

a) Licensing and inspection, including nuclear safety

As a result of Austria's federal structure, licensing procedures involve federal *(Bund)* as well as regional *(Länder)* authorities. The construction and operation of installations for the handling of radioactive materials and ionising radiation-emitting equipment require a licence [Radiation Protection Act, Sections 5-7]. Under that Act, licensing is a shared responsibility, mainly held by the Federal Minister for Women's Affairs and Consumer Protection (within the Federal Chancellery). The distribution of responsibilities is specified in Section 41 of the Act. The examination of licences is dealt with primarily in the Radiation Protection Act and the Radiation Protection Ordinance of 12 January 1972 [BGBl No. 47/1972]. The licensing procedure is subject to the provisions of the General Administrative Procedure Act *(Allgemeines Verwaltungsverfahrensgesetz)* [BGBl No. 51/1991].

An operating licence is granted where the installation has been built in compliance with specified conditions, a radiation protection officer has been appointed and the regular operation of the installation entails no hazard from ionising radiation [Section 6(2)].

The operation of installations for the handling of radioactive materials or for housing radiation-emitting equipment in accordance with the Radiation Protection Act is monitored and inspected at regular intervals by the licensing authority as specified in the applicable legislation [Section 17].

On the subject of nuclear safety, it is of relevance to note that Austria ratified the 1994 Convention on Nuclear safety on 26 August 1997.

b) Emergency response

The Radiation Protection Act provides that in the event of imminent danger coming from an installation in which radioactive materials are handled or ionising radiation-emitting equipment is housed, the authorities must take all appropriate measures to avert the danger. They may issue provisional instructions and, after consulting the radiation protection officer of the installation, shall proceed in compliance with Section 4 of the 1950 Act on the Enforcement of Administrative Decisions (*Verwaltungs-vollstreckungsgesetz*).

i) National emergency arrangements

Section 38 of the Radiation Protection Act sets forth general principles concerning measures to be taken in the case of radioactive contamination. In general, the competence for taking such measures lies with the Regional Governor *(Lande-shauptmann)*, subject to orders from the Federal Department of Radiation Protection within the Federal Chancellery.

For radiological emergencies, a national contingency plan – containing, in particular, provisions on the exchange of information, civil protection measures, warning and informing the public and convening the National Crisis Management Board – has been drawn up. Together with appropriate general recommendations issued by the federal authorities, this plan serves as the basis for preparatory measures to be taken at the regional level.

The Federal Alarm Centre *(Bundeswarnzentrale)* of the Federal Minister of the Interior acts as a "message relay centre" for the Radiation Protection Department of the Federal Chancellery, whose experts are available around the clock. If an incident is reported to the Federal Alarm Centre, the radiation protection experts are immediately called in. If they come to the conclusion that there is imminent danger, all competent authorities are informed.

The Federal Chancellery may decide on any urgent preliminary counter-measures. If necessary, the National Crisis Management Board *(Koordinationsausschuß des Staatlichen Krisenmanagements)* will convene. Its membership comprises all Federal Ministries, the regional governments and socio-professional interest groups as well as the Austrian radio and television network (ORF) and the Austrian Press Agency. This team of experts advises the Federal government, co-ordinates all measures necessary for an emergency response at short notice and makes arrangements for a long-term concerted strategy at all levels of public administration.

ii) The Austrian Radiation Early Warning and Monitoring System

A special chapter of the Austrian Radiation Protection Act deals with large-scale radiation surveillance, monitoring emergency situations and the implementation of remedial counter-measures.

Pursuant to this Act, the Austrian Federal Chancellery (Department for Radiation Protection) operates both an automatic Radiation Early Warning System and a Laboratory-Based Monitoring Network in order to comply with the requirements of rapid recognition and precise determination of radioactive contaminants. In addition, several hundred car-borne and several air-borne dose rate measurement units have been installed in the networks of the Federal Minister of the Interior and the Federal Army. Furthermore, the Federal Chancellery plays an important role as the competent authority for the planning and implementation of counter-measures.

The Laboratory-Based Monitoring Network *(Laborgestütztes Überwachung-snetz für Radioaktivität)* handles the radionuclide-specific monitoring of air, precipitation, surface water bodies and foodstuffs.

The Radiation Early Warning System *(Strahlenfrühwarnsystem)* continuously monitors external gamma dose rates throughout the country. Near the Austrian borders, several aerosol and radioiodine warning devices have been installed. This automatic computerised system is managed by the Federal Chancellery and has been in operation since 1979.

All in all, 336 sensor stations, 9 regional centres and a national centre have been set up. The System design meets the requirements of operational safety and reliability. From the sensor stations, data is transmitted to the regional centres at approximately three-minute intervals and also on-line to the national centre. Thus, it is possible to monitor the nuclear radiation situation in all of Austria.

The public has permanent access to the data via the ORF-TELETEXT service. The data gathered by the Radiation Early Warning and Monitoring System are exchanged on-line with

corresponding systems in the neighbouring Slovak Republic and it is planned to enhance this exchange further.

At international level, Austria ratified the 1986 Convention on Early Notification of a Nuclear Accident on 18 February 1988, and it has been a Party to the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency since 21 November 1989.

5. Trade in Nuclear Materials and Equipment

Under the Non-proliferation Act of 1991 [*Sicherheitskontrollgesetz* 1991, BGBl No. 415/1992] and in compliance with Austria's international obligations under the Nuclear Non-proliferation Treaty (NPT), the export of nuclear materials and related non-nuclear materials as well as nuclear equipment is subject to a licence granted in accordance with the provisions of the NPT, by the Federal Chancellery *(Bundeskanzler).*

The Export Control Ordinances [BGBl No. 629/1975; BGBl No. 518/78] designate the items subject to export licences [Non-Proliferation Act, Article II, Section 4 (8-11)].

The list of goods which may not be exported without a licence, in accordance with the Non-Proliferation Act, was amended by an Ordinance of 14 November 1990 [BGBl No. 685/1990]. The amendment includes numerous items involving nuclear materials. The last amendment, introduced by Ordinance of 14 December 1993, includes systems, equipment and components for use in aerodynamic enrichment plants, chemical exchange or in exchange enrichment plants, laser-based enrichment plants, plasma separation and electromagnetic enrichment plants for the conversion of uranium.

6. Radiation Protection

The main focus of Austrian nuclear safety legislation is radiation protection, dealt with primarily in the 1969 Radiation Protection Act and the 1972 Radiation Protection Ordinance.

These instruments define general measures to protect the lives and health of individuals and future generations against the hazards of ionising radiation, as well as licensing conditions for the construction and operation of installations designed to handle of radioactive materials, as explained under Section 4 "Nuclear Installations" above.

The radiation protection provisions contained in the Act and in the Ordinance are designed:

- to ensure that exposure of individuals to radiation is kept "as low as possible";
- to restrict the absorption of radioactive materials by the human body to a minimum; and
- to ensure that only the smallest possible quantities of radioactive materials are released into the air, water or soil.

The Radiation Protection Act requires pre-employment medical examinations and periodic health checks of exposed workers as well as their dosimetric surveillance. It also provides that special radiation protection provisions are to be defined in a specific Radiation Protection Ordinance.

At present (1999), the Radiation Protection Act as well as the Radiation Protection Ordinance are being adapted to the requirements of the law of the European Union in this field. Article 55 of EU Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation provides that EU Member States adapt their respective legal instruments before 13 May 2000 in order to comply with this Directive.

Matters of a more general nature concerning the health aspects of radiation protection may be brought to the attention of the Radiation Protection Commission *(Strahlenschutzkommission* – SSK*)* which acts as an advisory body to the Minister for Women's Affairs and Consumer Protection.

As the Radiation Protection Act 1969 is based upon the Imperial Health Act [*Reichssanitätsgesetz* – RGBl[2] No. 68 dated 30 April 1870], a new Radiation Protection Act is currently being prepared and will take account of the latest developments in this field.

7. Radioactive Waste Management

Since Austria does not operate nuclear power plants, there is no major production of high level radioactive waste (HLW) and consequently no need for intermediate or final HLW storage facilities. The relatively small quantities of HLW resulting from the Austrian research reactors are covered by a framework contract for "US-origin nuclear fuel" and shall be returned to the US during the next decade.

Low and medium level radioactive waste (L/MLW) from hospitals, industry and research laboratories (30-40 tonnes/year) is collected and treated by the Austrian Research Centre Seibersdorf. The research centre is equipped with suitable facilities to process and condition the waste, *e.g.* incinerator, supercompactor and waste water evaporator. As a conditioning process, cementing is predominantly used.

On the basis of a joint agreement between the Republic of Austria, the community of Seibersdorf and the Austrian Research Centre Seibersdorf, the intermediate storage facility on the site of the research centre, with a capacity of 15 000 drums of conditioned waste is scheduled to be operational until 2012. After this date, the waste will be transferred to a final storage facility to be built on a site to be selected at the beginning of the next decade.

The 1972 Radiation Protection Ordinance contains detailed provisions concerning the handling of radioactive waste, which mainly relate to radiation protection measures. According to the current (1999) draft legislation modifying the Radiation Protection Ordinance, the licensing of installations requires both the applicants for new licences and the operators of existing installations to furnish waste management schemes. The decision on a specific repository site shall take account of the requirements of the 1993 Environmental Impact Assessment Act [*Umweltverträg-lichkeitsprüfungsgesetz*] and of the procedure laid down in the land use legislation of the *Länder* [1972 Radiation Protection Ordinance].

The 1989 Ordinance on the Specification of Hazardous Wastes [*Verordnung über die Festlegung von gefährlicher Abfällen* – BGBl No. 607/1989] includes radioactive waste within the defined limits of the Radiation Protection Act. Accordingly, radioactive waste is included in a list of

2. RGBl: *Reichsgesetzblatt* = Imperial Law Gazette.

substances to which the 1989 Act on the Rehabilitation of Hazardous Waste Sites applies [*Altlastensanierungsgesetz* – BGBl No. 299/1989].

A further Ordinance on the Transfer of Radioactive Wastes [*Verbringung-sverordnung für radioaktive Abfälle* – BGBl No. 44/1997] relating to the supervision and control of shipments of radioactive waste into, out of and through the national territory, came into force on 1 March 1997. It was enacted pursuant to the Radiation Protection Act in order to implement the provisions of Council Directive 92/3/Euratom of 3 February 1992 on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community. The Annexes to the Ordinance define, *inter alia*, the applicable standard documentation and the list of quantity and concentration levels for radioactive waste.

8. Non-Proliferation and Physical Protection

Austria has been a Party to the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) since 27 June 1969 [BGBl No. 258/1970] and, in accordance with the Treaty, concluded an Agreement on 21 September 1971 with the International Atomic Energy Agency (IAEA) on the Application of Safeguards [BGBl No. 239/1972]. The legal basis for Austria's non-proliferation policy was established through the Austrian Nuclear Non-proliferation Act of 1972, amended in 1991. The authority responsible for safeguards and nuclear export controls is the Federal Chancellor.

Austria also ratified on 13 March 1998 the 1996 Comprehensive Nuclear Test Ban Treaty.

Following the Austrian accession to the European Union, the bilateral Safeguards Agreement with the IAEA was suspended and replaced by the trilateral agreement between the IAEA, Euratom and the non-nuclear-weapon states Members of Euratom.

As regards physical protection of nuclear materials, the 1991 Non-proliferation Act also contains provisions on interference or encroachment by unauthorised third parties. The Federal Minister of the Interior may impose any measures it considers necessary to ensure the protection of nuclear materials at the national level [Article II, Sections 6 and 7].

The Federal Minister of the Interior is responsible for issuing licences and for the adoption of security measures in connection with the handling of nuclear material, including protective measures against interference or encroachment [Sections 6 and 7]. Before decisions are taken, the Federal Chancellery (both the divisions for Safeguards and for Radiation Protection) shall be consulted. In addition, the Federal Minister of the Interior decides on protective measures with regard to the carriage of materials that come within the purview of the Act on the Transport of Dangerous Goods by Road.

Physical protection levels are based on the IAEA Guidelines and Recommendations for the Physical Protection of Nuclear Materials as published in IAEA document INFCIRC/225/Rev.3.

Austria has also been a Party to the 1979 Convention on the Physical Protection of Nuclear Material since 22 December 1988.

9. Transport

In Austria, the transport of radioactive material is strictly controlled so as to ensure maximum safety. Safety measures of a general nature are embodied in the 1969 Radiation Protection Act.

The transport of radioactive materials by **rail** is governed by the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID), an Annex to the Convention concerning International Carriage by Rail (COTIF), to which Austria is a Party. The RID applies to the international transport of dangerous goods to or from Austria. Under the Act on the Carriage of Dangerous Goods[3] of 1998 (GGBG), it also applies to transport operations within Austria.

The international transport of such material by **road** is primarily subject to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) to which Austria is a Party. In addition to ADR, there are provisions in the GGBG which refer to, implement and complete the ADR. Under the GGBG, ADR is also applicable to the domestic carriage of dangerous goods by road in Austria.

The GGBG also implements several directives of the European Union concerning the carriage of dangerous goods by road, rail and inland navigation, which refer to, implement and complete the international agreements mentioned above.

As regards **air** transport, the provisions of the International Civil Aviation Organisation (ICAO). Technical Instructions for the Safe Transport of Dangerous Goods by Air are implemented by the GGBG. Furthermore, the Dangerous Goods Regulations of the International Air Transport Association (IATA) constitute an integral part of any carriage contract concluded by an IATA-carrier.

Since the relevant international legal instrument for the transport of dangerous goods by **inland waterways** (ADN) has not yet entered into force, the transport of radioactive material by this means is subject to the provisions of an Ordinance[4] based on the 1997 Federal Act on Inland Navigation[5] and to the provisions of the GGBG, as far as they are common to all modes of transport.

Regardless of the applicable law of the state in which a harbour is located, the transport of radioactive materials by **sea** on ships registered in Austria has to comply with the International Maritime Organisation (IMO) Dangerous Goods Code. The provisions of this IMDG-Code are also referred to in the GGBG.

10. Nuclear Third Party Liability

The Nuclear Liability Act of 1964 (*Atomhaftpflichtgesetz)* was repealed and replaced on 1 January 1999 by the Federal Law on Civil Liability for Damages Caused by Radioactivity,[6] adopted by the Austrian Parliament on 7 October 1998. This Act governs civil liability for damage to persons or property resulting from ionising radiation from nuclear installations, nuclear substances or radioisotopes [Section 1]. This Act applies to nuclear damages caused after 1 January 1999.

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3. *Bundesgesetz über die Beförderung gefährlicher Güter und über eine Änderung des Kraftfahrtgesetzes 1967 und der Straßenverkehrsordnung 1960* (*Gefahrgut-beförderungsgesetz* – GGBG), BGBl I, No. 145/1998.

4. *Verordnung des Bundesministers für Wissenschaft und Verkehr über die Beförderung gefährlicher Güter auf Wasserstraßen* (ADN-*Verordnung*), BGBl II, No. 295/1997.

5. *Bundesgesetz über die Binnenschiffahrt* (*Schiffahrtsgesetz*), BGBl I, No. 62/1997.

6. *Bundesgesetz über die zivilrechtliche Haftung für Schäden durch Radioaktivität* (*Atomhaftungsgesetz* 1999), BGBl I, No. 170/1998.

The Act provides for the unlimited liability of the operator of a nuclear installation and the carrier of nuclear material. The operator of a nuclear installation is liable for all damage caused by the operation of that installation, including the dismantling of the plant and the disposal of the radioactive substances which are located there [Section 3(1)]. The operator is also liable for damages caused outside the installation by radioactive material originating from that installation if the damage is caused before another operator has taken charge of this material, or where the material has been sent to the operator, if the damage is caused after that operator has taken legal charge over the material [Section 3(2)]. The carrier of nuclear substances is liable for all damage caused during the carriage of nuclear material by land, air or sea, unless he proves that he did not know and could not have known that the goods transported were nuclear material [Section 4].

The operator of a nuclear installation situated on Austrian territory is required to maintain financial security to cover this liability of at least Austrian Schillings (ATS) 5.6 billion (approximately euros 400 million), as well as ATS 560 million (approximately euros 40 million) for interest and costs. For research facilities, the minimum amount is fixed at ATS 560 million plus ATS 56 million for interest and costs [Section 6]. The carrier of nuclear material is obliged to maintain financial security coverage of at least ATS 560 million (ATS 56 million for source material) and ATS 56 million (ATS 5.6 million for source material) for interest and costs [Section 7].

The liability imposed on the handler of radioisotopes is fault-based. Liability is also unlimited, and must be covered by financial security in the manner and to the extent customary in the ordinary course of business [Sections 9 and 10].

The definition of nuclear damage was significantly widened with the adoption of the 1998 Act. Damage now includes damage to persons or property, the costs of preventive measures and measures of reinstatement of the environment [Section 11].

Furthermore, the 1998 Act provides that the plaintiff is entitled to bring an action before a court in whose jurisdiction the damage was either caused or suffered. The objective of this provision is to ensure that if nuclear damage, although caused in a foreign territory, is suffered in Austria, then an Austrian court will have jurisdiction and Austrian law will be applicable.

II. INSTITUTIONAL FRAMEWORK

In Austria, the enforcement of federal legislation is in principle a matter for the *Länder* except in cases where the *Bund* (Federal government) is expressly made responsible under the Constitution [Federal Constitution, Article 15]. As regards nuclear energy legislation, therefore, the Federal government has no exclusive competence.

1. Regulatory and Supervisory Authorities

A. Federal Authorities (*Bund*)

Federal ministers are responsible for the application of the pertinent provisions of the Radiation Protection Act of 1969 with regard to:

- nuclear reactors;
- production of nuclear fuels or processing of irradiated nuclear fuels;
- particle accelerators;
- specified types of construction; and
- radiation activities carried out by doctors and in hospitals.

a) The Federal Chancellery

In his capacity as the national nuclear non-proliferation authority, the Federal Chancellor *(Bundeskanzler)* is responsible for nuclear material accountancy and control in accordance with the Non-proliferation Act of 1991. Under that Act, he is also responsible for the export control of fissionable material, non-nuclear material (*e.g.* heavy water, zirconium, etc.) and equipment. In his capacity as nuclear co-ordination minister, the Federal Chancellor is in charge of all issues involving the negotiation and implementation of legal instruments concluded with the IAEA.

b) The Federal Minister for Women's Affairs and Consumer Protection

The Federal Minister for Women's Affairs and Consumer Protection is generally responsible for radiation protection as far as health matters are concerned. The Minister is also responsible for issues relating to the long-term storage of radioactive waste, including the siting, construction and operation of storage facilities.

c) The Federal Minister of the Interior

The Federal Minister of the Interior is responsible for issuing licences and for the adoption of security measures in connection with the handling of nuclear material, including protective measures against interference or encroachment by unauthorised third parties [Safeguards Act, Part 3]. In addition, the Federal Minister of the Interior is in charge of transport safety measures with regard to the carriage of nuclear materials subject to the Act on the Transport of Dangerous Goods by Road.

d) The Federal Minister for Economic Affairs

The Federal Minister for Economic Affairs is responsible for a limited number of matters concerning the safety of nuclear installations, *e.g.* pressure vessels and power engines.

Under the 1995 Foreign Trade Act [*Außenhandelsgesetz*, BGBl No. 172/1995], the Federal Minister for Economic Affairs is responsible for the licensing of exports of nuclear-related "dual use" materials.

e) The Federal Minister of Finance

As far as nuclear third party liability is concerned, the Federal Minister of Finance decides whether the nature and amount of the financial security offered by the operator is sufficient to cover his liability under the Nuclear Liability Act of 1964 [Section 17(3)].

f) The Federal Minister of Labour, Health and Social Affairs

The Central Labour Inspectorate of the Federal Minister of Labour, Health and Social Affairs is responsible for the protection of the health of employees carrying out ionising radiation activities.

g) The Federal Minister of Science and Transport

The Federal Minister of Science and Transport is the competent authority for the transport of dangerous goods (including radioactive material) by all modes of transport in Austria and also for the approval of packages and shipments of radioactive material. It is the competent authority for the implementation and interpretation of the IAEA Regulations for the safe transport of radioactive materials (IAEA Safety Series Nos. 6, 7 and 37 as amended by IAEA Documents ST-1 and ST-2) as well as for the legislation enforcing these Regulations.

The Minister also bears responsibility for the co-ordination and strategic orientation of energy research and development in general and nuclear research in particular, and is the competent authority for the construction and operation of university-based nuclear installations.

h) The Federal Minister of Justice

The Federal Minister of Justice is responsible for legal matters related to the Nuclear Liability Act.

i) The Federal Minister for the Environment

The 1986 Federal Ministries Act provides that the Federal Minister for the Environment is responsible for protection of the environment against ionising radiation.

j) The Federal Minister for Foreign Affairs

The Federal Minister for Foreign Affairs is the competent authority representing Austria internationally.

B. Regional Authorities (*Länder*)

The Regional Governor *(Landeshauptmann)*, in his capacity as the highest authority in the *Land*, is the competent authority for the enforcement of Parts II and III of the 1969 Radiation Protection Act as far as installations requiring licences are concerned, except where the Federal Ministers are explicitly given responsibility by the Law [Section 41(1)(ii) and 41(2)]. The Regional Governor is also the competent authority for licensing X-ray equipment.

C. District Authorities (*Bezirksverwaltungsbehörden*)

In general, the district authorities are responsible for the application of Parts I to III of the Radiation Protection Act, except where the Law expressly provides that the Federal Minister or the Regional Governor is in charge [Section 41(1)(iii) and 41(2)].

Under the Constitution, responsibility for granting construction licences for installations which will handle radioactive materials would normally lie with the mayor of the town to which the site of the installation belongs. In practice, however, advantage is usually taken of the possibility of transferring this responsibility to the regional authorities' (*Länder*) level.

2. Advisory Bodies

a) Forum for Nuclear Questions

A Forum for Nuclear Questions (*Forum für Atomfragen*) was established by an Order of 30 April 1990 [BGBl No. 234/1990] as a nuclear advisory board. The Forum's task is to advise the Federal Chancellor on all questions relating to nuclear energy and ionising radiation which call for co-ordination.

The members of the Forum include experts in the fields of reactor technology, radiation protection, meteorology, nuclear medicine, ecology, biology, geology, energy economics, law and emergency management as well as government officials from various ministries.

b) Radiation Protection Commission (SSK)

The Radiation Protection Commission (*Strahlenschutzkommission* – SSK) was set up in 1961 under the Imperial Health Act [RGBl No. 68/1870, Section 17] and under the Federal Ministries Act of 1973 as the advisory body to the Federal Ministry for Women's Affairs and Consumer Protection.

The Commission's opinions are in the nature of recommendations. The Commission has 32 members and is chaired by the head of the Ministry's department for foodstuffs, veterinary administration and radiation protection.

3. Public and Semi-Public Agencies

a) The Seibersdorf Austrian Research Centre

i) Legal Status

On 15 September 1980, the Seibersdorf Austrian Research Centre (*Österreichisches Forschungszentrum Seibersdorf GmbH*) was formed from the Austrian Nuclear Research Centre set up in 1956. It is 51% owned by the Austrian Republic and in varying shares by industrial firms.

ii) Responsibilities

The Centre was originally set up to undertake research into the peaceful uses of nuclear energy. Since June 1980, the Centre's terms of reference have made provision for greater emphasis on studies involving alternative forms of energy, and for contract research. Therefore, the Centre's present activities include research and development in the areas of energy and safety; materials research; isotope and ionising radiation techniques; measuring and information processing techniques; environmental protection; health and food as well as industrial consulting.

iii) Structure

The Centre has two managing directors chosen by the Annual General Meeting. Its Supervisory Board consists of seventeen members chosen by the General Meeting for a term of four years.

iv) Financing

The Centre is financed basically by federal grants. These are supplemented by income from contract research projects and members' contributions.

b) The Graz Nuclear Institute

The Nuclear Institute in Graz has been operating an Argonaut Research Reactor since 1965. The reactor, with a generating power of 10 kW, is mainly used for training purposes within the education programme of the University of Graz.

c) The Nuclear Institute of the Austrian Universities

The Nuclear Institute of the Austrian Universities is the operator of the TRIGA Research Reactor. This research reactor has been in operation since 1962 and is used exclusively for educational and training purposes in relation to the education programme of Austrian universities.

d) The Institute of Risk Research, University of Vienna

The Institute of Risk Research (*Institut für Risikoforschung*) of the University of Vienna was founded in 1995 with the aim of supporting an interdisciplinary, independent and critical scientific discussion of risks to society and to manage relevant interdisciplinary projects. The Institute consists of a small international team of scientists from different disciplines. Originally, research focused on topics concerning nuclear safety, but has lately evolved towards more fundamental questions of risk research and more general aspects of risk.

BELGIUM

I. GENERAL REGULATORY REGIME

1. Introduction

In Belgium, nuclear energy is not a state monopoly. Most nuclear power production is in private hands, although under the surveillance of the public authorities.

Each of the chief federal ministries, for example, Justice and Economic Affairs, Public Health, Employment and Labour, Foreign Affairs and the Interior, exercises control over nuclear activities that falls within its responsibility.

The legislative and regulatory framework has developed in step with nuclear science and technology.

Adopted in implementation of the Act of 29 March 1958 concerning Protection of the Public against the Hazards of Ionising Radiation, the Royal Order of 28 February 1963 laying down General Regulations concerning the Protection of the Public and Workers against the Hazards of Ionising Radiation is the basic law regulating the nuclear field as a whole. In particular, it governs the licensing of nuclear installations, radiation protection, radioactive waste management, the import, transit and distribution of radioactive substances as well as their transport, and contains appropriate penal provisions. This Order has been amended on numerous occasions since its adoption in order to keep it up to date.

On 15 April 1994 the Parliament passed a Law relating to the Protection of the Public and of the Environment against the Dangers of Ionising Radiation and concerning the Federal Agency for Nuclear Control. This Law repeals the basic Law of 29 March 1958. On 17 September 1996, the Belgian Cabinet of Ministers approved a Royal Decree bringing into force a series of sections of the Law of 15 April 1994; these sections concern, for the most part, the creation of the Federal Agency for Nuclear Control. Furthermore, a Royal Decree of 2 October 1997, amending the Royal Decree of 28 February 1963, effects the entry into force of parts of the Act of 15 April 1994. The 1994 Act was partially amended by an Act of 3 May 1999, which rendered the Agency operational by providing for staff placements and by making available allocated budgetary commitments [see *infra* Part II, Section 2, (i), “Federal Agency for Nuclear Control”].

2. Mining Regime

Belgian regulations concerning prospecting and the export of ores contain no special provisions regarding nuclear ores.

3. Nuclear Installations

a) Licensing and inspection, including nuclear safety

The Act of 29 March 1958 on Protection of the Public against the Hazards of Ionising Radiation, as amended, constitutes the basic Belgian legislation in the nuclear field as amended by the Acts of 29 May 1963, 3 December 1969, 14 July 1987, 22 December 1989, 26 June 1992 and 6 August 1993.

Pursuant to this Act, Belgian regulations in this field are to be found in the above-mentioned Royal Order of 28 February 1963 laying down general regulations concerning the protection of the public and workers against the hazards of ionising radiation [as amended successively by the Orders of 17 May 1966, 22 May 1967, 23 December 1970, 23 May 1972, 24 May 1977, 12 March 1984, 21 August 1985, 16 January 1987, 11 February 1987, 12 February 1991, 6 September 1991 and 17 June 1992].

Civil nuclear installations in Classes I to III are governed by a preliminary licensing system. The latter is also subject to the provisions of the Act of 22 July 1985 on third party liability in the nuclear field. Class IV installations, which use smaller quantities of radioactive materials, are exempt from this system.

The decision to grant a licence for Class I installations – nuclear reactors, installations in which the quantities of fissile substances processed or held are above half the minimum critical mass, plants reprocessing enriched or non-enriched irradiated nuclear fuel – is made in the form of a Royal Order countersigned by the Minister of Social Affairs, Public Health and the Environment (hereinafter referred to as "the Minister of Public Health") and the Minister of Employment and Labour, on the opinion of a Special Committee on Ionising Radiation, following a public inquiry and consultation of the Board of Aldermen (*collège échevinal*) as well as a Provincial Executive Body (*députation permanente du Conseil provincial*).

Class II establishments are licensed by the Provincial Executive Body of the relevant Provincial Council, provided a favourable opinion is given by the Provincial Advisory Committee after consulting the Board of Aldermen.

Class III nuclear establishments are notified to the Governor of the Province for the purpose of licensing by the Provincial Executive Body.

State-run Class II establishments are licensed by Royal Order if the opinion of the Board of Aldermen and the Special Committee is favourable. Class III establishments operated by the state are licensed by the Minister of Public Health.

The purpose of the Ministerial Order of 9 March 1987 was to implement Section 13 of the Act of 22 July 1985 regarding the obligation to make available to the public the register containing the texts granting recognition to the operators of nuclear installations. The Order states that a register comprising a certified copy of the Royal Orders granting recognition and a map showing the location and boundaries of the site of each installation must be made available to the public by the Ministry of Justice and Economic Affairs in Brussels. The various council authorities must also comply with this obligation as concerns installations located on their territory.

The following bodies are responsible for ensuring that safety measures are complied with and that the safety and protection systems of nuclear installations are operating satisfactorily: experts from the health service of the installation, approved private bodies supervised by the responsible authorities, *i.e.* the Industrial Safety Department in the Ministry of Employment and Labour and, depending on the circumstances, the Public Health Service (Ministry of Public Health), or the Service of Health and Occupational Medicine (Ministry of Employment and Labour), and also these authorities themselves. The *bourgmestres* (mayors of communes) check that the establishments have been duly licensed.

When a nuclear operator plans to discharge radioactive effluents likely to cause radioactive contamination in a Member State of the European Communities (now the European Union), the Special Committee, in accordance with Article 37 of the Euratom Treaty, consults the European Commission through the Belgian Public Health Department.

In the event of a nuclear incident endangering public health, the King has the right to take all measures concerning nuclear establishments with a view to avoiding the danger of radioactive contamination [Royal Order of 28 February 1963, as amended].

At the international level, Belgium ratified the 1994 Convention on Nuclear Safety on 13 January 1997.

b) Protection of the environment against radiation effects

There is no specific legislation in Belgium concerning the protection of the environment against radiation. This subject is dealt with briefly in the Royal Order of 28 February 1963 laying down the General Regulations for the Protection of the Population and of Workers against the Hazards of Ionising Radiation, and in greater detail in the Royal Order of 11 February 1987 amending the above-mentioned Order.

Part IV "Radioactive Waste" (Chapter III) of the 1963 Order includes provisions [Sections 34(1), 34(2), 34(3), 36(1) and 37(3)] which prohibit the release of liquid radioactive waste into surface waters, soil, sewers or underground conduits and prohibits the discharge of radioactive substances in the atmosphere in the form of gas, dust, smoke or vapour, when their radionuclide content or radioactive substances exceed a certain maximum permissible concentration. They also prohibit the storage of radioactive waste on the surface or underground.

The Order of 11 February 1987 refers to Council Directive 80/836/Euratom of 15 July 1980 concerning the health protection of the general public and workers against the dangers of ionising radiation [amended by Council Directive 84/467/Euratom of 3 September 1984], and relates simply to standards for radio-active effluent releases into the environment, notably in liquid or gaseous form.

The Minister for the Interior, in conjunction with the Minister for Public Health, supervises the planning and execution of measures to be taken in case of accident or of abnormal rise in background radioactivity.

c) Emergency response

A Royal Order of 6 September 1991 amended the Royal Order of 28 February 1963 to bring it into line with Council Directive 89/618/Euratom on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency.

Another Royal Order, adopted on 27 September 1991, established an emergency plan for nuclear risks on Belgian territory. This emergency plan is to serve as a guide for the measures to be taken whenever necessary to protect the public and the environment [Annex, Section 1(2)]. It establishes the duties of the different services and bodies, in accordance with their responsibilities under national laws and regulations, and describes the general organisation. This plan is to be supplemented by intervention plans at the different levels involved: the provincial authorities, the communal authorities and the different institutions concerned [Annex, Section 1(3)(2)]. It is the Minister of the Interior's responsibility to decide on projects thus established [Section 2]. This Minister is also responsible for co-ordinating all measures required to implement the emergency plan [Annex, Section 2(1)(1)].

The plan mainly concerns large nuclear installations and the transport of nuclear fuels and radioactive materials, although lower risks from other activities are also covered [Annex, Sections 1(3)(1) and 1(3)(2)].

At the international level, it is of relevance to note that Belgium is a Party to both the 1984 Convention on Early Notification of a Nuclear Accident and the 1984 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency since 4 January 1999.

4. Trade in Nuclear Materials and Equipment

Belgium is active in the nuclear equipment and services market and participates in various industrial undertakings in this field.

Provisions relating to radioactive substances and nuclear equipment are contained in the above-mentioned Royal Order of 28 February 1963, and apply in particular [Section 1]:

- to the import, production, manufacture, possession, transport, and use for commercial, industrial, scientific, medical or other purposes, of apparatus, equipment or substances capable of emitting ionising radiation;

- to the offer for sale, sale or assignment for consideration or free of charge, of substances capable of emitting ionising radiation or of apparatus or equipment containing such substances;

- to the processing, handling, storage, removal and disposal of radioactive substances and waste.

The Order applies to all natural or legal persons who build and operate nuclear installations using fissile substances, radionuclides or apparatus generating X-rays, facilities for the storage and reprocessing of nuclear fuels and particle accelerators. A licensing system is laid down for each of these activities.

Persons and firms involved in the import into, or transit through Belgium of radioactive substances and apparatus emitting ionising radiation, must be duly licensed by the Minister of Public Health [Section 38(1)]. Licences may be either general or particular, and are granted for a given period. Licensing applications must include certain information such as the identity of the applicant, the policy corresponding to the classification of the establishment, the types of use, the characteristics of the substances and apparatus involved and the insurance policy covering third party liability [Section 38(2)]. Special accounting procedures are used with regard to the delivery of radioactive

substances [Section 41]. Importers and distributors are required to supply the Minister of Public Health on a monthly basis with information about imports and deliveries made and the consignees involved [Section 42].

Persons in possession of nuclear substances must take the necessary measures to prevent their theft, loss or misuse [Section 66]. Should the need arise, it is the Minister of Public Health's responsibility to prohibit the distribution of certain radioactive substances [Section 64(4)].

The Order also lays down the special conditions governing the import, transit and processing of radioactive substances.

The Ministerial Order of 29 November 1989 provides that the export of so-called strategic products listed in the Annex thereto, is subject to a licence, unless they are being exported to Luxembourg or the Netherlands. Another Ministerial Order of the same date provides that a licence is also required for the transit of the goods specified in the Annex to the above-mentioned Ministerial Order of 1989; similarly, this Order does not apply to goods in transit to or from Luxembourg or the Netherlands.

5. Radiation Protection

There are three basic legislative instruments in Belgium governing the field of radiation protection:

- the Act of 29 March 1958 on Radiation Protection [as amended by the Framework Act of 22 December 1989 which provides details concerning the powers of those responsible for ensuring compliance with the Act and its implementing Orders] (The Act of 29 March 1958 was repealed by the Act of 15 April 1994 on Protection of the Public and the Environment against the Dangers of Ionising Radiation, and on the Federal Agency for Nuclear Control, published in the *Moniteur belge* of 29 July 1994; however this legislation has only partly entered into force at the time of writing (1999)];

- the Royal Order of 28 February 1963 on the Protection of the Population and of Workers against the Hazards of Ionising Radiation (Chapter III) [as amended by the Royal Orders of 21 August 1985, 16 January 1987, 11 February 1987, 17 June 1992 and 2 October 1997], laying down the basic principles in this field; and

- the General Regulations of 1946 concerning Safety at Work [two Orders of the Regent of 11 February 1946 and 25 September 1947, as amended by the Acts of 10 June 1952 and 17 July 1957, and by the Orders of 5 December 1990, 31 March 1992 and 25 April 1997].

The Royal Order of 16 January 1987, amending the 1963 Order, brings Belgian radiation protection law into line with the provisions of Council Directive 80/836/Euratom of 15 July 1980 on the health protection of the general public and workers against the dangers of ionising radiation [as amended by Council Directive 84/467/Euratom of 3 September 1984]. The Order also takes into account Council Directive 84/467 of 3 September 1984 on the radiation protection of persons undergoing medical examinations or treatment. Also in implementation of Council Directive 84/467/Euratom, the Royal Order of 2 October 1997 requires persons responsible for the operation of establishments where radiological, radiotherapeutic or nuclear medicine installations are in use, to consult experts in radiophysics for the organisation and supervision of measures necessary for the protection of patients and to control the quality of the equipment. The Order lays down the criteria and

procedure for the official recognition of the experts. For its part, the Royal Order of 17 June 1992 replaced certain Sections of the 1963 Order to bring them into line with an opinion of the European Commission; this amendment dealt essentially with the monitoring of doses received by the public and the technical arrangements for such monitoring.

The Royal Order of 2 October 1997, amending the 1963 Order, aims to complete the implementation into Belgian law of a series of European Directives, including in particular Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in restricted areas. This Directive had been partially implemented by the adoption of a Royal Order of 25 April 1997 (which amended the General Regulations of 1946). In addition, this Decree completes the implementation of Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and about steps to be taken in the event of a radiological emergency. Furthermore, Chapter IV of the 1963 Order is replaced by provisions governing import, export, transit and distribution of radioactive substances. These provisions determine the formalities which must be carried out in order to obtain a licence for any of the above activities in relation to radioactive substances or waste.

The General Regulations of 1946 on safety at work were amended by the Royal Decree of 5 December 1990, the purpose of which was to incorporate the above-mentioned European Directives of 1980 and 1984 on radiation protection into Belgian law. Further amendments to certain provisions of the said Regulations were made by a Royal Order of 31 March 1992. The purpose of these amendments was to prevent certain international and national civil servants (namely, IAEA inspectors, persons designated as responsible for surveillance under the Euratom Treaty and the Act of 4 August 1955 on state security in the nuclear field, and work inspectors) being hindered in their control duties.

Several government bodies and various agencies are concerned with radiation protection questions. In regulatory matters, the Higher Council for the Safety, Hygiene and Enhancement of Workplaces and the Higher Council for Public Health are consulted by the Minister of Employment and Labour and by the Minister of Public Health respectively, with regard to the drafting and implementation of legislation on the safety and health of workers and the population. The Interministerial Commission for Nuclear Safety and State Security in the Nuclear Field draws up co-ordination plans for the various ministerial departments concerned with a view to improving the health protection of workers and the public. The Industrial Health and Medicine Department of the Ministry of Employment and Labour collects data on the radiation received by persons exposed to ionising radiation in the course of their work and draws the relevant inferences. The Public Health Department of the Ministry of Public Health, assisted by the Institute for Hygiene and Epidemiology, is responsible for enforcing the health protection of the population. The exposure of the public and of workers to ionising radiation must be kept as low as possible [Royal Order of 28 February 1963, Section 20(1)]. The Minister of Public Health is entrusted with monitoring radioactivity throughout Belgium and measuring the doses received by the population [Order of 28 February 1963, Section 70, as amended by the Order of 17 June 1992].

In the event of danger to the health of persons or animals, the Minister holding the portfolio of Public Health may prohibit the distribution of certain radioactive substances. He may also, after consulting the Higher Council for Public Health, authorise the irradiation of foodstuffs or medicines. Amongst other provisions, the Royal Order of 21 August 1985 allows medicines to be sterilised by ionising radiation subject to conditions to be set at the time of registration of the medicines concerned.

The purpose of the Ministerial Order of 3 November 1987 regulating the radioactive contamination of agricultural products was to implement at national level Articles 1 to 3 of Council Regulation 1707/86 of 30 May 1986 (as amended by Council Regulation 1762/86 of 5 June 1986) on conditions for the import of agricultural products from non-European Community States after the accident at the Chernobyl nuclear power plant. The Order provides that its provisions and the maximum permissible radioactivity limits will also apply to trade in foodstuffs with Community Member States. The European Regulation expired on 31 October 1987, but remains applicable in Belgium; the Belgian Order will cease to apply on the entry into force of a Community Regulation extending or replacing the existing Regulation.

6. Radioactive Waste Management

The Radiation Protection Order of 28 February 1963 contains a number of provisions concerning radioactive waste and waste storage [Chapter II, Part 2, and Chapter III, Part 4].

Under the licensing regime, detailed information has to be given about the measures to be taken for the storage, treatment and disposal of any radioactive waste, whether in liquid, solid or gaseous form.

The Order of 16 October 1991, amending the Royal Order of 30 March 1981 laying down the tasks and rules of procedure of the National Organisation for Radioactive Waste and Enriched Fissile Materials (ONDRAF) (See Part II "Institutional Framework" of this study *infra*) regulates the relationship between ONDRAF and the operators of nuclear installations.

All persons in possession of radioactive waste or who operate installations producing such waste or who plan to build such installations must provide ONDRAF with all the necessary information.

ONDRAF concludes an agreement with the operators of nuclear installations regularly producing a quantity of radioactive waste considered significant by ONDRAF, which relates to the implementation of the general radioactive waste management programme and lays down the rights and obligations of the parties concerned.

In addition, an agreement is concluded between the person in possession of the waste and the Organisation relating to the taking over of the radioactive materials by ONDRAF for conditioning, storage and transport. These agreements specify in particular the arrangements for the transfer of responsibility and the financial and technical conditions applying.

As far as decommissioned nuclear installations are concerned, ONDRAF is responsible for preparing management programmes for the waste resulting from decommissioning and must decommission nuclear installations at the request of the operator concerned or in the event of the incapacity of the operator.

The Royal Order of 2 October 1997 implements Council Directive 92/3/Euratom of 3 February 1992 on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community. In this respect, the Order sets out a model uniform document for the supervision and control of these transfers.

7. Non-Proliferation and Physical Protection

a) International aspects

Any persons or enterprises in any way producing, using or storing source and special fissile materials on Belgian territory must comply with the provisions in Chapter VII "Safeguards (Security Control)", of the Treaty establishing the European Atomic Energy Community and its implementing regulations, which form an integral part of Belgian law [Act of 2 December 1957].

They must also allow and facilitate inspections and checks by the International Atomic Energy Agency (IAEA) in order to verify the results obtained by the safeguards system of the European Atomic Energy Community [Act of 20 July 1978].

In addition, on 9 February 1981, an Act was adopted laying down a prior licensing system for the export of nuclear materials and equipment as well as of technological data, the details of which were to be specified in a Royal Order in the light of the international agreements entered into by Belgium in the nuclear field. This was done by the Royal Order of 12 May 1989 relating to the transfer to non-nuclear weapon states of nuclear materials, equipment, technological data and derivatives.

After obtaining the opinion of an advisory committee composed of representatives of the various ministries concerned, the Minister holding the portfolio of Energy verifies that the transfers will be carried out exclusively with a view to the peaceful use of atomic energy and subject to the required controls (safeguards system –physical protection) and in compliance with Belgium's commitments under the 1968 Treaty on the Non-proliferation of Nuclear Weapons, which it ratified on 2 May 1975. Belgium also ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 29 June 1999, as well as the 1979 Convention on the Physical Protection of Nuclear Material on 6 September 1991.

b) National control and security measures

Under the Act of 4 August 1955 concerning state security in the field of nuclear energy, research, materials and production methods carried out or used by institutions, establishments or physical or legal persons which have at their disposal information, documents or nuclear materials obtained either directly from the government or with its permission and which, in the interests of the defence of the national territory and of state security, come under the rules of secrecy, must comply with the security measures laid down in the Royal Order of 14 March 1956.

These measures govern the fitting out, protection and surveillance of premises, the classification of documents and materials, the safe-keeping of documents and the preservation of materials, the determination of criteria for their dissemination and the requirements for conducting an activity in or entering premises where such research and work is carried out [Order of 14 March 1956 as amended by Order of 18 October 1974].

In principle, Belgian nationality is required in this respect. Nevertheless, an exception may be made by decision of the Minister holding the portfolio of Energy if the foreign applicant possesses specialised knowledge.

The Royal Order of 12 February 1991 added a new Section 37 to the General Regulations for the protection of the population and of workers against the hazards of ionising radiation of 28 February 1963. It is specified that, without prejudice to the provisions of the Royal Order of 1956

concerning implementation of the above-mentioned 1955 Act, it is prohibited to enter the sites or premises referred to in the said Order or to visit them without the specific permission of the person in charge of the enterprise or his deputy. Official inspectors are exonerated from the obligation to seek such permission.

In addition, the disclosure of manufacturing secrets and inventions relating to the nuclear field which are not subject to the Act of 4 August 1955 but whose disclosure is declared jointly by the Minister holding the portfolio of Energy (responsible for industrial property) and the Minister of National Defence to be contrary to the interests of the defence of the territory or of state security, is prohibited, or else the conditions in which they may be exploited are temporarily determined and controlled by the said Ministers in accordance with the Act of 10 January 1955 relating to the disclosure and use of inventions and manufacturing secrets concerning the defence of the territory or state security. Prohibitions or limitations may be partly or totally lifted at any time by joint decision of the Ministers who issued them. An application may be made by the holder of the rights for the prohibition or limitation to be lifted.

The purpose of the Act of 17 April 1986 on implementation of the Convention on the Physical Protection of Nuclear Material is to implement Articles 7 and 8 of the Convention of 3 March 1980 in Belgian national law. Article 7 lays down that States Parties must provide for penalties for a number of serious offences with respect to nuclear material. Article 8 specifies the cases in which measures must be taken by States Parties to establish their jurisdiction over such offences. The 1986 Act therefore specifies that provisions on sanctions to be applied for these offences must be inserted in the Penal Code. It also states that provisions specifying that courts in Belgium are competent to deal with such offences committed in the territory of States Parties to the Convention or on board a vessel or aircraft registered in one of those States must be included in the Code of Criminal Procedure, if the presumed perpetrator of the offence is within national territory and the Government of Belgium has made no arrangements with the State concerned regarding extradition.

8. Transport

The transport of nuclear materials in general is governed by the amended Royal Order of 28 February 1963 laying down General Rules on the Protection of the Public and Workers against the Hazards of Ionising Radiation.

The requirements laid down by the general rules embody the international agreements on this subject, namely the IAEA Regulations for the Safe Transport of Radioactive Materials, the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID), the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the IMO International Maritime Dangerous Goods Code and the Ordinance concerning the transportation of dangerous goods on the river Rhine (ADNR) [Act of 24 January 1973, Act of 10 August 1960, Royal Order of 14 January 1960 as amended by Royal Order of 5 March 1971, Royal Order of 2 December 1971 as amended by Royal Orders of 29 December 1976, 1 February 1977, 24 December 1978 and 7 September 1979].

A licence issued by the Minister of Public Health and the Environment is required for the transport of radioactive substances. Licences may be of a general nature, when the carrier transports radioactive substances on a regular basis, specific, where the carrier occasionally transports such substances, or special, in the case of substances with a level of radioactivity above certain thresholds.

The Minister of Public Health receives from the carriers concerned a monthly report on their transport of radioactive materials.

Lastly, ONDRAF is responsible for organising the transport of radioactive waste from the installations producing it and for the transport of enriched fissile materials or plutonium-bearing materials whose quantity and enrichment rate exceed certain limits set by Section 2(2)(2)(a) of the Royal Order of 30 March 1981 as amended by the Royal Order of 16 October 1991; this may also cover surplus quantities of fresh or spent fuel it should take over.

9. Nuclear Third Party Liability

Belgian rules on nuclear third party liability are contained in the Act of 22 July 1985 on Third Party Liability in the Field of Nuclear Energy published in the *Moniteur belge* of 31 August 1985. This Act implements the 1960 Paris Convention and the 1963 Brussels Supplementary Convention, ratified by Belgium on 3 August 1966 and 20 August 1985 respectively.

The 1985 Act lays down the principle of strict liability, limited in amount and time, channelled to the operator of a nuclear installation. In this respect, Section 7 of the Act establishes the maximum amount of the operator's liability for nuclear damage at Belgian francs (BEF) 4 billion. Pursuant to the terms of the Act, the operator is obliged to take out an insurance policy, or another form of financial guarantee, to cover his liability up to the amount set out in the Act [Section 8]. The Act further establishes, as a corollary of this obligation, a procedure whereby the King recognises the operator as such [Sections 9 to 13].

Although the Act provides that the operator remains liable during the carriage of nuclear substances, it does not exclude the possibility of transferring liability to the carrier [Section 14]. In any event, the carrier is required to hold a certificate stating that he satisfies the financial security conditions [Section 15].

Section 23 of the Act establishes a prescription period of ten years from the date of the nuclear incident in respect of the right to claim compensation. Beyond this period, the state is responsible for the payment of compensation in respect of claims for damage which are time-barred, within a maximum period of 30 years from the date of the incident.

Several orders have been adopted to implement the 1985 Act, in particular:

- the Royal Order of 28 April 1986, determining the financial security certificate for transport of nuclear substances, whose purpose is to ensure that financial security certificates (given to all carriers of nuclear substances by the operator liable) comply with the Paris Convention requirements in this respect, as prescribed by the 1985 Act;

- the Ministerial Order of 9 March 1987 on the register concerning nuclear installations, which aims to implement Section 13 of the 1985 Act regarding the obligation to make available to the public the register containing the texts granting recognition to the operators of nuclear installations.

At the international level, Belgium ratified the 1971 Convention relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material on 15 June 1989.

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities

a) Minister holding the portfolio of Energy

The Minister holding the portfolio of Energy is responsible for nuclear energy as he is for other types of electricity production. A Secretary of State for Energy may act as deputy to the Minister.

The Minister is also responsible for nuclear research, in consultation with the Minister for Science Policy.

The Minister manages the nuclear sector on the same footing as other electricity-producing processes. The national investment programme for generating facilities and power transmission is submitted for the Minister's approval after examination by the National Energy Committee [Special Act of 8 August 1980 on institutional reforms, as amended by Special Acts of 8 August 1988 and 16 July 1993]. Research centres in the nuclear field (CEN, IRE) and the National Organisation for Radioactive Waste and Enriched Fissile Materials (ONDRAF) also come under the authority of the Minister.

Nuclear matters are handled by the Energy Department of the Ministry of Justice and Economic Affairs and in particular by the Electricity Service and Nuclear Applications Service, which also works in liaison with industry and the international organisations concerned with nuclear energy.

Generally speaking, the Minister holding the portfolio of Energy is responsible at national level for internal and external state security issues.

Nuclear Security Service

This is a highly technical security department set up in order to meet international commitments and is directly responsible to the Minister holding the portfolio of Energy.

Within its specific field, it ensures that safety and security measures are applied throughout the national territory. It supervises these measures and is especially responsible for tracking down and reporting any infringements made.

Under the Royal Order of 30 May 1960, this Service is also responsible for the application in Belgium of Euratom Regulation 3 pursuant to Article 24 of the Euratom Treaty (provisions concerning classified information).

The Service is also responsible for representing the Belgian Government and protecting national interests at inspections of nuclear installations under the provisions of the Treaty establishing the European Atomic Energy Community (Chapter VII, "Safeguards") and the International Agreement of 5 April 1973 concluded pursuant to Article III, paragraphs 1 and 4 of the Treaty on the Non-Proliferation of Nuclear Weapons (safeguards system) [Acts of 2 December 1957, 14 March 1975 and 20 July 1978].

Finally, it acts as adviser to the authority responsible for applying the Royal Order of 28 February 1963 [General Regulations on the Protection of the Public and Workers against the Hazards of Ionising Radiation] in relation to the physical protection of source materials and special fissile materials during use, storage and transport.

Under the Minister holding the portfolio of Energy, the Director of Nuclear Security is responsible for enforcing the security measures relating to classified information, documents and nuclear materials and those concerning land and premises used for research or production activities involving such information or materials [Royal Order of 14 March 1956 as amended by Royal Order of 18 October 1974]. He gives the necessary instructions for their application and takes the necessary decisions concerning clearance. He authorises the communication of classified documents and materials, and regulates their transfer. In his task, he is assisted by a security officer and by deputies, as well as by executive staff.

The Director of Nuclear Security, the security officer and their deputies, who act as auxiliary officers of the Criminal Investigation Department under the Royal Attorney, are appointed by Royal Order on the proposal of the Minister holding the portfolio of Energy [Order of 2 April 1957].

b) Minister of Social Affairs, Public Health and the Environment

The powers of this Minister are principally defined in the Royal Order of 28 February 1963.

The Minister is the supervisory authority for the Public Health Department which, more specifically, is responsible for the surveillance of nuclear installations from the standpoint of the protection of public health.

c) Minister of Employment and Labour

The Minister of Employment and Labour is responsible for the safety and health of workers exposed to the dangers inherent in nuclear installations. He approves the dosimeters to be worn by the workers exposed to ionising radiation in the course of their work.

He is the supervisory authority for:

- the Industrial Health and Medicine Department, which is responsible for the protection and medical supervision of workers;

- the Industrial Safety Department, which is responsible for the technical supervision of nuclear installations from the industrial safety standpoint.

d) Minister of the Interior

In the context of civil defence, the Minister of the Interior, in conjunction with the Minister of Public Health, has the task of drawing up the measures to be taken in the event of an accident or an abnormal rise in ambient radioactivity and for putting them into effect.

A Royal Order of 3 July 1995 designates the Minister of the Interior as the competent authority for the technical safety of nuclear installations. An Order of 7 August 1995 makes him the competent

authority for the protection of the population and the environment against the dangers of ionising radiation. As a result, the Service for the Technical Safety of Nuclear Installations (SSTIN) and the Service for Protection against Ionising Radiation (SPRI) have been placed under his authority.

The SSTIN forms an integral part of the Department and is comprised of technical and administrative sections.

The tasks of this Service are as follows:

- to act as the Secretariat for the Special Committee on Ionising Radiation and to carry out preliminary investigations of cases involving safety issues;

- to assist the Interministerial Commission for Nuclear Safety and State Security in the Nuclear Field;

- to investigate problems connected with the technical safety of nuclear installations and their operation;

- to co-ordinate the work of the various inspectorates supervising the health and safety of workers in nuclear installations and to provide the necessary scientific back-up in this connection;

- to propose the appointment of approved bodies to whom the state assigns specific tasks concerning the surveillance of nuclear installations and to check that the tasks entrusted to these bodies are carried out.

The SPRI, which forms part of the Public Health Department, is responsible for enforcing the General Regulations for the protection of the public and workers against the dangers of ionising radiation [Royal Order of 28 February 1963].

Its tasks include:

- investigating, together with the Technical Safety Service for Nuclear Installations (see above), applications for the licensing of nuclear power plants and other Class I establishments, as well as Class II establishments run by the state;

- investigating applications for the import, transit and transport of radioactive substances and ensuring compliance with the requirements laid down for these licences;

- examining applications for licences to use, manufacture and distribute radioactive substances for medical purposes (this provision also applies to irradiated foodstuffs);

- making proposals for the approval and testing of medical equipment emitting ionising radiation;

- acting as Secretariat for the Interministerial Commission for Nuclear Safety and State Security in the Field of Nuclear Energy;

- drawing up new rules concerning protection against ionising radiation and reviewing these rules at regular intervals.

The Civil Defence Department is kept informed of the activity of operators of nuclear installations. Within its field of responsibility, it collaborates with the Minister of Public Health in monitoring radioactivity within Belgium.

As part of its role as intelligence service to the Ministry, the *General Police Department of the Kingdom* gathers information on attempted attacks on nuclear installations or nuclear materials in transport. It takes all necessary steps for police force co-ordination in the prevention of such attempts.

e) Minister of National Defence

The Minister of National Defence has general authority over nuclear activities in military establishments.

Subject to favourable opinion from the Special Military Committee, he licenses military nuclear establishments and the production, possession, marketing and transport of nuclear materials for use by the armed forces [Royal Order of 11 May 1971, as amended by Royal Orders of 5 December 1975 and 15 November 1985].

In agreement with the Minister of Public Health and with the Minister of the Interior as regards civil defence, he co-operates with the public and private bodies responsible for monitoring radioactivity within Belgium.

The Minister is responsible, in the military field, for the protection of persons against the hazards of ionising radiation [Act of 9 August 1963].

f) Minister of Foreign Affairs

The Minister of Foreign Affairs is responsible for all international matters concerning nuclear energy.

In particular, he handles negotiations for Belgium's adhesion to, or participation in, international, bilateral or multilateral agreements and treaties and represents Belgium in international organisations.

More specifically, within the Foreign Affairs Department, the General Directorate for Policy (Scientific Service) is responsible for dealing with these matters.

Jointly with the other ministers involved, the Minister of Foreign Affairs is also responsible for international trade matters and for ensuring that Belgium's international commitments are honoured.

g) Minister for Science Policy

The Minister for Science Policy is responsible for generally co-ordinating the Federal government's activities relating to science policy. He shares the responsibility for nuclear research with the Minister holding the portfolio of Energy [Royal Order of 18 May 1971].

h) Regional Governments

Under the terms of the Special Act of 8 August 1980 on institutional reforms, as amended, a number of responsibilities, including those for town and regional planning, were transferred to regional authorities.

2. Advisory Bodies

a) National Energy Committee

The National Energy Committee (*Comité national de l'énergie)* examines the national programme for the construction of electricity-generating and power transmission facilities, and submits its conclusions to the Minister holding the portfolio of Energy [Act of 8 August 1980 on budgetary proposals for 1979-1980 and Royal Order of 12 December 1975 as amended by Royal Order of 23 November 1977].

b) Special Committee on Ionising Radiation and Provincial Advisory Committees on Nuclear Installations

The Special Committee on Ionising Radiation (*Commission spéciale des radiations ionisantes*) is a technical advisory committee set up by the Royal Order on Radiation Protection of 28 February 1963 to give its opinion on licensing applications for Class I and state-run Class II nuclear installations.

The Special Committee is alternately chaired by an official of the Ministry of Employment and Labour and an official of the Ministry of Public Health for periods of two years each. It has seventeen members, seven representing the various ministerial departments and bodies concerned and ten eminent scientists jointly appointed by the Minister of Employment and Labour and the Minister of Public Health for a renewable period of six years. Under the Royal Order of 12 March 1984, amending the 1963 Order, the Committee was enlarged to include the Government of the Brussels-Capital Region, the Walloon Government and the Flemish Government. Thus, those governments may each, if they so wish, appoint a delegate to participate in meetings of the Committee in an advisory capacity.

Each province has a Provincial Advisory Committee on Nuclear Installations (*Comité consultatif provincial pour les installations nucléaires*), similar to the Special Committee, which handles the licensing applications for Class II nuclear establishments not run by the state.

The Committees are alternately chaired by officials of the Ministry of Employment and Labour and of the Ministry of Public Health for periods of two years. Other members are six representatives of the Ministerial departments and bodies concerned, one secretary and one deputy-secretary present in an advisory capacity.

c) Higher Council for Safety, Hygiene and Enhancement of Workplaces

This Higher Council (*Conseil supérieur de sécurité, d'hygiène et d'embellissement des lieux de travail*) reports to the Minister of Employment and Labour. It is consulted when rules relating to the safety and health of workers are being drawn up. It also expresses an opinion when the rules of

procedure are prepared for the Services and Committees set up within nuclear enterprises to deal with health and enhancement of the workplace [Royal Order of 21 March 1958, Section 843 of the General Rules on Safety at Work of 27 September 1947, as amended].

d) Higher Council for Public Health

The Higher Council for Public Health (*Conseil supérieur d'hygiène publique*) is under the auspices of the Minister of Public Health [Royal Order of 14 September 1919].

It may submit opinions to the public health authorities on any matter concerning public health, and in particular when the regulations relating to the protection of the public against ionising radiation are being drafted.

The chairperson is appointed by the Minister of Public Health. The Secretariat is provided by the Secretary-General of the Ministry.

The Council has forty-five members chosen from among officials but also from university staff, scientists and experts on public health.

e) Interministerial Commission for Nuclear Safety and State Security in the Nuclear Field

The Interministerial Commission for Nuclear Safety and State Security in the Nuclear Field (*Commission interministérielle de la sécurité nucléaire et de la sûreté de l'État dans le domaine nucléaire*) was set up by the Royal Order of 15 October 1979.

For administrative and financial purposes, the Commission is under the auspices of the Minister of Public Health.

Its task is to seek ways of ensuring the protection of workers and the public against any hazards that might arise from activities connected with the use, processing, storage and transport of radioactive substances both within and outside installations where such activities are carried on. It draws up a plan for the co-ordination of the activities of the Ministerial departments concerned, namely the Technical Safety Service for Nuclear Installations in the Ministry of Employment and Labour, the Radiation Protection Service in the Ministry of Public Health, the Nuclear Security Service in the Ministry holding the portfolio of Energy, the Scientific Service in the Ministry of Foreign Affairs, the Civil Defence and General Police of the Kingdom Departments in the Ministry of the Interior, and the Service for Protection at Work of the General Headquarters of the Armed Forces under the Ministry of National Defence.

The Commission submits a report on its activities to the government at least twice a year.

The Interministerial Commission has ten members: the chairperson of the Special Committee on Ionising Radiation and nine members appointed by the ministers concerned. The chairperson is appointed by the Minister of Public Health, the vice-chairperson by the Minister of Employment and Labour.

The Interministerial Commission consults experts or delegates from other Ministries, whom it may invite to attend its meetings in an advisory capacity, whenever it considers they might be able to help resolve a specific problem. The amendments to the Royal Order of 15 October 1979 introduced

by the Royal Order of 14 February 1984 provide that the Government of the Brussels-Capital Region, the Walloon Government and the Flemish Government may, if they so wish, each appoint a delegate to take part in the Commission's meetings in an advisory capacity.

f) Advisory Committee on the Export of Nuclear Materials, Equipment and Nuclear Technological Data

In order to ensure that international agreements on the non-proliferation of nuclear weapons are honoured, Belgian law has imposed a licensing system on exports of nuclear materials and equipment, nuclear technological data and their by-products [Act of 9 February 1981].

Licences are granted by the Minister responsible for Energy after obtaining the opinion of this Advisory Committee (*Commission consultative pour l'exportation des matières et équipements nucléaires, ainsi que des données technologiques nucléaires*) on the non-proliferation of nuclear weapons, responsible for ensuring that the transfer concerned is intended for the peaceful use of nuclear energy.

The members of this Committee are appointed by the King and represent the chief Ministries involved.

Leading scientists may be requested by the Committee to give their opinions on specific matters.

g) National Council for Science Policy

The Council (*Conseil national de la politique scientifique*) is an advisory body reporting to the Minister for Science Policy. It delivers opinions and recommendations on the matters submitted to it by the Ministerial Committee on Science Policy (CMPS) and may be consulted about nuclear research, among other things [Order of 16 September 1954 as amended by Royal Orders of 14 April 1963, 11 May 1966, 27 December 1967 and 14 August 1968].

It has 34 members including representatives from scientific research and university circles and experts from the economic and social fields involved.

h) Commission for Assessing Nuclear Information

A Ministerial Order of 12 November 1991 set up, under the Ministry holding the portfolio of Energy, a Commission responsible for assessing information in the nuclear field (*Commission d'évaluation de l'information dans le domaine nucléaire*).

The Commission must ensure that the public is kept informed about the technical, health, ecological, economic and financial aspects of nuclear activities, and advises the Minister on the conditions for informing the public as well as proposing methods for disseminating such information.

The Commission is made up of Members of Parliament from constituencies directly concerned by the siting of nuclear installations, experts in communication, representatives of nature and environment associations, scientists and economists.

i) Federal Agency for Nuclear Control

The Royal Decree of 17 September 1996 brought into force certain sections of the Law of 15 April 1994 relating to the protection of the public and the environment against the danger of ionising radiation. These sections concern, for the most part, the creation of the Federal Agency for Nuclear Control (*Agence fédérale de contrôle nucléaire*) as a public body with legal personality. In particular there is established a Council of Administration composed of a president and thirteen members. These are appointed by the King for a renewable period of six years. The members of the Council were named by a Royal Decree of 14 January 1997.

The Framework Law of 12 December 1997 [published in the *Moniteur belge* of 18 December 1997] introduces an amendment into Article 45 of the Act of 15 April 1994; this provision regulates the transfer of personnel to the Agency from the Division of Technical Safety of Nuclear Installations, which is part of the Ministry of Employment and Labour, and from the Division for Protection against Ionising Radiation, which is part of the Ministry of Social Affairs, Public Health and the Environment. The Act of 3 May 1999 was adopted in order to establish transitional legal measures to allow the Agency to become operational as soon as possible. One such measure makes available staff from the two above-mentioned Divisions to the Agency. This transfer has been carried out on a voluntary basis and the civil servants maintain the rights and benefits which they had in their original position. During this transitory period, which shall not exceed two years, the Agency is required to adopt Staff Rules. When this has been completed, it will be possible to commence final selection and transfer of staff.

Furthermore, the Act of 3 May 1999 provides for the insertion of a new provision into Article 12 of the 1994 Act, pursuant to which the Agency is entitled to receive and use the payments necessary to cover its operating costs before the entry into force of the provisions governing its effective powers. At the time of writing (1999), certain provisions of the Law of 1994 have not yet entered into force.

Finally, the Act of 3 May 1999 gives retroactive effect to the above provisons, which are stated to apply as of 1 January 1998, date on which Articles 12, 45 and 46 of the 1994 Act came into force.

3. Public and Semi-Public Agencies

a) Institute for Hygiene and Epidemiology

The Royal Order of 6 March 1968 establishing the Institute for Hygiene and Epidemiology (*Institut d'hygiène et d'épidémiologie*) as a state scientific establishment defines one of its tasks as the study of scientific problems relating to the prevention and correction of factors likely to impair the health and well-being of mankind.

In practice, the Institute is the Ministry of Public Health's laboratory and scientific service. Its task is to supply permanent scientific assistance in various fields, including that of radioactivity, to the authorities concerned with public health and environmental protection at national, regional and local levels.

The Institute may, in the performance of its duties, call on the co-operation of outside bodies (CEN, universities, etc.).

b) Nuclear Energy Research Centre (CEN)

The development of nuclear energy applications, which resulted in the Nuclear Energy Applications Research Centre being faced with increasingly complex and diversified activities involving heavy investment which private industry could no longer finance on its own, led the Belgian Government to replace this non-profit-making association, set up on 19 April 1952, by the Nuclear Energy Research Centre (*Centre d'études de l'énergie nucléaire* – CEN), a public service (*établissement d'utilité publique*) with administrative headquarters in Brussels and scientific facilities in Mol.

i) Legal status

The Royal Order of 23 July 1957 [amended subsequently by Royal Orders of 4 August 1958 and 7 March 1963] founded the Nuclear Energy Research Centre as a public service. The relationship between the CEN and the national government was regulated by a Convention concluded between the Centre and the Minister holding the portfolio of Energy on 1 February 1963. It provided in particular that the Minister was the supervisory authority of the CEN. This Convention was replaced by a Royal Order of 16 October 1991 which lays down the rules for supervising the Centre and provides for its funding. The Royal Order also amended its Statute.

In accordance with the Special Act on institutional reforms of 8 August 1988 amending the Act of 8 August 1980, the Special Act for financing the communities and regions of 16 January 1989 and the Royal Order of 16 October 1991 concerning the transfer of some of the tasks, assets, rights and obligations of the Nuclear Energy Research Centre to the Flemish Region, the Centre's responsibilities, except for nuclear tasks and administration of the nuclear fuel cycle, were transferred to the Flemish Region together with the physical and real property corresponding to the tasks transferred and the members of staff involved.

ii) Responsibilities

The CEN is historically a nuclear research centre, with specific responsibility for basic and applied research (nuclear reactor and fissile fuel safety, radiation protection, safe conditioning and storage of radioactive waste, protection of nuclear infrastructures from attack, nuclear energy applications, update of scientific documentation, etc.). It therefore offers a major scientific and technical resource potential in the nuclear field, and its role is to pass that potential on to other bodies concerned and to industry.

iii) Structure

The CEN is run by a board of directors with a chairperson, two vice-chairpersons and a maximum of ten other members. A director-general is responsible for carrying out the decisions taken by the board.

iv) Financing

The CEN's budget is funded by appropriations in the budget of the Ministry of Economic Affairs and by its own revenue in the form of fees for services rendered and research contracts.

c) National Radioisotope Institute (IRE)

Because of the growth in the applications and uses of radioisotopes, the government set up a specialised national body: the National Radioisotope Institute (*Institut national des radioéléments* – IRE), based in Fleurus.

i) Legal status

The Royal Order of 20 October 1971 set up the National Radioisotope Institute as a public service. Its relationship with the national government was regulated by a Convention between the Institute and the Minister holding the portfolio of Energy signed on 28 July 1980. This Convention provided in particular that the IRE is subject to the control of the Minister. It was replaced by the Royal Order of 16 October 1991 laying down the rules relating to the supervision and financing of the National Radioisotope Institute, and amending its Statute.

In accordance with the Special Act on institutional reforms of 8 August 1988 amending the Act of 8 August 1980, the Special Act for financing the communities and regions of 16 January 1989 and the transfer of several activities within the competence of the Walloon region to private companies, the Institute only carries out work related to the nuclear fuel cycle.

ii) Responsibilities

The main tasks of the IRE are:

- to produce and condition radioisotopes;
- to study, promote and encourage applications of radioisotopes;
- to study and develop techniques for conditioning the radioactive waste arising from such activities;
- to study, from the standpoint of radiation protection, the safety of persons employed in Belgian firms and institutes using and applying radio-isotopes.

iii) Structure

The IRE is run by a board of directors consisting of a chairperson, two vice-chairpersons and ten other members. A director-general is responsible for carrying out the board's decisions.

iv) Financing

The IRE is funded from appropriations in the budget of the Minister of Justice and Economic Affairs by its own revenue, including fees for services rendered.

d) Higher Institute for Emergency Planning

The Higher Institute for Emergency Planning (*Institut supérieur de planification d'urgence*) was set up by the Royal Order of 29 July 1991 in pursuance of national legislation on protection against major industrial risks and Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency.

i) Legal status

The Institute is a public institution placed under the supervision of the Minister of the Interior.

ii) Responsibilities

The Institute's duties include:

- organising training for emergency planning and assistance;
- promoting the exchange of ideas on emergency planning between the authorities and operators of installations preventing potential major risks (including nuclear installations);
- disseminating adequate and regularly updated information to persons involved in emergency assistance about the risks they incur and the protection measures to be taken.

In the performance of its duties, the Institute organises conferences and seminars, sets up study groups and undertakes simulation exercises.

iii) Structure

The board of the Institute includes representatives of the different Ministries and regional authorities concerned and of various industries, as well as scientists and insurers. Members are appointed for a period of six years by the Minister of the Interior on the proposal of the Minister, regional governments and the institution or body concerned.

iv) Financing

The Institute's operating costs are included in the budget of the Minister of the Interior and of the Civil Service.

e) National Organisation for Radioactive Waste and Enriched Fissile Materials (ONDRAF)

In pursuance of Section 179(2) of the Act of 8 August 1980 relating to the 1979-1980 budget proposals, as amended by the Act of 11 January 1991, Belgium set up a National Organisation for Radioactive Waste and Enriched Fissile Materials (*Organisme national des déchets radioactifs et des matières fissiles* – ONDRAF). The tasks and operating conditions of this Organisation were laid down in the Royal Order of 30 March 1981, amended by a Royal Order of 16 October 1991.

Until ONDRAF began operations in 1982, responsibility for radioactive waste management lay with the waste producers in accordance with the licence granted to them by the authorities. In this context, the "Waste" Department of the Nuclear Energy Research Centre (CEN), which undertook the conditioning of radioactive waste, played an important role. ONDRAF was set up in order to ensure the long-term coherence and safety of the management of all radioactive waste produced in Belgium.

i) Legal status

ONDRAF is a financially independent public body and legal entity. It is answerable to the Ministers responsible for Economic Affairs and Energy [Order of 16 October 1991, Section 6(3)]. It is also supervised by two government representatives, one appointed by the Minister holding the portfolio of Energy, and the other by the Minister of Employment and Labour, and these representatives take part in the meetings of the board of directors.

ii) Responsibilities

ONDRAF's tasks include:

- the disposal, treatment and conditioning, on behalf of producers who have no equipment approved by ONDRAF for such use, the storage outside the producers' facilities and the transport of all radioactive waste (ONDRAF took over the tasks previously carried out by the CEN in this field – [Royal Order of 30 January 1981, Section 2(4)]);

- the transport of enriched fissile materials and plutonium-bearing materials (exceeding in quantities and in enrichment rate the limits set by Section 2(2)(2)(a) of the Royal Order of 30 March 1981, as amended by the Royal Order of 16 October 1991) and surplus quantities of fresh or spent fuel to be taken over by ONDRAF;

- the storage outside the producers' facilities, of surplus quantities of enriched fissile materials, plutonium-bearing materials and fresh or spent fuel;

- the management of waste of foreign origin within Belgium (for which ONDRAF first needs the approval of its supervisory authority);

- certain aspects of decommissioning of nuclear installations;

- the determination, in co-operation with operators, of research and development programmes required for implementing the tasks of ONDRAF;

- the establishment and implementation of an information programme covering all ONDRAF's activities. To this effect, ONDRAF has set up ISOTOPOLIS, an information centre on radioactive waste, located close to the premises where radioactive waste is treated.

The Organisation is responsible for management and has the choice either to undertake the operation itself or to subcontract these tasks, under its responsibility and supervision and the control of the competent authorities. Either way, it has to ensure that everything is done in compliance with the appropriate technical rules. It is also responsible, in liaison with waste producers, for inventing new waste conditioning and containment methods.

In order to carry out its tasks, ONDRAF draws up a general programme for radioactive waste management and prepares an inventory of all existing waste and a forecast of the volumes likely to be produced in the short, medium and long term.

In general terms, ONDRAF provides a public service. Its duties give it no right to encroach on the domain of the authorities responsible for protection or state security in the nuclear field. It must comply with the legislation in force and is subject to the national controls exercised by the Nuclear Security Service of the Minister of Justice, which has certain powers in such matters, and to the international controls exercised within the framework of Euratom and the IAEA.

iii) Structure

ONDRAF is run by a board of directors made up of a chairperson, two vice-chairmen and a maximum of eleven other members selected for their scientific or professional knowledge in the Organisation's fields of activity [Royal Order of 16 October 1991, Section 7(1)].

The chairperson and vice-chairpersons are appointed by the King after consideration by the Council of Ministers and on the proposal of the Minister holding the portfolio of Energy.

The other members of the board come either from the Ministerial departments and bodies concerned, or from the scientific and technical world. They are appointed by the Minister holding the portfolio of Energy, after consideration by the Council of Ministers.

Before taking any decision concerning waste management policy or financing, the board hears the opinion of a Standing Technical Committee made up of representatives of the waste producers.

iv) Financing

ONDRAF's income is made up of appropriations from the Ministry of Economic Affairs for use as working capital, bequests and grants made to it, statutory and regulatory payment for services rendered, subsidies and occasional revenues. The cost of ONDRAF's activities is recovered in full from the firms and bodies which have benefited from its services.

ONDRAF is obliged to balance its books. It may, however, be authorised to take out loans to finance its investments.

CANADA

Information Note

On 20 March 1997, the Nuclear Safety and Control Act received Royal Assent, the last stage through which this legislation had to pass before it could be proclaimed into force. This new and comprehensive legislation replaces the former Atomic Energy Control Act as the means by which the Canadian nuclear industry will be regulated in the future.

In particular, the Act dissolves the Atomic Energy Control Board (AECB) and establishes in its place a new Canadian Nuclear Safety Commission. The change of name not only reflects the regulatory agency's continuing focus on safety matters, but also emphasises that it is completely separate from Atomic Energy of Canada Limited, and Canada's National Research Council which promotes the peaceful uses of nuclear energy. In order to provide a broader range of expertise and to accommodate better regional representation, the number of members on the Commission has been increased to seven, by comparison with the Board's previous five.

The statutory mandate of the new Commission is clearly expressed to cover the establishment and enforcement of standards in the areas of health, safety, security and protection of the environment in connection with nuclear activities. The Commission is also empowered to require financial guarantees from licensees for decommissioning facilities, thereby eliminating the risk of such liabilities having to be borne by the public such as might occur in the case of a licensee's insolvency. It is also authorised to order remedial action in hazardous situations and to require that those responsible for the hazard bear the cost of such action. The new legislation declares the Commission to be a court of record, empowering it to conduct formal hearings, hear witnesses, take evidence and control its own proceedings. Finally, the Commission may engage in more active co-operation with the provinces in terms of regulatory control, by incorporating relevant provincial legislation by reference and by retaining provincial agencies to perform work on behalf of the Commission for an agreed upon fee.

The new Act contains clear and formal provisions for appeals in respect of actions taken and decisions made by the Commission and by its staff members. It enhances and more clearly defines the powers of inspectors, while at the same time recognising the rights of those subject to inspection. It also increases the maximum fine for violations of the Act or its regulations from Canadian dollars (CAD) 10 000 to CAD 1 000 000, bringing the penalties into line with current practices under other Canadian regulatory statutes.

The Nuclear Safety and Control Act will not be proclaimed into force until a series of regulations have been made which will set out the detailed requirements that are to apply to various nuclear activities.

This study is based on the existing situation at the end of 1999. It therefore describes the legislative and institutional regime in force at that date, and is not based on the above-mentioned Act.

I. GENERAL REGULATORY REGIME

1. Introduction

Nuclear power provides 15% of Canada's electricity overall; for the province of Ontario the figure is as high as 60%. At present, Canada has 21 nuclear power reactors and 9 research reactors in operation.

Ontario Hydro, the owner of all but two of the nuclear power reactors in Canada, announced in 1997 its intent to temporarily shut down seven units over the coming years.

Canada's national Parliament passed the Atomic Energy Control Act [R.S. 1985, c.A-16][1] in 1946, declaring that it was in the national interest that the development, application and use of atomic energy be regulated, and that Canada be able to participate effectively in international measures relating to the control of atomic energy. The federal government's constitutional power to legislate in this area was confirmed by the Supreme Court of Canada in 1972.[2]

The regulatory agency established by the AEC Act is the Atomic Energy Control Board (AECB) [Section 3]. The Board's principal regulatory mechanism is the power conferred by the Act to make regulations relating to all aspects of the control and supervision of atomic energy and radioactive substances. Thus, it is the Atomic Energy Control Regulations [C.R.C., Volume III c.365][3] which determine the licensing and control regime applicable to all nuclear activities.

In 1970, the Parliament passed the Nuclear Liability Act [R.S., 1985, c.N-28]. This Act deals with civil liability for damage arising from nuclear activities.

Other relevant legislation, which will be discussed below, includes:

- the Uranium and Thorium Mining Regulations (1988) [SOR/88-243] as amended;
- the Radiation Emitting Devices Act (1970) [R.S. 1985, c.R-1];
- the Export and Import Permits Act (1970) [R.S. 1985, c.E-19];
- the Transportation of Dangerous Goods Act [R.S. 1985, c.T-19];

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1. R.S. = Revised Statutes. The Atomic Energy Control Act was consolidated in 1985. This consolidated version entered into force on 12 December 1988.
2. *Denison Mines Ltd. v. Attorney-General of Canada* (1972) 32 D.L.R. (3rd) 419.
3. C.R.C. = Consolidated Regulations of Canada.

- the Transport Packaging of Radioactive Materials Regulations (1983) [SOR/83-740] as amended;

- the AECB Cost Recovery Fees Regulations (1993) [SOR/93-163] as amended.

The AECB Cost Recovery Fees Regulations implement the government's decision that the Atomic Energy Control Board should recover a proportion of its operating costs. As a consequence, most applications to the Board for licences and permits must be accompanied by the fee prescribed for that kind of application. However, publicly-funded health care and educational institutions and federal departments and agencies are exempt from the fees.

2. Mining Regime

Canada's constitutional arrangements result in a division of responsibility between the federal and the provincial governments in relation to uranium mining. While the federal government controls the uses of uranium, by virtue of the Atomic Energy Control Act, the provincial governments own the mineral rights and have jurisdiction over the exploitation of all mineral resources (including uranium).

The Atomic Energy Control Act gives the AECB the power to make regulations about mining, prospecting for, producing and refining "prescribed substances" [Section 9]. The term "prescribed substances" is defined in Section 2 of the Act to include uranium and thorium. Up until 1988, the mining of these substances had been subject to the same regulatory system as other nuclear facilities; both kinds of operation were subject to the licensing regime set up under the Atomic Energy Control Regulations. However, from 1988, mining operations have been dealt with separately in the Uranium and Thorium Mining Regulations [SOR/88-243 amended by SOR/90-193].

These Regulations do not cover prospecting activities or surface exploration for uranium or thorium [Section 4]. Similarly, they do not apply to the removal of radioactive substances from a deposit if less than 10 kilograms per year is removed. However, the general thrust of the Regulations is that no mine or mill can be constructed or operated, no uranium or thorium removed, and no mine or mill decommissioned or abandoned, except in accordance with a licence issued under the Regulations [Section 5].

The Regulations further provide that an application for a licence must include specific information, and that the licence may be issued subject to terms and conditions [Sections 11-15]. If the AECB intends to make a decision adverse to the applicant, the applicant has a right to a hearing before the Board [Section 16]. Once a licence to construct a mine or mill has been granted, the Board retains the right to seek information at any time during its construction from the licensee about the construction or operation of the mine or mill [Section 21]. Before the licensee commences the activity which has been licensed (whether it be the construction, operation or decommissioning of the mine or mill), the licensee must submit for the Board's approval a proposed code of practice for the activity [Section 22]. In addition to setting out the licensing process, the Regulations also deal with ventilation and dust control [Sections 26-30]; waste management [Sections 34-36]; the facilities, supervision and training to be provided to workers; the safety obligations imposed on workers; inspections; systematic medical surveillance of workers; and licensees' obligations to maintain records and to make reports to the Board.

In 1990 the Uranium and Thorium Mining Regulations were amended [SOR/90-193] to provide that all applications for licences and approvals under the Regulations must be accompanied by the

appropriate fee. These amendments are consequential to the AECB Cost Recovery Fees Regulations of 1993.

The Uranium and Thorium Mining Regulations were also amended in 1993 [SOR/93-463] to clarify inspectors' powers and again in 1994 to add provisions concerning financial assurances for decommissioning.

3. Radioactive Substances, Nuclear Fuel and Equipment

The AECB, with the approval of the Governor in Council,[4] has the power to regulate the possession, sale and use of radioactive substances, devices containing such substances, nuclear fuels and equipment for the production of nuclear power. This regulatory power is derived from Section 9 of the Atomic Energy Control Act, which confers to the Board the power to make regulations about the production, import, export, transportation, refining, possession, ownership, use and sale of "prescribed substances". "Prescribed substances" include: uranium, thorium, plutonium, neptunium, deuterium; their respective derivatives; and such other substances as the Board specifies, by regulation, to be capable of releasing atomic energy or as being requisite for the production, use or application of atomic energy [Atomic Energy Control Act, Section 2].

Under the Atomic Energy Control Regulations, a licence must be obtained from the AECB to possess or sell either prescribed substances or equipment containing prescribed substances [Sections 3 and 4]. However, there are two categories of substance that are exempt from this requirement. The first category is that of industrial materials which are "incidentally" radioactive but not associated with the nuclear fuel cycle or other uses of atomic energy. It was never the intention of the Atomic Energy Control Act to regulate many common industrial activities not associated with atomic energy, and an amendment was made to the Regulations in 1988 excluding this category from the Board's control [Section 2(1)]. Secondly, small amounts or low concentrations of radioactive substances (other than enriched uranium, plutonium and uranium-233) are not covered by the Regulations [Sections 4 and 6].

The AECB issues licences in respect of prescribed substances and equipment for a fixed term, and subject to specified types of condition [Section 7]. The application for the licence must contain details as to the applicant's activities in relation to the radioactive substance, the security and emergency measures, the training and experience of the people who will be dealing with the substance, and any other information necessary to evaluate the application [Section 7].

Every licensee is required to keep records relating to the use and disposal of the radioactive substance [Section 11(1)]. Supervision and enforcement of compliance with the regulations and licence conditions is performed by inspectors of the AECB [Section 12].

The Board has the power to revoke, suspend or amend a licence, and to alter the terms and conditions of any licence [Section 27]. If a licence has been revoked, suspended or amended, or if a licence condition has been breached, the Board may require the licence-holder to take any measures that it considers necessary for the protection of people and property [Section 28]. The Atomic Energy Control Act also provides for criminal sanctions against anyone who contravenes the Act or Regulations (for example, by dealing with radioactive substances without a licence). A person convicted under this provision [Section 20] may be fined, imprisoned or both.

4. "Approval of the Governor in Council" means, in effect, the approval of the government.

4. Nuclear Installations

The construction and operation of nuclear facilities is regulated by the Atomic Energy Control Regulations [C.R.C., Volume III c.365], made under Section 9 of the Atomic Energy Control Act.

The Regulations require two stages of approval from the AECB before a nuclear facility can begin to operate. The first is an approval to construct or acquire the facility [Section 10(1)]. The application for this approval must set out a description of the site, design and construction of the facility, make an assessment of any hazards that may result from its operation and the measures to be taken to counter those hazards, and give any other information required by the Board. The application must be accompanied by the fee set under the AECB Cost Recovery Fees Regulations [Section 10(3)]. The Board may make its approval subject to conditions in the interests of health, safety and security [Section 10(4)].

The second stage is a licence to operate the facility. The application for this licence must set out a description of the facility's operating procedures, the measures to be taken to prevent any person receiving a dose of ionising radiation above the specified limit, the measures to be taken to ensure the physical security of the facility and any nuclear material in it, information as to the compensation arrangements that have been made in case of the facility causing personal injury or damage, and any other information required by the Board [Section 9(1)(1)]. The application must be accompanied by the appropriate fee. In issuing the licence, the Board may impose conditions in the interests of health, safety and security [Section 9(2)].

Once a nuclear facility is operating, the licensee is obliged to keep comprehensive records relating to the operation and maintenance of the facility [Section 11], and to submit to inspections by Board inspectors [Section 12]. The inspectors are empowered to enter premises and inspect records. Where any breach of a licence condition or of the Regulations has occurred, the inspector may direct the licensee to take any action deemed necessary to remedy the breach and to minimise the consequences of it [Section 12(3)]. As mentioned above, any breach of the Act or the Regulations is also a criminal offence [Section 20 of the Act]. In practice, AECB inspectors are stationed at each nuclear power reactor to provide on-site surveillance of the facility's operation.

The AECB also regulates the final stage of the life of a nuclear facility, the decommissioning stage. In August 1988, the Board issued a Regulatory Policy Statement entitled "Policy on the decommissioning of nuclear facilities".[5] The Statement provides licensees and potential licensees with information about the Board's approach in administering the Regulations applying to the disposal or abandonment of prescribed substances.[6] The Atomic Energy Control Regulations provide that the holder of a licence issued by the Board must apply to the Board for permission to abandon or dispose of a prescribed substance, and must carry out the disposal in accordance with the licence conditions [Section 25]. In practice, the licensee must develop decommissioning plans and obtain the Board's approval for them during the early stages of the design of the nuclear facility. The Board must be satisfied that the proposal is technically feasible, and deals satisfactorily with health, safety, security and environmental protection issues. The proposal, once approved, will then be incorporated in the applicant's licence to operate the facility.

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5. In addition to the AECB's power to make regulations and to impose generic licence conditions, the Board also enacts policy statements and guides.

6. For further details on this Statement, see under Section 7 "Radioactive Waste Management".

In relation to environmental protection during the operation of the facility, the Atomic Energy Control Regulations provide that a licence for the operation of a nuclear facility may include conditions as to the quantities and concentrations of radioactive and other hazardous materials that may be discharged from the facility, and as to the method of disposing of radioactive or other hazardous material resulting from the operation of the facility [Section 9(2)].

It is relevant to note that, at the international level, Canada is a Party to the 1994 Convention on Nuclear Safety, ratified on 12 December 1995; it also ratified the 1986 Convention on Early Notification of a Nuclear Accident on 18 January 1990.

5. Trade in Nuclear Materials and Equipment

The Atomic Energy Control Act specifically gives the AECB the power to make regulations with respect to the import and export of prescribed substances (radioactive substances as well as deuterium) and "any other things that in the opinion of the Board may be used for the production, use or application of atomic energy" [Section 9(d)]. As already described, the basic mechanism of the Atomic Energy Control Regulations is a licensing system which prohibits, among other things, the sale, export or import of any substance covered by the Act except in accordance with a licence issued under the Regulations [Atomic Energy Control Regulations, Sections 3 and 4]. Section 5 of the Regulations deals specifically with export and import and applies not only to radioactive substances covered by the Act, but also to the export of "prescribed items". These are certain items included in the Export Control List (see below). Section 7(4) provides that the AECB may issue a licence allowing the export or import of prescribed substances and the export of prescribed items. These licences may be made subject to any conditions that the Board considers necessary in the interests of health, safety and security [Section 7(5)].

a) Exports

Canada exports uranium, heavy water, nuclear reactor and other fuel cycle equipment and technology for nuclear power use. Canada also exports radioisotopes, deuterium and uranium for agricultural, medical and industrial use. Apart from the Atomic Energy Control Act and Regulations, other legislation relevant to Canada's nuclear export activities is the Export and Import Permits Act [R.S. 1985, c.E-19].

Canada is a Party to the Treaty on the Non-Proliferation of Nuclear Weapons. Canada's exports of uranium, heavy water and nuclear equipment and technology for nuclear fuel cycle use are subject to Canada's nuclear non-proliferation policy (see Section 8 "Non-Proliferation and Physical Protection", *infra*).

The export of certain nuclear materials, equipment and technology requires a permit from the Secretary of State for Foreign Affairs and International Trade issued after advice from the Atomic Energy Control Board [Export and Import Permits Act, Section 7].

A person intending to export a prescribed item may, in addition to the AECB's licence, need to obtain a permit under the Export and Import Permits Act. That Act provides for the government to establish an Export Control List. The basic purposes of the List are to ensure that the government can prevent the export of articles with "a strategic nature or value" if their export could be detrimental to Canada's security, that it can implement its international commitments, and that it can control the export of Canada's natural resources [Section 5]. Anyone wishing to export an item on the List must

apply to the Secretary of State for Foreign Affairs and International Trade for a permit, which may be made subject to terms and conditions [Section 7]. Administrative arrangements ensure that terms and conditions of the permit issued under the Export and Import Permits Act do not duplicate conditions imposed on the licence issued by the AECB.

b) Imports

The possession, sale and importation of certain categories of equipment emitting radiation, but not intended for the production of atomic energy within the meaning of the Atomic Energy Control Act, are governed by the Radiation Emitting Devices Act (REDA) [R.S. 1985, c.R-1]. The Minister of Health and Welfare is responsible for implementing this Act. The REDA regulates the sale, lease and importation of all devices capable of producing and emitting radiation except those that are designed primarily for the production of atomic energy [Section 3]. The Act creates various classes of device, and regulations made under the Act prescribe standards relating to the design, construction and functioning of each class. The sale, lease or importation of a radiation emitting device that does not comply with the appropriate standard is prohibited [Section 4]. The prohibition is reinforced by the criminal law; a person convicted of an offence under the Act may be fined or imprisoned or both [Section 14].

6. Radiation Protection

A large section of the Atomic Energy Control Regulations is devoted to health and safety requirements [Part VI]. The main focus of these Regulations is the protection of workers from the effects of ionising radiation, although some provisions are aimed at minimising health risks to the general public.

The Regulations prescribe the maximum permissible doses and exposures for radiation workers and for the public [Section 19 and Schedule II]. Information requirements in respect of radiation workers are also prescribed. The obligation to keep within these limits is imposed on licensees by means of licence conditions which specify the measures to be taken by the licensee to prevent anyone receiving an excessive dose of ionising radiation as a result of the licensee's activities. Licences granted under the Uranium and Thorium Mining Regulations also contain similar conditions. The Regulations specify a smaller permissible dose for members of the public than for atomic radiation workers. The adoption of future regulations under the new Nuclear Safety and Control Act is expected to reflect the latest recommendations of the International Commission on Radiological Protection (ICRP) as to dose limits. They are also expected to incorporate the ALARA principle (As Low As Reasonably Achievable). It is now in force through licence conditions.

A large number of provisions in existing regulations deal specifically with radiation protection in the context of industrial radiography [Sections 18(1)-18(23)]. The regulations impose detailed obligations on the holders of licences in respect of the use or possession of radiography equipment. The requirements cover such aspects as the qualifications and training of the licensee's staff; the dose limits applicable to workers and non-workers; the levels of maintenance and security to be observed in relation to the equipment; the procedures to be followed by anyone operating the equipment; and obligations to measure and record radiation doses received by anyone who has operated the equipment. The regulations also include provisions requiring all licensees to provide the devices, equipment and clothing necessary for radiation protection.

The medical supervision of workers exposed to radiation because of their occupation is undertaken by government medical advisers appointed by the AECB [Section 15]. Each medical adviser is appointed in respect of a particular place or area. The functions of the medical adviser are to make recommendations to the Board about the medical examination of atomic radiation workers in general, and also about individual workers; to inspect the medical records that licensees are required by the Regulations to keep; to review the procedures at particular premises for the treatment of atomic radiation workers; and to carry out any investigation that may be necessary to identify a person who may have received an excessive dose of ionising radiation.

A person in charge of either a nuclear facility or a device or equipment containing radioactive prescribed substances has an obligation to report any occurrence that may result in any person receiving a dose of ionising radiation greater than the relevant limit set by the Regulations [Section 21]. The occurrence must be reported to an inspector within 24 hours; if the occurrence has resulted in someone receiving an excessive dose, this first report must be followed by a written report to the radiation safety adviser or committee appointed under Section 16, and to the medical adviser for the area concerned [Section 15(3)(e) and (f)]. In addition to these reporting obligations, the person in charge must take all appropriate measures to prevent or minimise the exposure of any person to ionising radiation as a result of the occurrence and must comply with all instructions given by the Board's inspector [Section 21(2)].

The Regulations also specify the kinds of warning signs which must be displayed in areas and equipment containing radioactive substances [Section 22].

7. Radioactive Waste Management

The Atomic Energy Control Regulations contain a general prohibition on the abandonment or disposal of radioactive substances covered by the Atomic Energy Control Act. Disposal must be carried out either in accordance with the conditions in an existing licence that has been issued by the AECB in relation to that particular substance, or in accordance with an approval of the Board that has been given in response to an application to dispose of the substance [Section 25]. The conditions imposed on a licence or approval in relation to waste management are aimed at ensuring the protection of health, safety and security. Some conditions also result from environmental protection considerations. Furthermore a licence to use, sell, possess etc. a radioactive substance, may include conditions respecting the method of disposing of the substance and stipulating the maximum quantity and concentration of radioactive substances that may be discharged into the air and water [Section 7(3)(d) and (e)]. Discharges are also controlled in licences for operation of the various nuclear facilities regulated by the AECB.

In 1987 the AECB issued a Regulatory Policy Statement entitled "Regulatory objectives, requirements and guidelines for the disposal of radioactive wastes – long term aspects" [Regulatory Document R-104]. The Statement sets out the objectives of radioactive waste disposal (minimising the burden on future generations, protecting the environment, protecting human health) and goes on to list the basic factors which must be addressed by any waste disposal proposal.

Radioactive waste management facilities are nuclear facilities for the purposes of the Atomic Energy Control Regulations [Section 2(1)], and therefore can only be operated according to the terms and conditions of a licence issued under the Regulations [Sections 8-10].

As mentioned above, in 1988 the Board issued another Regulatory Policy Statement, entitled "Policy on the decommissioning of nuclear facilities" [Regulatory Document R-90]. The document

explains that the Board applies and enforces its decommissioning policy by means of its system of licensing nuclear facilities. The Board is able to require licensees to address the question of decommissioning at various stages of nuclear facility licensing. Initial planning for decommissioning occurs at the facility design stage, with progressive refinement of the plans occurring during the life of the facility. When the decommissioning of a nuclear facility has been completed to the satisfaction of the Board, the licensee will be permitted to abandon the site and will be absolved from further responsibility for it under the Atomic Energy Control Act and Regulations. The Policy Statement explains that if radioactive substances are to remain at the site after the facility has been decommissioned, the Board may require a period of monitoring before it would approve an application from the licensee to abandon the site. Depending on the circumstances of the case, this monitoring period could last a number of years. Furthermore, in 1994, financial assurance requirements for uranium mining facilities were introduced.

It is relevant to note that at the international level Canada ratified the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 7 May 1998.

As far as the dumping of radioactive waste at sea is concerned, Canada is a Party to the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and other Matter (ratified on 13 November 1975). Canada has ocean dumping control legislation[7] which reflects its obligations under the Convention in its original form; that is to say, the dumping of high-level radioactive waste was prohibited but the legislation provided for the issue of a licence to dump low-level radioactive waste at sea. However, the recent amendment of the Convention extending the ban on dumping to low-level radioactive waste,[8] means that Canada is now obliged to prohibit the dumping at sea of all radioactive waste.

8. Non-Proliferation and Physical Protection

Canada ratified the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) on 8 January 1969, as well as the 1996 Comprehensive Nuclear Test Ban Treaty on 18 December 1998 and it participates actively in international atomic energy control measures. The AECB administers the bilateral nuclear co-operation agreements that Canada has signed, covering trade with 38 countries in nuclear materials, equipment and technology. In accordance with Canada's nuclear non-proliferation policy, nuclear co-operation will be authorised only for those non-nuclear weapon states that have either ratified the NPT or have taken an equivalent binding step and have thereby accepted IAEA safeguards on the full scope of their nuclear activities. Furthermore, nuclear exports can go forward only to those states (both nuclear and non-nuclear weapon states) that have undertaken to accept in a formal nuclear co-operation agreement a number of additional requirements designed to minimise the proliferation risk associated with Canadian nuclear exports.

As noted above, the AECB and the Department of Foreign Affairs and International Trade exercise control over the export of nuclear materials, technology and equipment by means of licensing and permit systems.

Safeguards inspectors from the IAEA carry out regular inspections of Canadian nuclear installations to ensure that Canada complies with its own NPT-type full scope safeguards agreement

7. The Ocean Dumping Control Act [R.S. 1985, c.O-2] was passed in 1975.

8. The ban, which is to remain in force for 25 years, became effective on 20 February 1994.

with the Agency. The AECB, through its Safeguards Section, facilitates the implementation of this agreement [IAEA:INFCIRC/64] by providing information on and access to nuclear material for accounting and verification.

Canada ratified the 1979 Convention on the Physical Protection of Nuclear Material on 21 March 1986. As a result of Canada's obligations as a party to that Convention, and having regard to IAEA recommendations, the Physical Security Regulations [SOR/83-77] were made under Section 9 of the Atomic Energy Control Act. The regulations define levels of security (or "physical protection measures") according to the nuclear facility and/or the nuclear material in use, storage or in transport. The licensee is required to establish a security perimeter and to provide a perimeter barrier either equipped with intrusion detection devices or that is under surveillance by security guards. Additionally, the licensee is required to make arrangements with a response force (police, military) that will provide armed assistance when it is required.

The Regulations prohibit the entry of a person into any area of the facility, except with the written authorisation of the licensee. Entry to an inner area of a facility is only allowed with the written authorisation of the AECB. The Regulations also provide for special authorisations to be issued to inspectors appointed under the Regulations and IAEA inspectors. The purpose of these authorisations is to facilitate the discharge of the IAEA inspectors' duties in relation to safeguards.

9. Transport

The AECB has the power to make regulations governing the transport of radioactive substances [Atomic Energy Control Act, Section 9]. The Transport Packaging of Radioactive Materials Regulations were made in 1983 [SOR/83-740] and are administered by the Board. The Regulations deal with the packaging and safety marking of radioactive materials preparatory to their transport. The other relevant legislation is the Transportation of Dangerous Goods Act [R.S. 1985, c.T-19] enforced by the federal Department of Transport. The AECB provides advice to the Department of Transport in relation to the Regulations as they relate to the carriage of radioactive material.

On the whole, the rules governing the transport of radioactive substances are based on the international standards established by the IAEA. Future regulations under the new Nuclear Safety and Control Act are expected to be in line with the 1990 edition of the IAEA's Regulations for the Safe Transport of Radioactive Materials.

The Transport Packaging of Radioactive Materials Regulations divide radioactive substances into various categories; one category covers all fissile material while other categories apply to radioactive material of differing levels of activity. The Regulations stipulate different packaging requirements for each category of substance to be transported. The Schedules to the Regulations set out in great detail the specifications for each type of package. Radioactive material must not be transported unless it is contained in a package whose design has been approved by the Board, by means of either a certificate issued under Section 15 or an endorsement issued under Section 16 [Sections 9 and 10]. The certificate may be made subject to any limitations or conditions on the use or transport of the package that the Board or its authorised officer considers to be necessary in the interest of health, safety or security [Sections 15 and 16]. The certificate is annulled if any limitation or condition is not complied with.

For packages originating in a foreign country, the Board may issue an endorsement of a certificate issued by a competent authority in that country. The endorsement indicates that the Board

accepts that the design of the package meets requirements substantially equivalent to the requirements of the Canadian Regulations [Section 16].

The Regulations also provide for various different safety marks which must be affixed to any package or container containing radioactive material [Section 20].

In 1990 amendments were made to the Transport Packaging of Radioactive Materials Regulations and the AECB Cost Recovery Fees Regulations to enable the AECB to charge fees for some applications relating to packaging.

Under the Transportation of Dangerous Goods Act, there are the Transportation of Dangerous Goods Regulations. These regulations establish classes of dangerous goods, an identification list of common dangerous goods and the safety requirements for identification, packaging and shipment of these dangerous goods in a manner similar to the United Nations Recommendations on the Transport of Dangerous Goods. For radioactive material, the Transportation of Dangerous Goods Act and Regulations refer to the Atomic Energy Control Act and the Transport Packaging of Radioactive Materials Regulations, (which are similar to the IAEA Regulations) for the specifics of health and safety protection requirements for packaging and transport. For international air and sea transport, the Transportation of Dangerous Goods Regulations refer to the appropriate international regulations of the International Civil Aviation Organisation (ICAO) and the International Maritime Organisation (IMO).

10. Nuclear Third Party Liability

The Nuclear Liability Act [R.S. 1985, c.N-28] came into force in 1976.[9] Although Canada is not a party to any of the international Conventions on nuclear third party liability, the Nuclear Liability Act is largely based on the principles laid down in the Conventions.

The major elements of the Act are as follows:

i) Transboundary damage

The operator of a nuclear facility in Canada is not liable for damage occurring outside Canada. However, the Act contains a mechanism for the making of reciprocal arrangements with other countries [Section 34(3)]. This mechanism was used in 1976, resulting in the Canada-United States Nuclear Liability Rules. Under these Rules, Canadian operators are liable for injury or damage that is suffered in the United States but caused by a nuclear incident occurring in Canada.

ii) Nature of liability

The operator of a nuclear facility has a duty to ensure that no personal injury or property damage is caused by nuclear material within that operator's control [Section 3]. In the event of a breach of this duty, the operator's liability is absolute; in other words, there is no need to establish fault on the operator's part [Section 4].

9. A consolidation of the Act was passed in 1985 [R.S. 1985, c.N-28].

Two or more operators may be jointly and severally liable, but apart from this case, the operator's liability is exclusive; no other person is liable for the damage [Section 11].

iii) Time limits for making claims

A person seeking compensation from an operator of a nuclear facility for injury (other than loss of life) or for property damage must bring an action within three years from the date on which the person knew, or ought reasonably to have known, of the injury or damage; in the case of a claim for loss of life, the action must be brought within three years of the death. Regardless of these three-year rules, no action can be commenced after the end of the period of ten years from the date of the breach of the operator's duty [Section 13].

iv) Insurance and other financial arrangements

The Atomic Energy Control Board, with the approval of the Treasury Board, prescribes a basic level of insurance for each nuclear facility. The amount prescribed is not to exceed Canadian dollars (CAD) 75 million [Section 15]. Where the basic insurance amount for a particular facility is less than CAD 75 million, supplementary insurance to make up the difference must be obtained, with the Canadian Government acting as reinsurer [Section 16].

The Act allows for the possibility of state intervention to provide compensation where either the CAD 75 million is likely to be insufficient to meet the claims, or the nuclear incident is such that it is in the public interest for special compensation measures to be provided [Section 18]. In such a situation, the operator's liability to claimants ceases, but in its place a liability arises to indemnify the government for amounts awarded by the Nuclear Damage Claims Commission [Sections 19 and 20]. The Commission, consisting of judges or experienced barristers, has exclusive jurisdiction to hear every claim arising from the nuclear incident and to award amounts of compensation [Section 24].

Where there is no state intervention, a person seeking compensation as a result of a nuclear accident must bring an action against the operator of the nuclear facility that caused the accident. The action must be brought in a court exercising jurisdiction in the place in Canada where the injury or damage was suffered, or, if this would result in several courts hearing claims in respect of the same incident, in a court exercising jurisdiction in the same place as the nuclear facility which caused the incident [Section 14].

II. INSTITUTIONAL FRAMEWORK

In Canada, the Atomic Energy Control Board (AECB) has power to control all nuclear activities. It exercises this power in co-operation with the other federal and provincial departments concerned. In addition to these bodies, the national corporation, Atomic Energy of Canada Ltd., was set up in 1952 to ensure the transfer of knowledge for the benefit of private industry and to support the Canadian nuclear industry in international markets.

1. Regulatory and Supervisory Authorities

a) Governor in Council

Regulations made by the Atomic Energy Control Board concerning the use of nuclear energy are subject to the Governor in Council's approval.

The Governor in Council appoints the members of Atomic Energy Control Board, and appoints one of the members as president.

b) Minister of Natural Resources

The Minister of Natural Resources (NRCan) is currently the Minister for the purpose of the Atomic Energy Control Act. The Act has given the Minister a general mission relating to the development and use of atomic energy.

The Minister has the authority to undertake research in the nuclear energy field. With the approval of the Governor in Council, the Minister may acquire ore deposits and nuclear materials and equipment, and may acquire and dispose of nuclear patent rights.

With the approval of the Governor in Council, the Minister is empowered to set up government corporations for the use of atomic energy; the entire share capital of such corporations is held by the Minister on behalf of the Crown, except shares necessary to qualify other persons as directors.

The AECB reports to Parliament through the Minister of Natural Resources. The Minister is also responsible to Parliament for Atomic Energy of Canada Ltd.

c) Various departmental powers

Various other federal departments also have powers in the nuclear energy field; the most important of these are Health and Welfare, Environment, Human Resources Development, Transport and the Treasury Board.

d) Atomic Energy Control Board (AECB)

The Atomic Energy Control Board (AECB) was constituted in 1946 by the Atomic Energy Control Act to provide for control and supervision of the development, application and use of atomic energy in Canada.

i) Legal status

The Board is a corporation. It performs its various missions as an agent of the Crown, reporting to Parliament annually through the Minister of Natural Resources, to whom it regularly submits reports of its activities.

ii) Responsibilities

The Board was established to supervise the application and use of atomic energy and to ensure compliance with Canada's national policy and international commitments concerning international atomic energy control measures. With this in mind, the AECB was designed as a regulatory body, with considerable powers in the whole area of authorisations, and as an agency for controlling nuclear activities. In respect of these matters, the AECB is an independent agency and is not under the supervision of the Minister.

Regulatory Powers:

The powers granted to the Board in the area of nuclear regulations are contained in the Atomic Energy Control Act. These regulations are made by the Board with approval of the Governor in Council and cover all stages involved in the nuclear fuel cycle, from implementation of rules that govern mining of radioactive substances to the standards determining the authorisation regime and inspections for the production and use of nuclear energy. The Board can also make regulations for the transportation and marketing of nuclear materials. Subject to the approval of the Governor in Council, the Board can make regulations to promote nuclear research and protect nuclear industrial ownership rights. At the international level, moreover, the Board is responsible, with the approval of the Governor in Council, for making appropriate regulations to foster scientific co-operation in the nuclear field.

The Board also makes rules for its internal operations. Of its own authority, for example, the Board establishes its own by-laws and appoints the administrative, scientific and technical staff it needs. With the approval of the Minister, the Board determines the duties of its staff and sets their pay scales, subject to approval by the Treasury Board.

Administrative Powers:

The Board, following authorisation and control procedures defined in the Atomic Energy Control Regulations, supervises all activities related to nuclear materials and devices.

For example, the Board or designated officer is the authority that rules on applications for licences to mine, produce, use and market nuclear materials, as well as licences for the possession, use and sale of nuclear equipment. The Board also issues licences for the operation of nuclear facilities, after first approving their site and construction. Applications for site approval must include an evaluation of the potential dangers from the operation of the nuclear facility on that site and a description of the steps required to prevent such dangers. Licences may be subject to any conditions which the Board deems appropriate in the interest of health, safety, security and the environment, after examination of the information supplied by the applicant. The safety standards applicable are determined in co-operation with the advisory committees on safety and radiation protection. Before their approval by the Board, draft standards are published to allow for public comment.

In the transportation of radioactive materials, the Board acts as a consultant to agencies responsible for the regulation of transport. The Board applies its own controls concerning packaging and labelling prescriptions.

Powers of control:

The role of the Board is not limited to issuing licences; its responsibilities as a control agency carry right through nuclear operations and are exercised in consultation with the federal and provincial departments concerned.

Technical supervision of nuclear facilities by the Board takes several forms. Inspections may be provided either by staff members posted at the nuclear facility or by staff from the Board's licensing Division, who visit licence holders periodically.

The Board also requires operators of nuclear facilities to submit regular reports and to investigate and notify it of all incidents.

In addition, the Board acts as a radiological control agency for personnel. The Board or an appointed officer designates medical advisers, proposed by the competent federal or provincial departments and agencies, as well as by Atomic Energy of Canada Ltd., to ensure medical supervision of radiation workers. Medical advisers thus designated for a given area act in close co-operation with both the Board's medical adviser and the officials of the federal Department of Health and Welfare in advising the Board on any medical matter.

The Board has set up an internal group of radiation protection specialists to develop and assess protection standards. Before being approved by the Board, draft standards are referred to the advisory committees and then made available for public comment.

Other activities:

The Board has since 1980 developed a policy of public access to information on regulatory matters such as the granting of licences. Under this policy, the public may examine all documents supporting licence applications, the reports of advisers to the Board and the final report by the Board's staff on any licence application, as well as the reports that licence holders are required to submit under the Atomic Energy Control Regulations or the terms of licence. In addition, the Board reports, through the media, on each stage of the process of issuing licences for nuclear installations, on important events requiring that remedial action be taken or ordered and on situations where the Board is aware of any present or future concern for the public and the environment.

Dissemination of this information to the public is controlled by the Board and does not involve the release of secrets relating to nuclear industrial property; information that is private or commercial, or confidential because of domestic or international political commitments, or likely to compromise security is not disseminated to the public.

In research and development, the Board concentrates its resources on projects which support its regulatory activities. The Board's research programme is intended to provide the independent advice and information it needs to perform its regulatory functions with minimal dependence on the industry being regulated. The Board does only a small portion of its research itself, giving most of it under contract to independent researchers and agencies.

The Board's international activities form an important part of its work. As the government's representative, the Board maintains relations with foreign governments and international organisations to establish standards in the field of nuclear energy and discuss questions of common concern.

Moreover, the Board's staff may be consulted for advice on matters falling within their expertise and may participate in international negotiations, discussions, conferences etc.

iii) Structure

The Atomic Energy Control Board consists of five members and is referred to as "the Board". The President of the Board, who is the Chief Executive Officer of the AECB, is the only full-time member. The President of the National Research Council of Canada is an *ex officio* member of the Board.

The AECB staff organisation comprises the President's Office, the Secretariat, the Directorate of Reactor Regulation, the Directorate of Fuel Cycle and Materials Regulation, the Directorate of Analysis and Assessment, and the Directorate of Administration.

The AECB staff implements the policies of the Board and makes recommendations to the Board concerning the issuing of licences, and other regulatory matters. The functions of corporate management and corporate policy development are carried out by the Executive Committee, which consists of the President and the senior officer of each of the five organisational units.

The President supervises and directs the work of the organisation. A Legal Services Unit (two lawyers from the Department of Justice), a Medical Liaison Officer and an Official Languages Adviser report to the President.

Through the President, the Board receives advice from two independent committees, the Advisory Committee on Radiological Protection and the Advisory Committee on Nuclear Safety, composed of technical experts from outside the AECB. They advise on generic issues and are not involved with licensing actions.

Through the Medical Liaison Officer, the President receives advice from the AECB's Medical Advisers who are senior medical officers, nominated by the provinces, AECL Research Co., the Department of National Defence and Health Canada. They are appointed by the Board under the Atomic Energy Control Regulations.

The Secretariat is responsible for the functions of Secretary of the Board, the Office of Public Information, the Advisory Committee Secretariat and the Research and Safeguards Division. It also is responsible for corporate planning, co-ordination of policy development, implementation of internal audit and programme evaluation plans, as well as liaison with provincial, federal and international agencies, including the Minister's office. Administration of the Nuclear Liability Act and compliance with the provisions of the Access to Information Act and the Privacy Act rest with the Secretariat, as does responsibility for training programmes.

The Directorate of Reactor Regulation is responsible for the regulation of power and research reactors, heavy water plants, and for examining the qualifications of reactor operators.

The Directorate of Fuel Cycle and Materials Regulation is responsible for the regulation of uranium mines, mills, refineries and conversion plants; radioactive waste management facilities; accelerators; and the use of radioisotopes. Additional responsibilities include the analytical laboratory facilities, regulating the transport packaging of radioactive materials and regulating the decommissioning of nuclear facilities.

The Directorate of Analysis and Assessment is responsible for the detailed review and assessment of the arguments submitted by licensees to demonstrate the safety of their designs in both normal and accident situations, the adequacy of their quality assurance, and the protection from radiation hazards threatening both workers and the environment.

The Directorate of Administration is responsible for the management and administration of the AECB's human, information, financial and physical resources.

iv) Financing

The Board's financial resources come in part from appropriations voted by Parliament. The government recovers a part of the Board's operating costs by means of the Board's licensing fees. As mentioned earlier, the AECB Cost Recovery Fees Regulations have, since 1990, enabled the Board to require most applications to it to be accompanied by a fee.

The Auditor General of Canada is responsible for auditing the Board's accounts and financial statements.

2. Public and Semi-Public Agencies

a) National Research Council (NRC)

Created in 1916 under the National Research Council Act [R.S. 1985, c.N-15] the National Research Council (NRC) is a departmental Crown corporation reporting to Parliament through a designated minister. Since its inception, the NRC has played a major role in Canada's scientific development. Today, it constitutes a national scientific laboratory which performs much of its research in collaboration with industry and universities. It also operates a national library for science and engineering and provides support to industrial research through financial contributions and technical assistance.

The President of the National Research Council is appointed to that position by the Governor in Council and is a member by right of the Atomic Energy Control Board.

b) Natural Sciences and Engineering Research Council

Formed in 1978, the Natural Sciences and Engineering Research Council is a departmental Crown corporation under the Natural Sciences and Engineering Research Council Act [R.S. 1985, c.N-21] and reports to Parliament through a designated minister. The Council promotes and supports research in the natural sciences and engineering, except the medical sciences, and advises the Minister on aspects of such research, on request. The Council is responsible for grants to universities and to academic researchers, and for scholarships to graduate students.

CZECH REPUBLIC

I. GENERAL REGULATORY REGIME

1. Introduction

On 1 January 1993, the former Czechoslovakia was divided into the Slovak Republic and the Czech Republic. To ensure a smooth and continuous transition, it was agreed that all acts, regulations and decisions in the field of nuclear energy and ionising radiation would continue to apply until subsequent legislation was enacted. Since then, several acts and regulations have been adopted to establish a comprehensive legal system in this field.

In the Czech Republic, nuclear power generated electricity constitutes 20% of the country's supply (1998). There is one nuclear power station at Dukovany in South Moravia with four operational units. Two additional units are under construction at the Temelin Power Station. In addition, the Czech Republic has three research reactors. The research reactor SR-0 at Skoda, a.s., Pilsen has been decommissioned. There are also three radioactive waste disposal facilities, a spent fuel interim storage facility at Dukovany, and other smaller facilities used for radioactive waste treatment. At the state-owned firm, *Diamo*, there are spoil banks and lagoons of slurry which originate from uranium mining and milling operations.

In the former Czechoslovakia, the predominant regulatory body was the Czechoslovak Atomic Energy Commission. By Constitutional Act No. 4/1993 [Coll.* of 15 December 1992], the functions and responsibilities of the Commission were transferred to the State Office for Nuclear Safety (*Státní úrad pro jadernou bezpecnost* – SÚJB), which is the state supervisory and regulatory body with respect to the use of nuclear energy and ionising radiation for peaceful purposes.

The general act governing all activities in the field of nuclear energy was adopted on 24 January 1997, and is entitled "Act on the Peaceful Uses of Nuclear Energy and Ionising Radiation and on Alteration and Amendments of Related Legislation" [No. 18/1997 Coll.] (the Atomic Act). Its main purpose is to regulate all activities involving the utilisation of nuclear energy and ionising radiation and to protect the public and the environment against their harmful effects. The Act aims to ensure that nuclear energy and ionising radiation are used exclusively for peaceful purposes, and that the benefits of their use are balanced against their potentially harmful effects. The Act is of an administrative nature, but it also incorporates rules on civil law while addressing other areas, such as criminal law, labour law, environmental law, trade law, transport law and public health.

The Act entered into force on 1 July 1997, with the exception of Chapter 4 (Radioactive Waste Management), Chapter 5 (Civil Liability for Nuclear Damage) and Section 48 (Transfer of Responsibilities for Radioactive Waste Repositories), all of which entered into force upon the date of

* Coll. = Collection of the Czech Laws.

adoption (24 January 1997). The Act repeals 14 legislative instruments on nuclear energy.[1] Thirteen new decrees and two governmental regulations implementing the Act have been adopted by SÚJB, and one further regulation is being drafted. The new decrees and regulations concern the following:

- nuclear safety and radiation protection during the siting of nuclear facilities and workplaces using very significant ionising radiation sources;
- accounting for and control of nuclear materials;
- quality assurance for activities involving the use of nuclear energy or exposure to ionising radiation;
- radiation protection requirements;
- radiological emergencies and emergency plans;
- transportation of nuclear materials and radioactive sources;
- packaging requirements for the transportation and storage of nuclear materials, radioactive sources and other products;
- physical protection of nuclear materials and nuclear facilities;
- professional qualifications of workers in nuclear safety and radiation protection;
- lists of dual-use and other items in the nuclear field;
- nuclear safety, radiation protection and emergency preparedness requirements;
- decommissioning of nuclear installations or workplaces with significant or very significant ionising radiation sources;

1. According to Section 49, the Atomic Act abolishes the following acts and decrees: Act No. 287/1993 Coll. on Competence of the State Office for Nuclear Safety, in the wording of Act No. 85/1995 Coll.; Act No. 28/1984 on State Supervision of Nuclear Safety of Nuclear Installations; Decree No. 59/1972 Coll. on Protection of Health from Ionising Radiation and Decree No. 76/1991 Coll. on Reduction of Exposure from Radon and Other Natural Radionuclides, both of the Health Ministry of the Czech Republic; Decree No. 28/1977 Coll. on Accountancy for and Control of Nuclear Materials. Decree No. 67/1987 Coll. on Nuclear Safety Assurance in the Process of Radioactive Waste Management, Decree No. 100/1989 Coll. on Security Protection of Nuclear Installations and Nuclear Materials, Decree No. 191/1989 Coll. which Lays Down Methods, Terms and Conditions for Verification of Special Professional Qualification of Selected Workers in Nuclear Installations, and Decree No. 436/1990 Coll. on Quality Assurance of Selected Facilities with Regards to Nuclear Safety of Nuclear Installations, all of the Czechoslovak Atomic Energy Commission; and finally the following directives: Directive No. 2/1978 Coll. on Nuclear Safety Assurance within the Process of Designing, Licensing and Realisation of Constructions Including Nuclear Energy Installations, Directive No. 4/1979 Coll. on General Criteria of Nuclear Safety Assurance within the Siting of Constructions Including Nuclear Energy Installations, Directive No. 6/1980 Coll. on Nuclear Safety Assurance within the Process of Nuclear Power Installation Commissioning and Operation, Directive No. 8/1981 Coll. on Testing of Equipment for Transportation and Storage of Radioactive Materials, and Directive No. 9/1985 Coll. on Nuclear Safety Assurance of Nuclear Research Installation, all of the Czechoslovak Atomic Energy Commission.

- amount and method of levies to the nuclear account (payment basis, payment vote, etc.); and

- limits of concentrations and quantities of nuclear material for exemption from the application of provisions concerning civil liability for nuclear damage (currently under preparation).

Part I of the Atomic Act lays down the general conditions for activities related to the use of nuclear energy and ionising radiation, the rules related to radioactive waste management and third party liability for nuclear damage, state supervision and penalties. Parts II-IV are entirely devoted to necessary amendments of the related legislation, while Part V contains general transitional and final provisions. An Annex lists the documentation required for particular licensed activities pursuant to Section 13 of the Act.

The following activities involving the use of nuclear energy and radiation practices are covered by the Atomic Act [Part I, Chapter 1, Section 2(a) and (b)]:

- siting, design, construction, commissioning, operation, reconstruction and decommissioning of nuclear installations;

- design, manufacturing, repair and verification of nuclear installation systems or their components, including materials used for their production;

- design, production, repair and verification of packaging assemblies for transportation, storage or disposal of nuclear materials;

- management of nuclear materials, selected items and, where used in nuclear activities, dual use items;

- research into and development of the activities mentioned above;

- professional training of personnel;

- transport of nuclear materials;

- any practice resulting in exposure to ionising radiation.

2. Mining Regime

The Czech Republic has relatively rich uranium resources. Uranium mining started in 1946 and reached its peak in 1960 with an annual production of 3 000 tonnes. There are four uranium deposits and two uranium mines now in operation. The operator of all uranium production facilities is the exclusively state-owned company *Diamo* (formerly *Ceskoslovensky Uranovy Pruysl* – CSUP).

In 1988, the former Czechoslovak Republic adopted Act No. 44/1988 Coll. on the Protection and Use of Mineral Wealth, which laid down general rules concerning the use of resources and the protection of mineral wealth. That same year, the Czech National Council adopted Act No. 61/1988 Coll. on Mining Operations, Explosives and the State Mining Administration, which more specifically dealt with the safety and procedures of mining operations. The licensing of mining activities is regulated by the Decree on Mining Licences [No. 15/1995 Coll.].

A new Mining Act is being prepared, which will regulate the prospecting for, and mining of minerals.

3. Radioactive Substances, Nuclear Items, Fuel and Equipment

The rules specifying procedures for the handling, use and safety of ionising radiation sources, and nuclear items, fuel and equipment have now largely been incorporated into the Atomic Act and implementing decrees such as Decree No. 184/1997 Coll. on requirements for radiation protection, and Decree No. 142/1997 on type-approval.

a) Ionising radiation sources

According to Section 2(c) of the Atomic Act, an "ionising radiation source" means:

- a radionuclide source which is a substance or an object containing radionuclides or contaminated by radionuclides to a level exceeding the values set out in implementing regulations [see Decree No. 184/1997 Coll. on the requirements for radiation protection]. The exemption values correspond to the values used in Council Directive 96/29/Euratom;

- equipment containing a radionuclide source;

- equipment, the operation of which generates radionuclides;

- equipment, the operation of which generates ionising radiation, with energy exceeding 5 keV.

Ionising radiation sources are divided into five categories, the criteria for which are laid down by regulation [Decree No. 184/1997 Coll.]. These are: 1) insignificant sources, the handling of which neither poses a risk of a radiation incident nor generates any radioactive waste; 2) minor sources, the handling of which does not create a risk of a radiation accident, although it may generate radioactive waste; 3) simple sources, the management of which creates a risk of a radiation accident, but no resulting acute health effects; 4) significant sources, the management of which might produce a radiation accident with acute health effects, but not a radiation emergency; and finally 5) very significant sources, which may cause a radiation emergency. A licence is required for all ionising radiation sources, except insignificant sources or type-approved minor sources used in accordance with the instructions approved by SÚJB [Sections 21 and 23]. Finally, an "ionising radiation source workplace" is defined as an area where such sources are used or handled in a conscious and intentional manner, justifying special ionising radiation protection measures [Sections 2(s) and 4(10)].

b) Nuclear items

The 1997 Atomic Act [Section 2(j)] defines the term "nuclear items" as follows:

- nuclear materials, such as source materials, special fission materials and other materials so determined by regulation [Decree No. 145/1997 Coll.];

- classified items, which are materials, equipment and technology designed and manufactured to be used in the nuclear industry as set out by regulation [Decree No. 147/1997 Coll.];

- dual-use items, *i.e.* materials, equipment and technology not designed and manufactured for use in the nuclear field, but which may be so used, as set out by regulation [Decree No. 147/1997 Coll.].

Pursuant to the Act, "source materials" are uranium containing a mixture of isotopes occurring in nature, uranium depleted in isotope ^{235}U, and thorium in whatever form they are found, as well as other substances or materials containing one or more of these items in a concentration or an amount exceeding the limits laid down by Decree No. 145/1997 Coll. "Special fission materials", on the other hand, are ^{239}Pu, ^{233}U, uranium enriched in the isotope ^{235}U and/or ^{233}U and materials containing one or more of these radionuclides, except source materials, in concentrations or amounts exceeding the limits laid down by a regulation. With respect to the international transfer of nuclear items, the Act prohibits such transfers where they would be in breach of the international commitments of the Czech Republic [Section 5].

c) Spent fuel and equipment

In the former Czechoslovakia, spent fuel from the Dukovany station was originally sent to Russia for disposal, until such time as Russia decided to accept it only for reprocessing, following which it was sent to an interim spent fuel storage facility at the Bohunice plant in the Slovak Republic. However, in 1993 the Slovak utility SEP, which operated the Bohunice plant, decided to no longer accept the fuel and in November 1995, the Slovak utility began shipping Dukovany's spent fuel back to the Czech Republic, aiming to return all such spent fuel by 1997.

To address this problem, Dukovany began re-racking the fuel assemblies in its spent fuel ponds, which increased capacity by about 90%. In addition, the utility *Ceske Energeticke Zavody a.s.* (CEZ) built a 600 metric ton interim dry storage facility on site, which began trial operation in March 1997, and whose extension is already planned. CEZ has also made a site characterisation (by geological and hydrological prospecting) of the locality for siting a central interim storage facility that could store fuel assemblies from the Dukovany and Temelin plants. In addition, the Czech Republic has launched a project, under the auspices of the Nuclear Research Institute, to study the disposal of waste in a deep geological repository. The chosen repository site is not due to become operational until 2035.

The management of spent or irradiated fuel will be subject to the same requirements as for radioactive waste, if the generator and SÚJB declare it to be radioactive waste [Section 24(3)] (See, *infra*, Section 7 "Radioactive Waste Management").

4. Nuclear Installations

The definition of a "nuclear installation" under the Atomic Act [Section 2(h)] covers a variety of facilities: constructions or operational units which make up a nuclear reactor using a fission chain reaction; facilities for production, processing, storage and disposal of nuclear materials; repositories of radioactive waste, with the exception of repositories containing exclusively natural radionuclides; and facilities for the storage of radioactive waste, for which the radioactivity exceeds the limits laid down by regulation. An "ionising radiation source workplace" is a place where ionising radiation sources are used or handled in any other conscious or intentional manner [Section 2(s)].

a) Licensing and inspection, including nuclear safety

i) Licensing

In accordance with the Atomic Act [Section 9(1)], a licence granted by SÚJB is required for:

- siting and construction of a nuclear installation or a very significant ionising radiation source workplace;
- particular commissioning stages, operation and decommissioning of a nuclear installation or a workplace with a significant or very significant ionising radiation source;
- restart of a nuclear reactor following a fuel reload;
- reconstruction or other changes affecting nuclear safety, radiation protection, physical protection and emergency preparedness of a nuclear installation or workplace with a significant or a very significant ionising radiation source;
- discharge of radionuclides into the environment;
- handling of ionising radiation sources, as specified by Decree No. 184/1997 Coll.;
- radioactive waste management;
- import or export of nuclear items and transit of nuclear material and selected items;
- handling of nuclear materials;
- transport of nuclear material and radionuclide sources, as specified by Decree No. 183/1997 Coll.;
- training of classified personnel at a nuclear installation or ionising radiation source workplace;
- re-importation of radioactive waste resulting from the processing or re-processing of material exported from the Czech Republic.

Under the Act, licence applications must be submitted to SÚJB with documents giving basic information about the licence applicant and the proposed activity for which a licence is sought. Further specific documents required by SÚJB for each licensed activity are set out in the Appendix to the Act. The Act also makes an environmental impact assessment a necessary condition for the issuance of a licence for siting or decommissioning [Section 13(4)]. The requirements for this assessment are set out in Act No. 244/1992 Coll. on Environmental Impact Assessment.

SÚJB's decision must be issued within a specified time period after the applicant has submitted its documentation. This period varies, depending upon the type of licence sought [Section 14]. SÚJB has the exclusive power to change, revoke or terminate a licence under conditions specified in the Act. Termination of the licence will generally take place after its expiry or upon the licensee's bankruptcy or ceasing to exist. The revocation of a licence, on the other hand, can be imposed in the case of non-compliance with requirements under the Act or can be sought by the licensee upon written

application, provided that nuclear safety and radiation protection concerns are satisfied [Section 16]. All licensees are registered by SÚJB in its national register.

After the issue of a licence therefor, the commissioning and operation of a nuclear installation remain subject to the provisions of the Atomic Act, and its implementing Decree No. 106/1998 Coll. on Ensuring Nuclear Safety in Nuclear Installations during their Commissioning and their Operation.

ii) Inspection

Inspection activities are performed by nuclear safety and radiation protection inspectors appointed by the Chairperson of SÚJB. An inspector must be competent to perform legal acts, have a relevant degree and three years of professional experience, be competent and of moral integrity and fulfil other requirements [Section 39(2)].

Inspectors verify whether licensees (and other registered owners of radiation sources) under the Atomic Act are adhering to the Act's provisions, its implementing regulations and the relevant licence conditions. Inspectors are authorised to:

- at any time, enter the licensee's premises and other workplaces where activities involving nuclear energy utilisation or resulting in radiation exposure take place;
- check compliance with requirements and conditions of nuclear safety, radiation protection, physical protection and emergency preparedness;
- carry out measurements and collect samples;
- perform a physical inspection of nuclear items or ionising radiation sources, including checks on accounting and control procedures;
- verify professional competence.

An inspector identifying discrepancies is authorised under Section 40 of the Atomic Act to:

- require the licensee to remedy the situation, within a determined time period;
- order the licensee to perform technical inspections, reviews or tests to verify nuclear safety status;
- revoke a licence attesting to the special competence of an employee of the licensee;
- recommend a penalty.

SÚJB is also authorised to impose provisional corrective measures at the licensee's cost [Section 40(2)].

iii) Nuclear Safety

Under the Atomic Act, nuclear safety falls entirely under the jurisdiction of SÚJB [Section 3(2)]. "Nuclear safety" is defined as the condition and ability of a nuclear installation and its

servicing personnel to prevent the uncontrolled development of a fission chain reaction or an inadmissible release of radioactive substances or ionising radiation into the environment, and to reduce the consequences of accidents [Section 2(d)]. Anyone engaged in activities associated with nuclear energy utilisation or radiation practices is required to ensure that nuclear safety and radiation protection are matters of priority [Section 4(3)].

The Czech Republic is a Party to the 1994 Convention on Nuclear Safety, which was approved on 18 September 1995 [Communication of the Ministry of Foreign Affairs No. 67/1998 Coll.].

b) Emergency response

The Czech Republic succeeded to both the 1986 Convention on Early Notification of a Nuclear Accident and the 1986 Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency on 24 March 1993. The Atomic Act sets out the general rules for emergency response in accordance with these Conventions. A "radiation accident" is defined as an event resulting in an inadmissible release of radioactive substances or ionising radiation, or an inadmissible exposure of people. A "radiation emergency" is defined as a radiation accident requiring measures to be taken to protect the public and the environment [Section 2(k) and (1)].

An "emergency plan" is defined as a set of planned measures to deal with a radiation accident or radiation emergency and to limit their consequences. According to the Act [Section 2(m)] there are three types of emergency plans:

- an on-site emergency plan, designed for nuclear installations or ionising radiation source workplaces;
- an emergency rule for the transport of nuclear materials or ionising radiation sources; and
- an off-site emergency plan for the region in the vicinity of a nuclear installation or ionising radiation source workplace where an emergency planning zone has been established.

The Act lays down the licensees' obligations in the event of a radiation accident [Section 19]. The licensee must have an on-site emergency plan, approved by SÚJB and, in the event of an existing or potential radiation emergency, the licensee must immediately notify the relevant District Council, SÚJB and other relevant bodies, and ensure that a warning is issued to the public within the emergency planning zone. In addition, the licensee must stop or limit the consequences of a radiation accident while taking protective measures for employees. In the event of a radiation emergency, the licensee must, in addition, participate in the operation of the National Radiation Monitoring Network [Governmental Regulation No. 11/1999 Coll.] (see *infra*, Part II). For radiation accidents or emergencies during transport, similar obligations apply. Emergency rules should be included in the documentation for a licence to transport nuclear materials and radionuclide sources.

The licensee must also submit information to the relevant District Council to help it prepare an off-site emergency plan and co-operate to ensure emergency preparedness in the emergency planning zone. In addition, the licensee is also obliged to contribute financially to the National Radiation Monitoring Network. Finally, it must participate in running a press and information campaign to ensure that the public is prepared for radiation emergencies.

In the event of a radiation accident, SÚJB is obliged to co-ordinate actions of the National Radiation Monitoring Network, ensure operation of the Emergency Response Centre and provide an international exchange of radiation data.

Section 46 of the Atomic Act determines the responsibilities of State Administration Central Bodies for emergency preparedness. The Ministry of Defence is to ensure, in relation to civil protection, emergency preparedness, a monitoring system, a notification and warning system, and the means to protect the public and mitigate the consequences of a radiation accident. The Ministry of Health is to provide for special medical care to exposed persons. [Section 46]. The Ministry of Internal Affairs in agreement with SÚJB shall control and co-ordinate district authorities in matters of emergency preparedness and elimination of the consequences of radiation emergencies. The emergency legislation in the Czech Republic is now undergoing revision and is expected to be completed during 2000.

c) Decommissioning

"Decommissioning" means activities aimed at releasing nuclear installations or ionising radiation source workplaces, following the termination of their operation, for their utilisation for other purposes or to exempt them from the effect of the Atomic Act [Section 2(n)]. The decommissioning of a nuclear installation or any other significant or very significant ionising radiation source workplace requires a licence from SÚJB, which in turn requires an environmental impact assessment, a quality assurance programme, an on-site emergency plan and methods of ensuring physical protection [Section 13]. Finally, the operator of a nuclear installation or ionising radiation source workplace is required to keep a financial reserve for the decommissioning of his facility. Control over these reserves is to be exercised by the Radioactive Waste Repository Authority (*Sprava ulozist radioaktivnich odpadu*) (see, *infra*, Section 7 "Radioactive Waste Management" and Part II).

5. Trade in Nuclear Materials and Equipment

Nuclear trade is now regulated by the Atomic Act and Decrees No. 145/1997 Coll. and No. 147/1997 Coll.

A licence is required from SÚJB for the import or export of nuclear items or transit of nuclear materials and selected items [Section 9 of the Atomic Act], as is a licence from the Ministry of Industry and Trade under Act No. 21/1997 Coll. on Control of Export and Import of Goods and Technologies Subject to International Inspection Modes. In principle, the Atomic Act prohibits the international transfer of nuclear items into states that would contravene its international commitments under the Non-Proliferation Treaty and the Treaty on the Prohibition of the Emplacement of Nuclear Weapons and Other Weapons of Mass Destruction. Import of radioactive waste into the Czech Republic is prohibited. However, the Act does allow the re-import of ionising radiation sources and radioactive waste from materials exported from the Czech Republic for processing or reprocessing, if approved by SÚJB.

6. Radiation Protection

The Atomic Act defines "radiation protection" as a system of technological and organisational measures to reduce exposure of persons and the environment [Section 2(e)]. State supervision over

radiation protection is entrusted to SÚJB pursuant to the Atomic Act [Section 3]. Dose limits, constraints and guidance levels are set out in Decree No. 184/1997 Coll.

Dose limits must take into account exposures from other practices. Medical exposures, natural exposures and exposures received during a radiation accident are regulated by guidance levels corresponding to reasonably achievable levels of radiation protection. In general, the extent to which natural radiation exposures must be reduced is dependent upon the detriment caused, balanced against the benefits to be gained.

Radiation protection must also be respected during transportation of nuclear materials and in radioactive waste management activities. Compliance with applicable limits will be verified by SÚJB's inspectors and violations can result in the imposition of penalties.

The Act, together with Decree No. 184/1997 Coll. on Radiation Protection Requirements, is based on the 1990 Recommendations of the International Commission for Radiological Protection (ICRP) and the International Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources, and correspond to Council Directive 96/29/Euratom. The general principles of radiation protection, such as justification of radiation practices and the optimisation of radiation protection and dose limitation are covered. Dose limits for the public are decreased from 5 mSv to 1 mSv per year or, as an exception, 5 mSv per five consecutive years starting from the year 1998, and for radiation workers from 50 mSv per year to 100 mSv per five consecutive years starting from the year 2000.

7. Radioactive Waste Management

The handling, disposal and management of radioactive waste are governed by the Atomic Act and corresponding regulations such as Decree No. 184/1997 Coll. on Radiation Protection Requirements. According to the Act, "radioactive waste" is waste substances, items or equipment for which no further use is foreseen by their owner, with a radionuclide content or surface radionuclide contamination exceeding the limits permissible for discharge into the environment. Such waste will have to be disposed of in radioactive waste repositories, *i.e.* an area, structure or facility at the surface or underground, for the purpose of radioactive waste disposal. "Radioactive waste and spent fuel storage" refers to the temporary emplacement of radioactive waste or spent or irradiated nuclear fuel into areas, facilities or installations designed for this purpose, whereas "disposal" refers to the permanent emplacement of radioactive waste into areas, facilities or installations without the intention of its retrieval. [Section 2(o), (p) and (q)]. Both storage and disposal of radioactive waste and spent fuel require a licence issued by SÚJB [Section 9(c)].

The Atomic Act further provides that the owner or generator of radioactive waste is financially responsible for its management, from its time of origin to its disposal, including monitoring after closure of the radioactive waste repository, and any necessary research and development activities [Section 24]. A "generator" is an owner of radioactive waste or any other person or entity managing an owner's assets in such a manner that radioactive waste is generated. The state, on the other hand, is responsible for guaranteeing the safe disposal of all radioactive waste, including monitoring and supervision of repositories after their closure, and for this purpose the Act requires the Minister of Industry and Trade to establish a Radioactive Waste Repository Authority (*Sprava ulozist radioaktivnich odpadu*) as a state organisation.

The Authority, established on 1 June 1997, is funded through levies imposed on generators of radioactive waste, and is responsible for accepting all radioactive waste, including spent or irradiated

fuel, and providing for its safe disposal, including monitoring and supervising repositories after their closure [see *infra* Part II]. The Authority's activities are, in part, determined by the term of its agreement with the waste generator. Waste will be accepted only if it meets the acceptance criteria for disposal, as determined by SÚJB. Upon acceptance of the waste, it becomes state property under the exclusive supervision of the Authority [Section 31].

At the international level, the Czech Republic approved the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 25 March 1999.

8. Non-Proliferation and Physical Protection

The Atomic Act defines "physical protection" as a system of technological and organisational measures preventing unauthorised activities with nuclear installations, nuclear materials and selected items [Section 2(f)]. It provides that SÚJB is responsible for physical protection and non-proliferation issues, and authorises it to maintain a national system of accounting for and control of nuclear materials. SÚJB approves the inclusion of a nuclear installation or its components and nuclear materials into a category for physical protection and approves methods of physical protection [Section 3(2)(d)]. It also makes decisions concerning the management of nuclear items, if the owner or other person responsible fails to comply with requirements under the Act [Section 3(2)(q)]. In addition, the Act makes the police responsible for ensuring emergency services to protect nuclear installations and for participating in the physical protection of nuclear material during its transportation [Section 44]. The licensee is responsible for ensuring physical protection of nuclear material [Section 17].

In respect of non-proliferation, the Czech Republic succeeded to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 1 January 1993 [Communication No. 61/1974 of the Foreign Ministry on the Non-Proliferation Treaty] and succeeded to the 1979 Convention on the Physical Protection of Nuclear Material on 24 March 1993 [Communication No. 144/1996 Coll. of the Ministry of Foreign Affairs]. The provisions of these Conventions are implemented by the Atomic Act and by Decree No. 145/1997 Coll. on Accounting for and Control of Nuclear Materials and their Further Delimitation, Decree No. 144/1997 Coll. on Physical Protection of Nuclear Materials and Nuclear Installations and on their Insertion into Particular Categories, and Section 186 of Act No. 290/1993 Coll. on Illegal Production and Handling of Radioactive Materials. The Czech Republic also ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 11 September 1997.

Inspectors from the International Atomic Energy Agency, together with those from SÚJB, are authorised to inspect nuclear material and the accounting and control system, according to the Non-Proliferation Treaty and the Treaty on the Prohibition of the Emplacement of Nuclear Weapons and Other Weapons of Mass Destruction on the Seabed and the Ocean Floor and in the Subsoil thereof [Section 39(5)].

9. Transport

The Atomic Act also addresses the transport of nuclear materials and radionuclide sources [Section 20]. Such transport is subject to a licence to be issued by SÚJB in accordance with Decree No. 143/1997 Coll. The licence does not have to be obtained by the carrier unless that person is also the shipper, consignor or consignee [Section 9(m)], but the licensee must ensure that the consignee is authorised to handle nuclear materials or ionising radiation sources according to the rules set out in the Act, and that the packaging assemblies are "type-approved" by SÚJB [Section 20(1)(a) and (c)].

The licensee must also comply with specific legislation on transport, including Decree No. 143/1997 Coll., Act No. 111/1994 Coll. on Road Transport and its associated Decree No. 187/1994 Coll., Act No. 266/1994 Coll. on Railways, Appendix 1 to Decree of the Minister of Foreign Affairs No. 8/1985 Coll. on the Convention on International Rail Transport (COTIF), Act No. 114/1995 Coll. on Inland Navigation, Decree No. 17/1966 Coll. on Air Transport Rules in the wording of Decree No. 15/1971 Coll. and Decree No. 184/1997 Coll. and Decree No. 144/1997 Coll. on radiation and physical protection requirements. The licensee must also report to a border customs office, the transfer, entry into or exit from the Czech Republic of nuclear items or radionuclide sources, other than dual-use items. Breach of this condition could result in the withholding of the goods to be transported.

10. Nuclear Third Party Liability

The Czech Republic succeeded to the 1963 Vienna Convention on Civil Liability for Nuclear Damage and the 1988 Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention, on 24 March 1994 [Communication No. 135/1994 Coll. of the Ministry of Foreign Affairs]. As a result, the Atomic Act incorporates the basic principles of nuclear third party liability found in the Vienna Convention, including the exclusive liability of the operator for any third party nuclear damage resulting from an accident at his nuclear power plant and compulsory insurance coverage for any such damage. Furthermore, the state will provide compensation for any such damage exceeding the amount of the operator's financial security limit.

The Act defines an "operator of a nuclear installation", by reference to the Vienna Convention, as the holder of a licence to operate a nuclear installation, to perform any other activity in relation thereto or to transport nuclear material [Section 33(1)]. The Act specifies that the extent and manner of compensation for nuclear damage is to be regulated by Civil Act No. 40/1964 Coll. [Section 34(1)]. Nuclear damage is defined to include the cost of preventive measures and measures of reinstatement of the impaired environment [Section 34(2)]. The operator's liability is limited to Czech Republic koruna CZK 6 billion [approximately Special Drawing Rights (SDRs) 150 million] per nuclear installation, whereas for facilities with reduced risk and transport the liability limit is CZK 1.5 billion (approximately SDRs 37.5 million) [Section 35]. The time limit for bringing claims for compensation is ten years from the occurrence of the nuclear incident with a "discovery period" of three years [Section 38].

To cover this liability, the operator is obliged to have insurance or other financial security of not less than CZK 1.5 billion for nuclear power plants and their stipulated associated activities, or CZK 200 million for lesser risk facilities and transport [Section 36(3)]. This security must be obtained from an authorised insurer and the policy conditions must be approved by a state insurance supervision authority. To cover these liability claims, a nuclear insurance pool was established in the Czech Republic in July 1995.

The Atomic Act further provides for state guarantees to ensure compensation up to the established liability limits if liability claims exceed the mandatory insurance of the operator [Section 37].

The provisions contained in general regulations on liability for ordinary damage apply only if international agreements to which the Czech Republic is a Party or the Atomic Act do not provide otherwise [Section 32(2)].

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities

a) State Office for Nuclear Safety (SÚJB)

In 1993, pursuant to its Constitutional Act No. 4/1993 Coll., and to Act No. 21/1992 Coll., the Czech Republic transferred supervisory functions and responsibilities in the nuclear safety area from the former Czechoslovak Atomic Energy Commission to the State Office for Nuclear Safety (*Státní úrad pro jadernou bezpecnost* – SÚJB). Its competence as the regulatory authority responsible for supervising the use of nuclear energy and ionising radiation sources is set out in the Atomic Act of 1997 [Section 3(2)]. In general, SÚJB supervises nuclear safety, physical protection, radiation protection and emergency preparedness on the premises of a nuclear installation or in ionising radiation source workplaces, as well as the management of radioactive waste. The Chairperson of SÚJB is nominated by the Government of the Czech Republic.

SÚJB is empowered to issue licences for activities regulated by the Act and to maintain a register of such licences. In addition, it approves types of packaging assemblies for transport and storage of nuclear materials and radionuclide sources. SÚJB maintains the state system of accounting for and control of nuclear materials and determines the requirements for their registration and inspection. It maintains a registration system of radiation exposure of the general public and of persons who have working contact with ionising radiation sources. It also establishes commissions to verify the special qualifications of selected personnel.

Further, SÚJB provides data to municipalities and District Councils on radioactive waste handling within their area of administration, co-ordinates the operation of the National Radiation Monitoring Network, ensures the operation of the Emergency Response Centre (ERC), provides international data on radiation levels and ensures international co-operation with the IAEA.

SÚJB has three sections: nuclear safety, radiation protection and management and technical support, each with its own deputy chairperson.

The Nuclear Safety Section comprises three departments: Assessment of Nuclear Installations, Control of Nuclear Installations and Nuclear Materials.

The Radiation Protection Section comprises three departments: Radiation Sources and Nuclear Energy, Exposure Regulation, Environment and Waste Management, and a Licensing Division.

The Management and Technical Support Section consists of the Departments of International Co-operation, Financial Management and the SÚJB Bureau.

Finally, within SÚJB there is the Emergency Preparedness Division and the Quality Assurance Division, which report directly to the chairperson. The Emergency Preparedness Division ensures that the Emergency Response Centre is ready to function in technical terms, and serves as SÚJB Contact Point. SÚJB also incorporates seven regional centres and two local offices at Dukovany NPP and Temelin NPP. It is furthermore the managing authority of the National Radiation Protection Institute in Prague.

b) Ministry of Industry and Trade

The Ministry of Industry and Trade is responsible for:

- developing domestic legislation and preparing intergovernmental treaties in the nuclear field;
- proposing strategic reserves of nuclear materials;
- co-operating with other government agencies in developing emergency preparedness plans and environmental protection principles;
- co-ordinating activities in the nuclear field in relation to the government's economic policy;
- developing governmental policy in the nuclear area including the management of radioactive waste and spent nuclear fuel;
- monitoring the Dukovany NPP operation and Temelin NPP construction.

The construction, operation and decommissioning of nuclear installations as well as waste management are the responsibility of the Ministry of Industry and Trade.

c) Ministry of the Interior

The Ministry of the Interior is responsible for establishing details of the preparation of district emergency plans and off-site emergency plans by the various District Councils. The police are also responsible for providing emergency protection of nuclear installations and for participating in the physical protection of nuclear materials during their shipment.

d) Ministry of the Environment

The Ministry of the Environment is responsible for regulating nuclear activities to ensure that they comply with environmental laws. It also ensures that the procedures for environmental impact assessment are applied as a prerequisite to obtaining a licence, based on Act No. 244/1992 Coll. on Environmental Impact Assessments.

2. Advisory Bodies

a) Radiation Monitoring Network (RMN)

The Radiation Monitoring Network (RMN) of the Czech Republic is co-ordinated by SÚJB. Under normal circumstances, it monitors radiation levels for the early detection of accidents; under emergency conditions, it evaluates the consequences of a radiation accident. Normal monitoring involves the following:

- an early warning network, which comprises 60 measuring points;

- a territorial network of 206 measuring points equipped with thermoluminescent dosimeters (TLD);

- local TLD networks with 90 measuring points in the surroundings of the Dukovany and Temelin nuclear power plants;

- a territorial network of 11 air contamination measuring points;

- a network of 9 laboratories with gamma spectrometric and radiochemical analytical instrumentation.

The monitoring results are set out in the Annual Reports on the Radiation Conditions in the Czech Republic, which are submitted to the Governmental Commission for Radiation Accidents and to the public.

b) Emergency Response Centre (ERC)

The Emergency Response Centre (ERC) was established by SÚJB pursuant to the Atomic Act. Its main tasks are to:

- ensure Contact Point functions;

- collect and assess data from the Radiation Monitoring Network and nuclear installations;

- predict the development of emergencies and evaluate the safety status of a nuclear power plant in the event of an accident or emergency; to assess the radiation situation;

- evaluate radiation conditions in the Emergency Planning Zone and on the territory of the Czech Republic and advise the relevant national and local authorities on protection of the public;

- prepare public information reports.

The ERC is mobilised in the event of a crisis (radiation emergency) or during exercises testing preparedness for such situations. It provides support to the Emergency Division of SÚJB.

3. Public and Semi-Public Agencies

a) CEZ, a.s.

i) Legal Status

Before the dissolution of Czechoslovakia, the utility *Ceske Energeticke Zavody, a.s.* (CEZ) was state-owned. As part of its move to a market economy, the Czech Republic aimed to privatise the CEZ, and now 32% of its stock is publicly owned, while almost all of the remaining 68% is held by the Czech Government. This will be reduced to 51% when privatisation has been completed. CEZ reports directly to the Czech Ministry of Industry and Trade.

ii) Responsibilities

CEZ is predominately responsible for electricity generation and very high-voltage transmission on 220-400 kV level in the Czech Republic. It is also responsible for taking regulatory decisions and for the operational performance of nuclear undertakings. It sells electricity to regional distribution companies.

b) National Radiation Protection Institute (NRPI)

i) Legal Status

NRPI is a state organisation founded on 1 June 1995 by SÚJB, as its expert advisor in the field of radiation protection. The budget of the Institute is fully covered by the state through SÚJB. The chairperson of SÚJB appoints the director of NRPI.

ii) Responsibilities

The major task of NRPI is to perform all scientific activities necessary to support SÚJB as the main regulatory body in the field of radiation protection. NRPI participates in the monitoring of the radiological situation within the national territory and supports SÚJB in the co-ordination of the nation-wide Radiation Monitoring Network.

c) Radioactive Waste Repository Authority

i) Legal Status

The Radioactive Waste Repository Authority was established by the Ministry of Industry and Trade on 1 June 1997. It is a state organisation responsible for ensuring the safe disposal for radioactive waste and the monitoring and supervision of repositories after their closure.

ii) Responsibilities

The Authority is responsible for the following waste management activities:

- preparation, construction, commissioning, operation and closure of radioactive waste repositories and the monitoring of their impact on the environment;
- conditioning of spent or irradiated nuclear fuel into a form suitable for its disposal or further utilisation;
- record keeping of accepted radioactive waste and its generators;
- administration of levies for the Nuclear Fund;

- promotion and co-ordination of research and development in the field of radioactive waste management.

iii) Structure

The Authority has a management board and a director who are appointed by the Minister for Industry and Trade. The director, who is the statutory representative of the Authority, may act on its behalf and may participate in board meetings.

The board consists of 11 members, three of whom are representatives of the state administration bodies, four of whom represent the waste generators and a further four represent the public. The board supervises the efficiency with which resources are spent on the Authority's activities and recommends activity plans and budgets to the Minister.

iv) Financing

The Authority is funded through levies imposed on the producers of radioactive waste. The levies are put into a "nuclear account" managed by the Ministry of Finance and are used to finance the various operations by the Authority.

d) Diamo

Diamo (formerly *Ceskoslovensky Uranovy Prumysl* – CSUP) is an exclusively state-owned company acting as operator of all uranium production facilities. It is responsible for the extraction and processing of uranium ore and for the implementation of the state programmes on reducing the uranium industry and rehabilitation of former uranium production sites.

e) Nuclear Physics Institute (NPI)

The Nuclear Physics Institute was founded in 1955 and has undergone various changes since, including having served as the Nuclear Research Institute of the former Czechoslovak Commission for Atomic Energy. In 1993, after the dissolution of Czechoslovakia, the Nuclear Physics Institute became part of the Czech Academy of Sciences and now includes the Institute of Radiation Dosimetry and the Neutron Activation Analysis Laboratory. The NPI is comprised of the Departments of Theoretical Nuclear Physics, Nuclear Spectroscopy, Neutron Physics, Nuclear Reactions and Radiation Dosimetry.

f) Nuclear Research Institute Rez, a.s. (NRI)

The NRI is the successor to the Nuclear Research Institute which was founded in 1955. In 1971, it came under the authority of the Czechoslovak Atomic Energy Commission and in 1992 it was transformed into a joint-stock company with the Czech Government holding 50% of its shares, CEZ holding 26%, the Skoda Holding Company 9.8% and Skoda Nuclear Engineering 2.7%.

The NRI's objective is to carry out research and development into nuclear technologies and to implement the results achieved. Employing 600 members of staff, NRI operates the divisions/departments of Nuclear Power and Safety, Integrity and Materials, Fuel Cycle Chemistry, Reactor Services, Radiopharmaceuticals. It provides support services to SÚJB.

DENMARK

I. GENERAL REGULATORY REGIME

1. Introduction

At present Denmark has no nuclear power programme (although it has two small research reactors). In 1985, a Resolution of the Danish Parliament determined that nuclear power was not to be generated in Denmark and that the sites that had been reserved for the construction of nuclear power plants were to be released. As a result of that, by means of a specific decision, it was agreed that future Danish public energy planning should be based on the assumption that no new nuclear power plants would be built.

Nevertheless, there exists in Denmark legislation and rules governing activities involving nuclear and radioactive materials. The principal instruments are the 1953 Radioactive Substances Act and the 1962 Nuclear Installations Act. An Act on Nuclear Installations [Act No. 244 of 1976] was adopted in 1976 but has not yet entered into force, with the exception of Section 11 and the first paragraph of Section 12. This legislation will only come into force if the 1985 Resolution is reversed and a decision is made to implement a nuclear power programme. It would also be necessary that the Danish Parliament approve a new Act enforcing the provisions of the 1976 Act.

The first part of this study briefly reviews some of these provisions while the following part will consider the institutional framework within which they are applied.

2. Mining Regime

There is no special legislation in Denmark on nuclear ores. Under the general Danish mining law [Act No. 213 of 1981], ores found in the subsoil are state property, therefore the state alone is entitled to prospect for and use such ores.

The government grants concessions to prospect for and extract ores for not more than fifty years. The Danish Geological Survey Bureau must be informed of the discovery of ores and controls prospecting and extraction operations.

As regards Greenland, prospecting, exploration for and exploitation of minerals, including uranium, is covered by the Act on Mineral Resources in Greenland [Act No. 166 of 1965]. This Act is administered by the Mineral Resources Administration for Greenland (MTG) under the Danish Ministry for the Environment and Energy.

3. Radioactive Substances, Nuclear Fuel and Equipment

No radioactive substance whether in a natural state, in the form of a mixture or incorporated into machines or instruments can be manufactured, possessed or imported without a licence from the Board of Health (formerly referred to as the National Health Service) [Radioactive Substances Act No. 94 of 1953, Section 1].

Exceptions to the licensing rule are however provided by a Decree of the Minister of the Interior for certain nuclear substances and for most natural radioelements and chemical compounds [Decree No. 546 of 1981].

Permanent licences to hold and produce radioactive substances may be granted by the Board of Health to scientific institutes and university laboratories provided that these substances are intended solely for the purposes of teaching or research in such institutes [Section 2].

Licences issued to hospitals using radioactive substances for diagnostic purposes are granted on the basis of a list containing authorised radioactive materials which are available to users. These licences must also take into account the maximum level of activity authorised in the hospital department concerned, which depends on the type of treatment being applied and on the laboratory's facilities [Regulation No. 435 of 1974].

The Board of Health is authorised to issue further general regulations and to lay down special rules for each case of licensing with regard to storage, warning signs, qualifications of the user responsible, premises, transport, treatment of waste and reporting of incidents [Sections 2 and 3].

The licence is issued to the person responsible provided that he possesses the qualifications required; it remains valid so long as this person retains his post and until the relevant authority decides otherwise. The licence authorises its holder to perform laboratory experiments, to use the radioactive substances in proven diagnostic methods and also for element research in accordance with the above-mentioned list of radioactive substances for medical purposes. The holder of the licence may also use these substances in new diagnostic and research methods provided prior notification of such use is sent to the Board of Health [Regulation No. 356 of 1978].

Apart from the standard licence, it is possible to obtain a special licence permitting the use of the radioactive drugs which are on the above-mentioned list.

An Executive Order of 1972 issued by the Ministry of Education under Sections 8 and 38(3) of the 1962 Nuclear Installations Act [Act No. 170 of 1962] provides that a licence is required for the possession of nuclear materials, defined as uranium, plutonium and thorium, unprocessed – apart from ores – or processed, in metallic form, alloy or chemical compound [Order No. 315 of 1972, Section 1].

This licence is issued by the Energy Agency which replaced the Atomic Energy Commission in this respect.

Anyone in possession of nuclear materials must:

- keep records of their possession of such materials and insofar as nuclear facilities are concerned, maintain records of operational conditions;

- submit reports on the results from the above-mentioned records;

- give advance notice to the Ministry of the Interior of imports of nuclear materials; and

- co-operate in the implementation of the control referred to in Section 4 of the 1972 Executive Order.

The Order provides that persons specified in the licence will be authorised to have access to undertakings etc., holding nuclear materials and be entitled to take the necessary control measures, including examination of records, stocks and facilities, measurements and sampling [Section 4].

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

At present, licensing matters concerning existing nuclear installations (Risø National Laboratory) are governed by the Nuclear Installations Act [No. 170 of 1962]. However, as any possible future nuclear installation in Denmark will be subject to the provisions of the Act of 1976 (which, if it were to come into force, would repeal the 1962 Act), the licensing procedure laid down in that Act is described in the following.

The licensing procedure involves three permits – site approval, construction permit and operating permit – all granted by the Minister of the Interior subject to such conditions as are deemed necessary with regard to safety or other vital public interests [Section 2]. These conditions may, at any time, be replaced by other conditions, or a permit can be withdrawn.

Applications must be accompanied by the appropriate documentation regarding nuclear safety and environmental aspects [Section 4(3)].

The nuclear safety aspects of an application for any permit are examined by the Emergency Management Agency (formerly referred to as the Civil Defence and Emergency Planning Agency; this new denomination is a result of the Danish Emergency Preparedness Act of 23 December 1992) and the Board of Health. The agencies submit recommendations to the Minister of the Interior [Section 4(1)].

The Emergency Management Agency is assisted by the Inspectorate of Nuclear Installations which is under its authority. Recommendations to the Minister submitted by the Agency must be accompanied by statements prepared by the Nuclear Installations Inspectorate [Section 12(2)].

For nuclear reactors, public hearings are held with respect to site applications. The hearings are arranged by the Minister of the Interior in co-operation with the regional and municipal authorities concerned before the recommendations of the Emergency Management Agency are submitted to the Minister. During these hearings, information is provided on the essential assessments of safety and environmental protection matters which are made in connection with each application [Sections 3 and 14(7)].

For nuclear reactors, reprocessing or waste storage facilities the regional and municipal authorities concerned have to deliver their opinion on the site application.

Applications for site approval for nuclear reactors, reprocessing or waste storage facilities must be approved by parliamentary decision upon proposal of the Minister of the Interior before the

Minister can issue a site approval. For other types of nuclear installations, the Minister of the Interior must consult the relevant parliamentary Committee. The final decision on a site approval is made by the Minister of the Interior; in the case of nuclear reactors, reprocessing or waste storage facilities, following consultation with the Minister for the Environment and Energy [Section 3(1)].

Construction and operating permits are granted by the Minister of the Interior after consultation with the relevant parliamentary committee. Concerning the conditions attached to the permit, the Emergency Management Agency, upon recommendation from the Nuclear Installations Inspectorate, and the Board of Health, may specify supplementary conditions for the construction – and operation – of the installation [Sections 3(2) and 5(2)].

For each nuclear reactor a Special Advisory Safety Council is set up. This Council is composed of representatives from the plant personnel and management, the Directorate of Labour Inspection, the Emergency Management Agency and the municipal authorities as well as elected representatives of the population concerned.

This Council must, either upon request or at its own initiative, provide advice to the operator of the reactor and the authorities responsible for ensuring nuclear safety.

At the international level, Denmark ratified the 1994 Convention on Nuclear Safety on 13 November 1998.

b) Emergency response

Denmark expressed its consent to be bound to the 1986 Convention on Early Notification of a Nuclear Accident on 26 September 1986.

5. Trade in Nuclear Materials and Equipment

Denmark's import and export policies reflect the fact that Denmark is a Party to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons. An Executive Order of 1972 issued by the Ministry of Education under Sections 8 and 38(3) of the 1962 Nuclear Installations Act [No. 170 of 1962] provides that nuclear materials shall not be exported from Denmark without the authorisation of the Energy Agency.

6. Radiation Protection

The main purpose of Danish legislation governing nuclear activities is to ensure protection against radiation hazards; however there exist provisions which apply more particularly to radiation protection in the Order on the Safe Use of Radioactive Substances [Order No. 574 of 1975]. Other relevant provisions in connection with the protection of the public are the Regulations on Protective Measures against Accidents in Nuclear Plants [Regulation No. 278 of 1963] and various Orders, detailed below, concerning the installation and operation of X-ray apparatus.

The Order on the Safe Use of Radioactive Substances provides for safety measures to be taken in connection with the import, production, use, storage, transport and disposal of radioactive materials used for medical, industrial, agricultural, scientific and other purposes. The provisions of the Order specify that the protection measures must comply with the recommendations of the International

Commission on Radiological Protection (ICRP) whose maximum permissible doses must not be exceeded. Radiation doses must at all times be kept as low as possible and every effort must be made to limit the number of persons exposed to ionising radiation. The Board of Health is authorised to lay down special safety rules for each individual case [Order No. 574 of 1975, Section 1].

With respect to nuclear installations, the Minister of the Interior not only determines the maximum release of radiation to the general public permitted during normal operation of the plant, but also lays down maximum radiation doses for persons which should, if possible, not be exceeded in the case of an accident [Regulation No. 278 of 1963, Section 1(1) and (2)].

At the request of the Emergency Management Agency, an emergency plan to be approved by the Minister of the Interior must be established for every nuclear plant and every Danish port to which nuclear vessels are admitted. This plan establishes the safety measures to be implemented when the population is exposed to radiation as a result of a nuclear incident [Regulation No. 278 of 1963, Section 7].

Such measures include, for example [Regulation No. 278 of 1963, Section 8(1)]:

- measurement of radioactivity;
- warning systems;
- evacuation and billeting.

The implementation of any of these measures shall be decided by the Emergency Management Agency after consultation with an expert committee appointed by the Minister of the Interior and with the police authority concerned. It is provided that this committee, which may be directed by the Minister of the Interior to take over preparation of the emergency plan referred to above, should consist of representatives of the Emergency Management Agency, although it has the power to call in other experts [Section 9].

Various Orders have been passed dealing with safety measures in relation to people exposed to ionising radiation in the course of their employment or in the course of medical treatment. Many of these Orders implement Council Directives 80/836/Euratom and 84/466/Euratom which deal respectively with health protection of the general public and workers against the dangers of ionising radiation and radiation protection standards governing persons undergoing medical examination and treatment. The Order concerning Medical Surveillance of Work with Ionising Radiation [No. 821 of 1990] requires that those who work in conditions that are likely to expose them to ionising radiation in doses exceeding 15 millisieverts (mSv) per year must undergo a medical examination before commencing that work. They are also subject to an annual medical examination as long as they engage in such work, and to a special examination in the event of any incident (such as improper handling or an accident involving radiation). The worker is obliged to give the medical practitioner relevant information to enable an effective examination to occur. Medical records of the examinations must be forwarded to the State Labour Inspectorate and be kept for at least thirty years after the people concerned have ceased such work. The Order contains criminal sanctions for non-compliance with these provisions.

Other Orders specify dose limits for ionising radiation for both workers and the general public [No. 823 of 1997], pursuant to Council Directive 96/29/Euratom of 13 May 1996, and requirements for dose monitoring of workers exposed to ionising radiation [No. 821 of 1990]. Orders relating to radiation protection in the context of medical treatment include the Order on X-ray Diagnostic

Equipment for Medical Use [No. 217 of 1977] and the Order on the Use of Unsealed Radioactive Sources in Hospitals, Laboratories, etc. [No. 307 of 1984]. This Order establishes a licensing system for the purchase and use of unsealed radioactive sources and requirements for their storage and disposal. The licensing authority is the Board of Health. Other Orders made in implementation of the Euratom directives referred to above include: the Order on the Use of Electron Accelerators for Treatment of Patients [No. 319 of 1991]; the Order on Smoke Detectors and Consumer Articles containing Radioactive Materials [No. 154 of 1990]; and the Order on Industrial Gamma Radiography Treatment [No. 308 of 1984]. In 1995, the Board of Health issued seven Orders concerning the medical application of ionising radiation [Nos. 18-24 of 1995]. These Orders, all of which amended existing Orders of the Board of Health, were made to take into account Council Directive 93/42/EEC of 14 June 1993 regarding EC labelling of medical devices. The Board of Health also issued Order No. 918 of 4 December 1995 on the use in Denmark of sealed radioactive sources in industry, hospitals, laboratories etc.

7. Radioactive Waste Management

There is no legislation in Denmark dealing specifically with the management of radioactive waste. Denmark is a Party to both the 1972 Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (the London Convention, ratified by Denmark on 3 November 1976) and the 1974 Convention on the Protection of the Marine Environment of the Baltic Sea (the Helsinki Convention) and as such prohibits the dumping of any radioactive waste at sea.

Denmark accepted the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 3 September 1999.

8. Non-Proliferation and Physical Protection

The Nuclear Installations Act [No. 170 of 1962] specifies that a licence to operate (or construct) an installation may be refused for reasons of security or other reasons of public policy. The Act further specifies that the Minister of the Interior may make the necessary regulations in the event of international conventions providing for inspections to guarantee that nuclear installations are used solely for peaceful purposes and specifies that these regulations may include directives allowing inspectors to enter installations to make the necessary checks [Sections 4 and 8].

Denmark has ratified both the 1968 Treaty on the Non-Proliferation of Nuclear Weapons, on 3 January 1969, and the 1979 Convention on the Physical Protection of Nuclear Material, on 6 September 1991. It also ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 21 December 1998. The Nuclear Installations Act [No. 170 of 1962] gives the Emergency Management Agency and the Nuclear Installations Inspectorate a right of access, without grant of any judicial warrant, to nuclear installations for the exercise of inspections in connection with the implementation of international agreements to ensure that nuclear installations are used exclusively for peaceful purposes [Section 7].

9. Transport

The legal basis for regulations concerning the transport of radioactive materials in Denmark is the Radioactive Substances Act [No. 94 of 1953]. Under the Act, the Minister of the Interior is

authorised to issue Orders concerning the necessary precautionary measures relating, amongst other things, to the transport of radioactive materials. Accordingly, the Order on the Transport of Radioactive Materials [No. 731 of 1989], which implements the transport requirements of Council Directive 80/836/Euratom on health protection of the general public and workers against the dangers of ionising radiation has been issued and lays down rules for transport by road, rail, air and sea. The provisions are based on the IAEA Regulations on the Safe Transport of Radioactive Materials (1985 edition).

The Order nominates the Board of Health as the authority responsible for the transport of radioactive materials. It provides that the consignor of the radioactive substances must hold a licence for their use under the 1953 Act. The consignor is responsible for the packaging of the substances and must designate an appropriately qualified person to supervise and implement the safety controls required during the transport operation. The carrier must ensure that staff are aware of the relevant regulations (for example, those dealing with loading and storage); that safety devices are functioning properly; and that the substances carried are protected against theft and damage. The carrier must be approved by the Board of Health, which can impose conditions on the transport operation. The Board has access to consignments, documentation and the means of transport at all times. Any decision of the Board relating to a particular consignment may be appealed to the Ministry for the Interior.

The Order also requires that an approval certificate be obtained for the transport of certain types of radioactive material. This certificate is issued by the Board of Health in the case of land transport, the National Aviation Department for air transport, and the Maritime Navigation Department for sea transport.

The Order lays down procedures to be followed in the case of an accident. The Board of Health and other authorities concerned must be informed immediately. The personnel in charge of the transport must restrict access to the affected area, keep it under surveillance and monitor radiation levels. The authorities must also be informed immediately in the event of any loss or theft in the course of transport.

10. Nuclear Third Party Liability

Denmark is a Party to the following international instruments on nuclear third party liability:

- the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy and the 1963 Brussels Convention Supplementary to the Paris Convention, both of which were ratified on 4 September 1974, as amended by the two 1982 Protocols;

- the 1971 Brussels Convention On Civil Liability in the Field of Maritime Carriage of Nuclear Material, also ratified on 4 September 1974;

- the 1988 Joint Protocol relating to the Application of the Paris Convention and the Vienna Convention, ratified on 26 May 1989.

The national legislation which implements Denmark's obligations under these treaties is the Act on Compensation for Nuclear Damage [No. 332 of 1974].

The aggregate liability of the operator of a nuclear installation situated in Danish territory is limited to Special Drawing Rights (SDRs) 60 million for any one nuclear incident [Section 21(1)].

The Act provides that the operator of a nuclear installation situated in Denmark must take out insurance to cover his liability and must, in addition, obtain the approval of the Minister of Justice in relation to such insurance [Section 26(1) and (2)].

If, nevertheless, the operator's insurance is inadequate and he is, therefore, unable to pay the compensation for which he is liable, the state will provide financial assistance up to the liability of the operator in question.

The state will also intervene up to the limit provided for in the Brussels Supplementary Convention, to compensate any claim in excess of the amount of the insurance or financial security provided by the operator, subject to compliance with the provisions of the Act. The maximum coverage involving state funds now stands at the figure of SDRs 300 million.

II. INSTITUTIONAL FRAMEWORK

In Denmark, several Ministers, in particular the Minister of the Interior, share power with respect to nuclear activities and the Board of Health and the Emergency Management Agency also have extensive responsibilities in this field. Assistance is provided to these authorities by various advisory councils and technical and research institutes.

1. Regulatory and Supervisory Authorities

a) Minister for the Interior

Pursuant to a Royal Decree on reorganisation of the competent authorities concerned with nuclear installations, which came into effect in 1988, the administration of the 1962 Nuclear Installations Act [No. 170 of 1962] was transferred from the Minister for the Environment to the Minister of the Interior. By virtue of this change, the tasks of the previous Atomic Energy Commission as a nuclear safety authority were assigned to the Emergency Management Agency (formerly referred to as the Civil Defence and Emergency Planning Agency), which, together with the Board of Health, form the bodies responsible for nuclear safety.

As was seen in Part I, Section 4 "Nuclear Installations" *supra*, the Minister of the Interior would also be the licensing authority for all three permits required under the 1976 Act governing the safety and environmental conditions applicable to nuclear installations. Furthermore, he is responsible for the granting of approvals, licences and exemptions which are necessary for the siting and operation of a nuclear reactor and are laid down in a number of other Acts dealing with land-use planning and environmental protection.

The Minister also has general legislative competence with respect to the safe use of radioactive substances and materials and may lay down regulations for the inspection of nuclear installations provided for by international agreements [Act No. 94 of 1953]. If the Act governing the Safety and Environmental Conditions Applicable to Nuclear Installations [No. 244 of 1976] were to be brought

into force, the Minister would also have administrative responsibilities regarding the arrangement of public hearings with respect to site applications for nuclear reactors and setting up of emergency plans for all nuclear plants. The Minister would also have regulatory powers in relation to installations for the storage and processing of spent fuel and radioactive waste [Section 3]. Finally, the Minister has powers with respect to regulating the transport of radioactive materials [Order No. 574 of 1975].

b) Minister for the Environment and Energy

Immediately after the oil crisis in 1973-1974, the Danish Government decided to give the Minister for Trade and Industry (now the Minister for the Environment and Energy) responsibility for all matters concerning energy policy. Specifically, the 1976 Act on Energy Policy Measures [No. 194 of 1976] requires the Minister to prepare statements on energy policy including assessments of energy requirements and possibilities of energy supply, objectives and programmes for a rational supply and utilisation of different forms of energy, and programmes for energy research and development.

c) Minister for Justice

As was seen in the Part I, Section 10 "Nuclear Third Party Liability" *supra*, the Minister of Justice has the power, in certain cases, to fix the maximum amount of liability of the operator of a nuclear installation. In all cases, he must give his approval with regard to the insurance taken out by an operator to cover his liability [Act No. 332 of 1974].

d) Minister for Public Works

This Minister is the regulatory authority for the transport of radioactive materials by rail.

e) Minister for Foreign Affairs

The general responsibility for Danish participation in international co-operation in the nuclear field lies with the Minister for Foreign Affairs.

f) Board of Health

Because of the variety and the importance of responsibilities allocated to it, the Board of Health (formerly the National Health Service) may be considered as the principal government agency competent in the field of radiation protection. This is demonstrated not only by the general powers conferred by its constituent instrument, *i.e.* the Act on Public Health Central Administration [No. 182 of 1932] which designates it as the main supervisory authority for public health in Denmark, but also by the special functions assigned to it by a number of legislative and regulatory texts containing specific provisions on radiation protection, nuclear installations and the transport of radioactive materials.

Thus, as seen above, the Board has both licensing and regulatory powers in relation to the manufacture, possession or import of radioactive materials and equipment as well as powers of inspection with regard to medical equipment [Act No. 94 of 1953].

In relation to nuclear installations, the Board would, if the 1976 Act [No. 244 of 1976] were brought into force, determine the maximum release of radiation permitted during operation and would have important duties in ensuring that nuclear installations are operated under safe conditions.

The Board of Health has authority to lay down specific rules for the transport of radioactive materials and is responsible for supervising observance of the regulations applicable for all modes of transport.

State Institute of Radiation Hygiene

The State Institute of Radiation Hygiene, which forms part of the Board of Health, in fact carries out all the latter's tasks, as described above, with regard to radiation protection [Act No. 94 of 1953].

The Institute is run by a director and is divided into three departments covering X-rays, radiation medicine and other types of radiation respectively. The staff of the Institute are government officials [Act No. 170 of 1962].

g) Emergency Management Agency

As a result of the Danish Emergency Preparedness Act of 23 December 1992, the former Civil Defence and the Emergency Planning Agency are now incorporated in the Emergency Management Agency. This Act also established a new organisation, the National Rescue Preparedness Service, which takes over the functions of the former National Fire Service and the Civil Defence.

As seen in Part I, Section 6 "Radiation Protection" *supra*, the Emergency Management Agency has a duty to decide on the prescribed emergency safety measures to be taken when the population has been exposed to radiation as a result of a nuclear incident. Like the Board of Health, the Agency also has extensive duties with respect to the safe operation of nuclear installations, including the power to impose supplementary conditions on construction and operating permits (see Part I, Section 4 "Nuclear Installations" *supra*). The Agency is in charge of studying all questions related to nuclear safety and will establish collaboration with other national and international authorities competent in this field. It may also request the help of the Risø National Laboratory and other national and international institutions [Act No. 244 of 1976].

h) Nuclear Installations Inspectorate

In 1988, the Nuclear Installations Inspectorate, which had formerly operated as an independent institution under the National Environmental Protection Agency, was transferred to the Emergency Management Agency.

As its name implies, this Inspectorate is concerned with supervising the safe operation of nuclear installations and, as was seen in Part I, Section 4 "Nuclear Installations" *supra*, has been given corresponding powers. It shares this task with the Board of Health and the Emergency Management Agency, but the Inspectorate is more concerned with the technical aspects of safety [Act No. 244 of 1976].

2. Advisory Bodies

a) Energy Agency

The Danish Energy Agency was established as a directorate under the Ministry of Energy (now the Ministry for the Environment and Energy) by the Act of 1976 on Energy Policy Measures [No. 194 of 1976] to assist the Ministry and other public authorities. It surveys and evaluates energy production, supply, consumption and research activities in Denmark and abroad.

The Energy Agency retains, amongst other things, administrative powers with regard to administration of laws and regulations concerning energy, collection of energy data and international collaboration concerning energy.

The mandate of the Energy Agency is outlined in Notice No. 236 of 10 May 1976, as supplemented by Notice No. 20 of 17 May 1978, both issued by the Ministry of Trade and Industry whose responsibilities with respect to energy, as mentioned above, have been transferred to the Ministry for the Environment and Energy.

b) Council for Energy Planning and Research

The Council for Energy Planning and Research was set up under the 1976 Act on Energy Policy Measures [No. 194 of 1976] to advise the Minister for the Environment and Energy in the preparation of reports on energy policy.

The Council consists of a chairperson and eleven other members who are appointed by the Minister. It is provided that the Council shall be composed of four scientists competent in the field of energy and seven members nominated respectively by the Economic Board of the Danish Labour Movement, the Industrial Council, the Association of Danish Electricity Producers, the Joint Representation of the Oil Industry, the Association of Danish Gas Producers and the Danish Association for District Heating.

The Minister, who lays down the working procedure of the Council and decides upon the organisation of its secretariat, can assign to the Council representatives from other ministries concerned.

3. Public and Semi-Public Agencies

Risø National Laboratory

Risø National Laboratory (established by Act No. 1076 of 1995) conducts basic and applied scientific research to provide the Danish public with the potential for technological developments.

The research is directed towards areas that will contribute to the competitiveness of Danish industry, and to a reduction of environmental burdens in industry, energy and agriculture.

Risø Laboratory has a special responsibility for maintaining the necessary scientific knowledge base to advise the Danish authorities on nuclear matters.

This institution is under the auspices of the Ministry of Research and is directed by a board composed of up to ten members appointed by that Minister.

FINLAND

I. GENERAL REGULATORY REGIME

1. Introduction

Finland's nuclear activities are governed by three main legislative instruments, which are supplemented by various secondary instruments (decrees, ordinances, rules, etc.). The main Acts are:

- the Nuclear Energy Act 1987 [No. 990/87 as amended by Acts Nos. 797/89, 1420/94, 593/95, 1078/96, 1077/98, 635/99 and 870/99];

- the Radiation Protection Act 1991 [No. 592/91, as amended by Acts Nos. 1334/94, 594/95, 490/97 and 1142/98];

- the Nuclear Liability Act 1972 [No. 484/72, as amended by Acts Nos. 388/86, 820/89, 588/94, 588/94 and 89/99].

In 1987, the Nuclear Energy Act replaced the Atomic Energy Act, which dated from the 1950s. The stated purposes of the 1987 Act are to ensure the non-proliferation of nuclear weapons and the safety of both man and the environment [Section 1]. The Act establishes general principles governing the regulation of the use of nuclear energy, the establishment of a licensing procedure and nuclear waste management. The Act was amended in 1994 to take into account Finland's accession to the European Union and the Euratom Treaty. The amendment entered into force on 1 January 1995, by Decree No. 1589/94. Changes to the Finnish Nuclear Energy Decree of 1988 [No. 161/88] were also required as a result of Finland's entry into the European Union.

The Radiation Act, passed in 1991, replaced radiation protection legislation dating from 1957. It aims to protect human health from the adverse effects of radiation.

The Nuclear Liability Act of 1972 implements Finland's obligations as a Party to the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy and the 1963 Brussels Supplementary Convention as amended by the 1982 Protocols. The Act has been amended from time to time in line with Finland's changing obligations under international treaties.

These Acts and related legislation will be discussed in more detail under the various headings which follow.

There are currently four nuclear power reactors in Finland, two of which are owned by a company in which the state is the majority shareholder and the other two by a private enterprise. In addition, there is a research reactor run by a research centre.

2. Mining Regime

All mining activities in Finland are regulated by the Mining Act No. 503/65.

The Nuclear Energy Act [No. 990/87] provides that a mining or enrichment operation aimed at producing uranium or thorium is a "use of nuclear energy" for the purposes of the Act [Section 3]. Since the use of nuclear energy is prohibited without a licence [Section 8], any person wishing to engage in mining operations of this kind must obtain a licence to do so from the Council of State (the Finnish Cabinet of Ministers) [Section 16]. Under the Act as amended by the 1994 Act, this kind of licence may be granted to Finnish citizens, corporations or foundations as well as to natural persons, entities or authorities residing within the countries of the European Union.

There are currently no uranium or thorium ore mining or enrichment operations in Finland.

3. Radioactive Substances, Nuclear Fuel and Equipment

Both the Nuclear Energy Act [No. 990/87] and the Radiation Act [No. 592/91] are relevant to this topic. The Radiation Act regulates all activities which cause or may cause exposure to radiation. Any activity of this kind requires a licence under the Act if not specifically exempted from this requirement [Section 16]. Any "use" of nuclear energy, as defined by the Nuclear Energy Act, is exempted from most of the provisions of this Act [Section 3].

The Nuclear Energy Act prohibits any use of nuclear energy unless it is licensed under the Act [Section 8]. Among the activities defined by the Act as "uses of nuclear energy" are the possession, manufacture, production, transfer, handling, use and storage of nuclear materials [Section 2]. The Nuclear Energy Act [Section 3] and the Nuclear Energy Decree [No. 161/88, Section 1] define "nuclear materials" in the same terms as Article XX of the Statute of the International Atomic Energy Agency. Nuclear materials thus include uranium, thorium and plutonium, as well as any substance containing any such materials (including fresh and spent nuclear fuel).

The Nuclear Energy Act also defines as the "use" of nuclear energy and consequently as an activity requiring a licence, any possession or transfer of non-nuclear material, devices or equipment which are relevant to the proliferation of nuclear weapons. The Nuclear Energy Decree [No. 161/88, Chapter 3] defines a list of these materials, devices and equipment. This list is compatible with the Trigger List in the Annex to IAEA INFCIRC/254/Rev.2/Part 1.

Licences for the uses of nuclear energy described above are granted by the Ministry of Trade and Industry (*Kauppa-ja teollisuusministeriö* – KTM) or by the Finnish Radiation and Nuclear Safety Authority (*Säteilyturvakeskus* – STUK) [Nuclear Energy Act, Section 16]. With certain limited exceptions, the licence can be granted only to persons or entities residing within the European Union [Section 17]. The principal criteria for the granting of a licence include: adequate arrangements for the health and safety of the workforce to be involved in the activity and also for the protection of the public and the environment; adequate arrangements for the management of any nuclear waste produced; adequate arrangements to ensure that STUK has the possibility of monitoring the manufacture of fuel elements, including those manufactured abroad; and sufficient expertise and appropriate financial resources on the part of the applicant [Section 21]. The licence, if granted, is for a fixed term and may be made subject to conditions [Sections 24 and 25]. In certain circumstances the licence may be revoked [Section 26]. The Act establishes criminal offences, in particular for the unauthorised use of nuclear energy [Section 72]. The offences are punishable by fines and terms of

imprisonment of up to the maximum term provided in the Penal Code, with the exception of a life sentence.

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

The Nuclear Energy Act [No. 990/87] provides that the construction and operation of nuclear facilities is prohibited without a licence. The licence may only be granted to persons and entities residing in the European Union [Section 17]. Permission to construct a nuclear facility having a thermal power capacity of more than 50 megawatts requires the approval in principle from the highest level of the Finnish Government (the Council of State), which must base its decision on the requirement that the construction proposal be consistent with "the overall good of society" [Section 11]. If this approval is obtained, the Council of State's decision is then submitted to the Finnish Parliament which may either accept or reject (but may not modify) the Council's decision [Section 15].

Before the Council of State makes a decision on the merits, a lengthy and wide-ranging consultation procedure must be followed, which includes an assessment in accordance with the Act on Environmental Impact Assessment [No. 468/94]. In particular KTM must obtain a preliminary safety assessment on the proposed decision from Radiation and Nuclear Safety Authority (*Säteilyturvakeskus* – STUK), a statement from the Ministry of the Environment, and a statement from the municipal council responsible for the area proposed as a site for the facility. Statements must also be obtained from neighbouring municipal councils [Section 12]. In addition, the applicant for the licence must provide information to the public, in the form of a publication approved by KTM, concerning the safety and environmental aspects of the proposed facility. KTM is responsible for organising public hearings to enable residents and local authorities to make their opinions known [Section 13]. The substance of any submissions made by the public or by local authorities during this process, whether orally or in writing, must be transmitted by the Ministry to the Council of State [Section 13].

The Nuclear Energy Decree [No. 161/88] adds further requirements for consultation with numerous government agencies. KTM must obtain comments on the proposal from the Ministry of the Interior, the Ministry of Defence, the concerned State Provincial Office, Regional Council and Regional Environment Centre as well as the Advisory Committee on Nuclear Energy [Section 25]. In addition, KTM must submit to the Council of State a review which specifically addresses questions of nuclear waste management such as methods proposed, safety and environmental aspects, costs and suitability to Finnish conditions [Section 26].

Once all the information and comments required by the Nuclear Energy Act and the above-mentioned Decree have been collected and submitted to the Council of State, the Council may proceed to make its decision on the application. The Act provides that the Council must reject the proposal if the municipal council responsible for the proposed site opposes it. The Council itself can reject the application if it deems on the basis of STUK's preliminary safety assessment or otherwise that the installation cannot be established in a safe manner [Section 14, Nuclear Energy Act]. If neither negative opinion is forthcoming, the Council of State then proceeds to consider the issue from the perspective of the overall good of society, paying particular attention to the country's energy needs, the suitability of the intended site, the environmental impact of the facility and the methods proposed for management of the spent nuclear fuel and other nuclear waste [Section 14].

If the Council of State's decision is positive, it must then be submitted to the Parliament, which may either confirm or veto the decision [Section 15]. The applicant may not initiate any significant measures relating to the construction of the facility in anticipation of the Parliament's decision [Section 15]. Once Parliamentary approval is given, the grant of the construction licence is still contingent on a number of detailed criteria relating to public safety, workforce protection, environmental protection, town planning and building requirements, nuclear waste management and final decommissioning plans, technical expertise and adequate financial resources [Section 19]. If an applicant satisfies all these requirements, a construction licence for the proposed facility may then be granted by the Council of State [Section 16].

Once the construction of the facility is satisfactorily completed, a separate licence is needed for its operation. This licence is also granted by the Council of State [Section 16] after further examination of the criteria mentioned above (such as safety, environmental protection and waste management) [Section 20]. The commencement of operation of the facility depends not only on the granting of this licence by the Council of State, but also upon the approval of KTM and STUK. KTM must be satisfied that financial security requirements of the Act relating to waste management have been met, and STUK must be satisfied that the facility meets prescribed safety, physical protection, emergency planning and non-proliferation requirements, and that the operator has the prescribed financial guarantees to cover the possibility of nuclear damage caused by the facility [Section 20]. For further information on waste management requirements and financial guarantees for nuclear damage, see *infra* under Section 7 "Radioactive Waste Management" and Section 10 "Nuclear Third Party Liability" respectively.

Operating licences are granted for a fixed term [Section 24]. The licence is subject to conditions to ensure that the general principles on which the Nuclear Energy Act is based (for example safety, management of nuclear waste and implementation of Finland's international obligations) are reflected in practice [Section 25]. The licence's conditions may be changed during its period of validity by the Council of State [Section 25]. A licence may also be revoked altogether if the licensee seriously undermines any of the Act's basic principles by, for example, failing to comply with licence conditions or contravening certain key provisions of the Nuclear Liability Act [Section 26]. The licence may also be revoked if the licensee dies, loses legal capacity, becomes bankrupt or ceases to operate the facility for any other reason [Section 26].

The licence requirements of the Nuclear Energy Act are reinforced by provisions for criminal offences. The basic offence, namely the use of nuclear energy without the appropriate licence issued under the Act, is punishable by two years imprisonment or a fine [Section 72]. Other offences refer to the infringement of particular provisions of the Act, failure to observe licence conditions, failure to comply with safety, physical protection or emergency planning requirements, or interference with equipment installed by STUK to supervise and monitor nuclear power facilities as specified by the Act [Section 72].

The Act makes STUK the authority responsible for the supervision of nuclear energy activities and the enforcement of licensees' obligations [Section 63]. STUK is given powers of search and entry, access to records, power to take samples and install monitoring devices, power to require the operator to submit reports and the ability to give directions about the method of production of fuel or of the manufacture of equipment to be used in the nuclear activity in question. These powers are also extended to any international inspector carrying out functions under Finland's international agreements if the inspector is approved by the Finnish Government and accompanied by a representative from STUK [Section 63].

STUK can also direct the licensee to make changes to the physical structure of a nuclear facility and to operating practices and procedures [Sections 64 and 65]. Such instructions may be enforced by fines or by suspension or limitation of the operation in question [Sections 66 and 67].

A police authority may provide assistance in supervising compliance with the Act if requested to do so by either KTM or STUK [Section 68].

Finland is a Party to the 1994 Convention on Nuclear Safety which it accepted on 22 January 1996.

b) Emergency response

The Nuclear Energy Act [No. 990/87] states that a prerequisite for any use of nuclear energy is that there be sufficient emergency planning [Section 7]. "Emergency planning" is defined to mean, in relation to a nuclear facility, the measures needed to reduce nuclear damage at the facility or its precincts [Section 3]. Although emergency planning is an obligation imposed on the licensee by means of the application process and the licence conditions when granted, STUK is responsible for supervising and co-ordinating emergency planning measures [Section 55]. In order to enable it to carry out this and other functions, STUK is empowered to participate in the licensing process, impose and supervise licence conditions, issue and enforce regulations, provide expert advice and carry out research and development work [Section 55]. At the level of secondary legislation, the Council of State is empowered to issue general regulations about emergency planning. The General Rules for Contingency Plans at Nuclear Power Plants [No. 397/91] set out in detail the measures to be taken by operators to contain nuclear damage in the event of an incident.

Finland is a Party to both the 1986 Convention on Early Notification of a Nuclear Accident and the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, which were approved on 11 December 1986 and 27 November 1990 respectively.

5. Trade in Nuclear Materials and Equipment

The import and export of nuclear materials and certain non-nuclear materials as well as of certain devices or equipment are regarded as "uses" of nuclear energy and are, therefore, subject to the relevant provisions of the Nuclear Energy Act [No. 990/87]. Finland's import and export policies reflect the fact that Finland is a Member State of the European Union, a Party to the Treaty on the Non-Proliferation of Nuclear Weapons and that it has adopted the criteria set out in the Guidelines of the Nuclear Suppliers Group ("London Club").

A list of the non-nuclear materials, devices and equipment covered by the Nuclear Energy Act, has been established by the Nuclear Energy Decree [No. 161/88]. This list is compatible with the Trigger List in the Annex to IAEA INFCIRC/254/Rev.2/Part 1. The import and export of these items are prohibited without a preliminary licence under the Act [Section 8].

Licences may be granted to Finnish citizens or entities, to subjects residing within the European Union and also to entities or authorities outside that area [Section 17(1)]. In particular, a licence may be granted to a foreign entity to import or export nuclear material or waste that will simply be passing through Finland in transit to another destination [Section 17(2)]. A licence may also be granted to an international organisation or foreign authority carrying out supervisory and monitoring functions under an international treaty to which Finland is a Party [Section 17(3)].

The Nuclear Energy Decree sets out the procedure for obtaining an import or export licence. In most cases, licences are granted by STUK [Sections 53(a) and 54(a)]; however, if the licence covers import of sensitive nuclear items or export to a country which is not a member of the Nuclear Supplier Group, it is granted by KTM [Sections 53 and 54].

Following the entry of Finland into the European Union, transfers of nuclear industry goods used for peaceful purposes have been made easier within that area. An operator who has obtained a construction or operating licence for a nuclear facility, or who has some other operating licence mentioned in the Nuclear Energy Decree as amended, will now receive a Community Trade Licence for the import and export of nuclear goods pertaining to his business to and from other Member States. When such a Community Trade Licence has been obtained, the operator needs no other import or export licence from the Finnish authorities regarding shipments within the European Union [Section 50]. The Community Trade Licence does not, however, apply to imports or exports of sensitive nuclear items or nuclear waste.

In cases where KTM is responsible for granting a licence, it must obtain opinions of the Ministry of Foreign Affairs and of STUK before coming to a decision on an application [Nuclear Energy Act, Section 23; Decree, Section 54(c)]. The licence, when granted, must specify precisely what is to be imported or exported and, in the case of export, the country of destination and the recipient. Any conditions considered necessary may be attached to the licence [Sections 53(d) and 54(d)].

6. Radiation Protection

As mentioned earlier, the Radiation Act [No. 592/91] regulates all activities which cause or may cause exposure to radiation. The purpose of the Act is to protect human health from the adverse effects of radiation. The Act embodies the following principles as the basis for its regulatory control: justification of practices; the ALARA [as low as reasonably achievable] principle and individual dose limitation [Section 2]. The Act has different levels of licensing requirements (administered by STUK) and applies to activities involving exposure to ionising, non-ionising and natural radiation. In order to obtain a licence under the Act, the applicant must provide specific information to STUK about activities concerned. STUK must be satisfied that the equipment and protective shields used in the activities are of the required technical standard; that the personnel and work practices are of the correct standard; and that any radioactive waste is appropriately disposed of [Section 16]. The Act contains provisions for the monitoring and registration of individual radiation doses received by employees.

Any “use” of nuclear energy, as defined by the Nuclear Energy Act [No. 990/87], is exempted from the provisions of the Radiation Act, other than from the general principles of radiation protection and provisions concerning exposed workers [Section 3]. The Nuclear Energy Act deals with radiation in a general way, stating in the Chapter entitled “General Principles” that the use of nuclear energy must be safe and must not cause injury to people or damage to the environment or property [Section 6]. The ALARA principle is incorporated into every aspect of the Act’s licensing process and its regulation of nuclear activities. A later section of the Act makes it clear that the holder of a licence under the Act is responsible for the occupational health and safety of those employed in the nuclear facility [Section 59]. The section refers to employers’ obligations under the Work Safety Act [No. 229/58], the Radiation Act [No. 592/91], the Mining Act [No. 563/65] and any subordinate legislation that may be issued under the Nuclear Energy Act.

The Council of State is empowered to make general regulations dealing with the safety aspects of nuclear energy use [Section 81]. Under this authority, it has issued General Rules for the Safety of Nuclear Power Plants [No. 395/91]. These rules set radiation exposure limits for the general public and for workers in a variety of situations, specify design requirements to ensure safety and require certain monitoring and control equipment to be installed in every nuclear plant.

7. Radioactive Waste Management

Radioactive waste management is regulated by the Nuclear Energy Act [No. 990/87]. The Act allocates responsibility between waste producers and government authorities, incorporates waste management criteria into its licensing procedures and establishes the principles according to which the waste management system is to be financed. The provisions of the Act are supplemented by relevant parts of the Nuclear Energy Decree [No. 161/88].

The Act No. 990/87 establishes the principle that all nuclear waste which has been generated in Finland must be handled, stored and finally disposed of in Finland. Exceptions can be made for small amounts to be sent abroad for research purposes and for research reactor fuel [Section 6(a)]. The Act also provides that foreign nuclear waste cannot be handled, stored or finally disposed of in Finland [Section 6(b)]. Furthermore, as far as the dumping of radioactive waste at sea is concerned, Finland is a Party to both the 1974 Convention on the Protection of the Marine Environment of the Baltic Sea [the Helsinki Convention implemented in Finland by Act No. 11/80 and Decree Nos. 12/80, 68/80, 31/81, 17/84, 39/84, 65/58, 17/87] and the 1972 Convention of the Prevention of Marine Pollution by Dumping of Wastes and Other Matter [the London Convention, ratified on 3 May 1979 and implemented by Act No. 33/79 and Decrees Nos. 34/79 and 44/81].

The Nuclear Energy Act defines any facility which is used for handling or storage of nuclear waste as a nuclear facility. A nuclear waste repository is also a nuclear facility pursuant to the Act [Section 11]. The construction and operation of such facilities are subject to the approval and licensing requirements already discussed. In addition, the waste management aspect of any proposed nuclear facility is an issue at every stage of the approval and licensing procedure for that facility. The Nuclear Energy Act divides responsibility for state supervision of waste management planning and activity between KTM and STUK. In the first place however, it is the licensee who is responsible for the management of nuclear waste generated by the licensee's activities [Section 9]. KTM and STUK must ensure that the licensee fulfils this obligation and in order to do so, they may, after consulting the Ministry of the Environment, require the licensee to submit a nuclear waste management plan [Section 28]. KTM may order licensees to engage in joint waste management measures and may make an order as to the distribution of costs of any such joint measures [Section 29]. If KTM considers the licensee's measures to be unsatisfactory (because, for example, of a failure to meet an agreed timetable or to implement directions issued by the authorities), the state may assume ownership and responsibility for the waste [Section 31].

However, assuming that the licensee implements the agreed waste management measures and pays the required lump sum to the state [Section 32] and that STUK certifies that all the licensee's obligations with respect to the waste have been fulfilled [Section 33], ownership and control of the waste and all further responsibility for it is then transferred to the state [Section 34].

The Act contains detailed financial provisions for the cost of nuclear waste management [Sections 35-53]. The licensee is required to bear the costs incurred in implementing waste management obligations pursuant to the Act [Sections 9 and 35]. This is achieved by requiring the licensee to pay an annual fee into the State Nuclear Waste Fund (administered by KTM) and also to

give prescribed securities to the state as a precaution against insolvency [Section 36]. The basis on which the licensee's financial obligations are calculated, and the principles on which the state fund and the financial security system operate, are set out in Sections 37 to 53 of the Act. Important factors to be taken into account in the calculations are the amounts and types of nuclear waste currently produced and the anticipated costs of the management of those wastes. The aim of the State Nuclear Waste Fund and the securities system is to meet the total potential costs of Finland's nuclear waste management. Licensees may borrow from the Fund in order to finance their waste management activities.

The Nuclear Energy Decree [No. 161/88] contains provisions setting out in more detail the waste management obligations of licensees pursuant to the Nuclear Energy Act [Chapters 14-16, Nuclear Energy Decree]. Changes to the Decree necessitated by Finland's entry into the European Union are reflected in Decree No. 473/96 of 26 June 1996, which came into force on 1 July 1996. These changes were primarily required in order to take account of the Euratom Treaty and EU Council Directive 92/3/Euratom on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community.

In addition, the Nuclear Energy Act defines any possession, manufacture, production, transfer, handling, use and storage of nuclear waste as a "use" of nuclear energy [Section 2]. Consequently, these activities when pursued outside nuclear facilities require a licence under the Act.

8. Non-Proliferation and Physical Protection

Finland ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 5 February 1969 and the 1979 Convention on the Physical Protection of Nuclear Material on 22 September 1989. It also ratified the 1996 Comprehensive Nuclear-Test-Ban Treaty on 15 January 1999. As mentioned above, Finland also adheres to the NSG Guidelines for Nuclear Transfers.

As far as non-proliferation is concerned, the Nuclear Energy Act [No. 990/87] prohibits the importation, manufacture and possession of nuclear explosive devices [Section 4]. Finland is also a Party to the non-proliferation safeguards agreement between the IAEA, Euratom and the non-nuclear weapon Member States of Euratom. The Nuclear Energy Decree of 1988 was modified in 1996 Decree No. 473/96 to take into account Finland's entry into the European Union. As a result, it contains provisions concerning dual-use goods used by the non-military nuclear industry, which are listed in Non-proliferation: Council Regulation (EC) No. 3381/94 of 19 December 1994 setting up a European Union regime for the control of exports of dual-use goods, and in EU Council Decision 94/942/CFSP concerning the control of exports of dual-use goods.

In relation to physical protection, the Nuclear Energy Act states that "sufficient" physical protection arrangements are a prerequisite for the use of nuclear energy [Section 7]. At every stage of the licensing process the applicant must be able to satisfy STUK that these arrangements are in place [for example, Section 19(3) which relates to the granting of a licence to build a nuclear facility].

Under its power to make general regulations concerning physical protection [Section 81], the Council of State has issued the General Rules for Security Arrangements at Nuclear Power Plants [No. 397/91]. These outline the security measures to be taken by operators of nuclear facilities and the action to be taken when a threat to security arises.

STUK is the supervisory authority responsible for non-proliferation safeguards and physical protection [Nuclear Energy Act, Section 55]. STUK maintains the State System of Accounting for and Control of Nuclear Materials in Finland and monitors and regulates the non-proliferation and physical protection aspects of international trade in, transport, storage and use of nuclear material.

9. Transport

The Act on Transportation of Dangerous Substances [No. 719/94] regulates all modes of transportation of radioactive substances. It applies both to international transportation and to domestic transportation. Pursuant to this Act, the Ministry of Transport and Communications has issued separate regulations for each mode of transportation of dangerous substances within national boundaries. For international transportation, the regulations issued by the relevant international organisations pursuant to the following international agreements to which Finland is a Party are applied:

- European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR);
- Convention on International Carriage by Railroad (COTIF);
- International Maritime Dangerous Goods Code (IMDG);
- Convention on International Civil Aviation.

The Nuclear Energy Act [No. 990/87] includes the transport of nuclear materials and nuclear waste as a "use" of nuclear energy [Sections 2 and 3] and it is thus subject to the Act's licensing system. A licence for transport of nuclear material or nuclear waste within Finland or in transit through Finland can also be granted to an entity or authority outside the European Union.

According to the Nuclear Energy Decree [No. 161/88], the licence is determined by STUK [Section 56]. The application must contain specified information as to the method of transport proposed, the physical protection measures to be taken and the emergency plans that have been made [Sections 57 and 58]. The licence, if granted, must specify the type and quantity of material that is covered by the licence, any limitations to the route to be taken, the period of validity and any other conditions considered necessary [Section 60].

10. Nuclear Third Party Liability

Finland is a Party to the following instruments on nuclear third party liability:

- 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy (to which it acceded on 16 June 1972) and the 1963 Brussels Convention Supplementary to the Paris Convention (to which it acceded on 14 January 1977), as amended by the two 1982 Protocols;
- 1971 Convention on Civil Liability in the Field of Maritime Carriage of Nuclear Material (accepted on 6 June 1991);

- 1988 Joint Protocol relating to the Application of the Paris Convention and the Vienna Convention (ratified on 3 October 1994).

The national legislation which implements Finland's obligations under these treaties is the Nuclear Liability Act [No. 484/72 as amended by Acts Nos. 388/86, 820/89 and 588/94]. This latter Act was brought into force on 3 January 1995 by Decree No. 1040/94. The Act provides that in the event of nuclear damage, the Finnish operator's liability is strict, *i.e.* compensation is payable whether or not there is any fault on the part of the operator [Section 12]. "Nuclear damage" means:

- any damage caused by the radioactive properties of nuclear fuel or radioactive products or by a combination of radioactive properties with other hazardous properties; or

- any damage caused by ionising radiation emitted from any source of radiation inside a nuclear installation other than nuclear fuel or radioactive products [Section 1].

As a general rule, damage caused by a nuclear incident in Finland but suffered in a state which is not party to the Paris Convention ("a non-Contracting State") is covered by the Act, but damage caused by an incident occurring outside Finland and suffered in a non-Contracting State is not [Section 4]. However, the government (the Council of State) has the power to decide that, on the basis of reciprocity, a non-Contracting State is to be treated as a Contracting State to the Paris Convention for the purposes of the Act [Section 5].

The maximum amount of the operator's liability was raised from Special Drawing Rights (SDRs) 150 to 175 million of the International Monetary Fund by Decree No. 785 of 30 October 1998, which entered into force on 1 January 1999. The government may, taking into account the size or character of a particular nuclear installation, fix a lower amount for that installation of not less than SDRs 5 million [Section 17]. The operator of a nuclear facility (other than the state) must take out and maintain liability insurance to the extent necessary to cover his liability. Such insurance must be approved by the Insurance Supervision Authority [Section 23]. The government has the power to exempt an operator from this requirement if the operator is able to provide alternative financial securities to cover his potential liability [Section 28].

The Act contains detailed rules as to liability arising from a nuclear incident that occurs in the course of transport of nuclear substances. The provisions cover numerous situations and specify in each case whether liability rests with the consignor, the consignee or the carrier. In some situations liability may be apportioned [Sections 7 and 11]. The amount of liability for nuclear damage arising in the course of transport of nuclear substances, other than damage to the means of transport, must be at least SDRs 5 million [Section 18]. On 5 May 1994, the Council of State issued a Decision [No. 333/94] on the maximum amount of liability for nuclear damage caused by a nuclear incident that has occurred during the transport of non-irradiated uranium which has been enriched to at most 20% in the isotope ^{235}U. This amount is fixed at SDRs 13 million.

A victim of nuclear damage who wishes to claim compensation under the Act must do so within ten years of the nuclear incident and within three years from the date on which he or she knew, or ought reasonably to have known, that he or she was entitled to compensation [Section 22].

A person who is entitled to compensation but is unable to recover it from the operator's insurer may be compensated instead by the state [Section 29]. Similarly, a person who is no longer entitled to compensation due to the Act's time limits on bringing an action may be compensated by the state under certain circumstances [Section 33].

The Act also provides for supplementary payments to be made from public funds if the amount of the operator's liability proves to be too low to meet the claims of those entitled to compensation. In such a case the total amount of compensation available in respect of any nuclear incident is not to exceed SDRs 300 million [Section 32].

Finnish courts have jurisdiction to hear a compensation claim under the Act if:

- the nuclear incident occurred wholly or partly in Finland; or
- the relevant installation is situated in Finland and either the nuclear incident has occurred wholly outside the territory of any Contracting State to the Paris Convention or the location of the incident cannot be determined [Section 37].

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities

a) Ministry of Trade and Industry (KTM)

The Nuclear Energy Act [No. 990/87] provides that the Ministry of Trade and Industry (*Kauppa-ja teollisuusministeriö* – KTM) has overall responsibility for the use of nuclear energy in Finland [Section 54]. It is also responsible for co-ordinating Finland's participation in the activities of international bodies such as the International Atomic Energy Agency and the OECD Nuclear Energy Agency.

The Ministry plays a central role in the licensing system established under the Nuclear Energy Act. Even where it is for the Council of State to make a decision on the merits on a new power reactor, the Ministry is responsible for co-ordinating and supervising the lengthy and complex application procedure which involves numerous other ministries, national and local government authorities and public hearings.

The Ministry also supervises the operation of Finland's statutory provisions on waste management, and in particular has responsibility for administering the State Nuclear Waste Management Fund and for assessing and receiving the financial securities required from nuclear operators under the Nuclear Energy Act.

A prosecution for an offence under the Nuclear Energy Act can be initiated only if the prosecutor has received a statement on the matter from the Ministry.

b) Ministry of Social Affairs and Health

The Ministry of Social Affairs and Health has administrative and financial responsibility for the Radiation and Nuclear Safety Authority.

c) Ministry of the Interior

The responsibilities of the Ministry of the Interior include that of protection of the general public in the event of an emergency, including a nuclear incident. The Nuclear Energy Act requires that the Ministry be consulted at various stages of the licensing process.

d) Ministry of the Environment

The Nuclear Energy Act provides that the Ministry of the Environment must be consulted on various aspects of the regulation of activities involving nuclear energy and radiation hazards. Prominent amongst these aspects are issues relating to emergency planning and nuclear waste management.

e) Ministry of Foreign Affairs

Licensing authorities must seek comments from the Ministry of Foreign Affairs in relation to certain applications to export nuclear material.

2. Advisory Bodies

a) Advisory Committee on Nuclear Energy

The Nuclear Energy Act [No. 990/87] provides for the establishment of a permanent consultative committee on nuclear energy issues. The committee is appointed by the Council of State and works in conjunction with the Ministry of Trade and Industry.

b) Advisory Committee on Nuclear Safety

The Nuclear Energy Act [No. 990/87] also provides for the establishment of a permanent consultative committee on nuclear safety issues. The committee is appointed by the Council of State and works in conjunction with the Radiation and Nuclear Safety Authority.

3. Public and Semi-Public Agencies

a) Finnish Radiation and Nuclear Safety Authority (STUK)

i) Legal status

The Finnish Radiation and Nuclear Safety Authority (*Säteilyturvakeskus* – STUK) was established by Act No. 1069/83. The Act sets out the general functions of the Authority, while more

detailed provisions as to its structure and operations are contained in the Ordinance on the Finnish Radiation and Nuclear Safety Authority [No. 618/97].

The Authority is an independent body carrying out statutory functions; however it is linked at an administrative level with the Ministry of Social Affairs and Health.

ii) Responsibilities

The Authority's principal functions are to prevent harmful effects of radiation, to regulate the safe use of nuclear energy and radiation, to carry out research on radiation protection and to provide training and information. These functions are listed in the 1983 Act establishing the Authority (see above). Other legislation confers specific powers and duties on the Authority. The Nuclear Energy Act [No. 990/87], for example, gives the Authority overall responsibility for the regulation of nuclear safety, physical protection, safeguards and emergency planning in the nuclear context. In order to carry out these functions, the Authority is required by various provisions of the Act to participate in the licensing process, impose licence conditions and enforce their compliance, establish and ensure compliance with rules and regulations, provide expert advice to other authorities and carry out research and development work. All other state authorities are obliged to consult the Authority if a nuclear safety issue arises. Similarly, the Authority is the body responsible for administering the licensing system established by the Radiation Protection Act [No. 592/91] and for monitoring and enforcing the other requirements of that Act.

iii) Structure

The Authority is headed by a director-general. Its principal divisions are the Nuclear Safety Department, the Nuclear Material Department, the Research Department, the Department of Radiation Protection and the Administration Department. The Board of Governors carries out the administrative supervision of the Authority.

The Authority reports to the Ministry of Social Affairs and Health and to the Ministry of Trade and Industry.

iv) Financing

The Authority is funded from the annual state budget. The nuclear power companies bear the cost of nuclear regulation. The Authority is entitled to set the amount of the fees, based on the principles laid down in Decision 1285/93 by the Ministry of Trade and Industry.

b) State Nuclear Waste Management Fund

The State Nuclear Waste Management Fund (*Valtion ydinjätehuoltorahaston*) was established under the Nuclear Energy Act [No. 990/87] in order to guarantee the financing of the future costs of nuclear waste management operations. It is managed by a board of directors appointed by the Council of State for a term of three years. The Fund is linked administratively with the Ministry of Trade and Industry.

FRANCE

I. GENERAL REGULATORY REGIME

1. General Legislation

Nuclear legislation in France does not derive from any one general framework Act. It has developed in successive stages in line with technological advances and growth in the atomic energy field.

Many of the enactments governing nuclear activities in France are, therefore, to be found in the general legislation such as the environmental protection legislation, the Act on Water, the Act on Air and the Rational Use of Energy, the Act on the Control of Atmospheric Pollution and Odours, the Public Health Code and the Labour Code.

Nevertheless, Parliament has adopted a number of specific nuclear acts. Examples include Act No. 68-943 of 30 October 1968, as amended, laying down special rules as to third party liability in the field of nuclear energy (different from the ordinary French law on third party liability), Act No. 52-844 of 19 July 1952, now embodied in the Public Health Code specifying licensing requirements for the use of radioelements, Act No. 80-572 of 25 July 1980, as amended, on the protection and control of nuclear materials and Act No. 91-1381 concerning research on radioactive waste management.

Although French nuclear law is characterised by its variety of sources, as in other countries where nuclear energy has developed, the original features of this legislation derive chiefly from international recommendations or regulations. For example, radiation protection standards are derived from the Recommendations of the International Commission on Radiological Protection (ICRP) and directives issued by the European Union. Likewise, the French Act of 1968 on the liability of nuclear operators is directly derived from the Paris Convention of 29 July 1960.

French nuclear legislation began to develop from the time the Atomic Energy Commission (*Commissariat à l'énergie atomique* – CEA), a public establishment set up by the state in 1945 [Ordinance No. 45-2563 of 18 October 1945, as amended], which formerly reported directly to the Prime Minister, no longer held a monopoly for nuclear activities. This corresponded with the period when nuclear energy applications were entering the industrialisation stage, thus requiring the involvement of other electricity-generating and industrial fuel cycle operators. This development had several landmarks: in 1963, a system for licensing and controlling major nuclear installations was introduced, making central government responsible for decisions taken to ensure the safety of the population and workers. Prior to this, procedures concerning the licensing and control of industrial activities had been dealt with by the Prefect for each *département*. In 1973, this system was expanded to cover the development of the nuclear power programme, and the role of the state authorities was clearly defined at that time. Finally, Decree No. 66-450 of 20 June 1966, as amended, implemented Euratom Directives into French radiation protection legislation.

In the course of the 1980s, the enactments setting up the CEA were amended so as to strengthen its interministerial status and to back up the Atomic Energy Committee, which acts as a select interministerial committee on nuclear energy matters, by a tripartite Board of Administration including staff representatives.

The CEA is now answerable to the Minister for Economy, Finance and Industry and to the Minister for National Education, Research and Technology [Decrees No. 97-707 of 11 June 1997 concerning the duties of the Minister for National Education, Research and Technology and No. 97-710 of 11 June 1997 concerning the duties of the Minister for Economy, Finance and Industry].

The main task of the CEA was laid down in September 1992 by the state authorities: to concentrate on developing the control of the atom for purposes of energy, health, defence and industry, while remaining attentive to the requests made by its partners in industry and research.

2. Mining Regime

French nuclear mining legislation is governed by the Mining Code and its implementing legislation. The Code contains few specific provisions on nuclear substances [Decree No. 56-838 of 16 August 1956 laying down the Mining Code, as amended by Act No. 70-1 of 2 January 1970, partially repealed, Act No. 77-620 of 16 June 1977, as amended, and Act No. 99-245 of 30 March 1999]. Here, as with other substances, the French State does not hold a monopoly for prospecting and mining.

Decree No. 95-427 of 19 April 1995, as amended, on mining concessions contains all the rules relating to the issue, amendment and relinquishing of mining concessions, while underlying rules concerning prospecting continue to be incorporated – without modification – into the Mining Code. A special procedure has been laid down for the issue and control of mining concessions for substances of use in nuclear energy, whereby the Atomic Energy Committee must give its opinion before the application is sent to the General Mining Board *(Conseil général des mines)*. After a procedure involving a public inquiry, the decision is taken by the Minister responsible for mining.

Act No. 93-3 of 4 January 1993 concerning quarries made general amendments to the Mining Code and to Act No. 76-663 of 19 July 1976, as amended, relating to installations classified for environmental protection purposes. It specifies that the start-up of installations (defined by Decree of the Council of State), presenting a significant risk of pollution or accident, or of quarries and waste storage facilities, whether after an initial licence or after a licence for a change of operator, is subject to the provision of financial guarantees [Act No. 93-3, Section 4(2)]. A Departmental Quarries Commission is set up in each *Département* [Section 16(2)]. This Commission studies applications for licence to operate quarries, and issues a reasoned opinion thereon.

3. Radioactive Substances and Nuclear Equipment

Neither natural nor artificial radioelements are dealt with in one single instrument. They are governed by different pieces of legislation, some of which are grouped under the Public Health Code depending on the activities for which they are used.

For example, radioelements are:

- included in Table A on toxic products in the regulations on the import, trade, possession and use of poisonous substances [Decree of 9 November 1937, as amended];

- covered, as radioactive materials [Class VII], by the general regulations concerning the carriage of dangerous substances [Order of 15 April 1945, partially repealed];

- covered by Act No. 76-663 of 19 July 1976 on Installations Classified for Environmental Protection Purposes, which applies to premises where they are handled;

- referred to in the mining regulations of 1959 [Decree No. 59-285 of 27 January 1959, as amended] and in Act No. 61-842 of 2 August 1961, as amended, on the Control of Atmospheric Pollution and Odours;

- subject to Decree No. 66-450 of 20 June 1966, as amended, relating to protection against ionising radiation and to other radiation protection legislation.

The Public Health Code lays down specific rules on natural radioelements [Section L. 44(1) to (3)], although these have never come into force since no legislation has been adopted in order to implement Section 44(1).

Under Sections L.636 to L.640 of the Public Health Code, only the CEA or persons specially authorised may prepare, import, export, or use artificial radioelements, in any form, after obtaining the opinion of the Interministerial Commission for Artificial Radioelements (*Commission inter-ministérielle des radioéléments artificiels* – CIREA). Permission is given by either the Minister for Health or the Chairperson of the CIREA, depending on the proposed use to be made of the radioelements. If necessary, special conditions of use are laid down.

Decree No. 86-80 of 13 January 1986, as amended, on artificial radioelements, amending the Health Code takes into account the experience gained by CIREA and the evolution of regulations, particularly in the biomedical field. It lists the operations subject to licensing, namely the possession with a view to distribution or transfer, marketing or use, of artificial radioelements. It specifies that licences are granted for a maximum period of five years. Moreover, any loss or theft of radioelements must be notified to the prefect of the *département* concerned.

As for the Order of 28 April 1989, it defines the categories of products containing radioelements with a low specific activity or limited radiotoxicity which are exonerated from the licensing regime laid down by the Public Health Code for artificial radioelements for non-medical uses or not relating to human biology.

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

The basic instruments currently in force were adopted pursuant to Act No. 61-482 of 2 August 1961 on the Control of Atmospheric Pollution and Odours, which expressly provides that decrees will regulate the establishment, operation and supervision of nuclear installations [Section 8].

France approved the 1994 Convention on Nuclear Safety on 13 September 1999.

Section 2 of Act No. 95-101 of 2 February 1995 on Strengthening Environmental Protection, as amended, established a Commission for public discussion. This Commission itself is not the medium through which the discussions are organised, but its opinion is sought on the opportuneness of holding such discussions. Decree No. 96-388 of 10 May 1996, relating to consultations with the public and with those involved in decision-making, defines the operation of this Commission and sets out the conditions and terms for public discussion. The result of these texts is that, with regard to nuclear matters, a public discussion may be organised in the event of the construction of a major nuclear installation on a new site, if this installation will produce electricity or if it constitutes an investment of more than French francs (FRF) 2 billion.

Nuclear installations are divided into three categories on the basis of technical criteria: major nuclear installations (INB), major nuclear installations classified as secret (INBS) and the other nuclear installations which are classified for environmental protection purposes (ICPE).

i) Major nuclear installations (INB)

Implementing the Act of 2 August 1961, Decree No. 63-1228 of 11 December 1963 on nuclear installations (as amended in 1973, 1985, 1990 and 1993) lays down the criteria governing major nuclear installations (*installations nucléaires de base* – INB).

Major nuclear installations include:

- nuclear reactors, except for those forming part of a means of transport;
- particle accelerators (whose characteristics are defined by order) [Order of 27 April 1982];
- plants used for preparing, manufacturing or converting radioactive substances, and in particular for manufacturing nuclear fuels, separating isotopes, reprocessing spent fuel or processing waste (whose characteristics are defined by order) [Order of 11 March 1996];
- facilities for storing, stockpiling or using radioactive substances, including waste (whose characteristics are defined by order) [Order of 11 March 1996].

The Order of 11 March 1996 takes into account the regrouping of radioelements which resulted from Decree No. 88-521 of 18 April 1988 on the general principles for protection against ionising radiation. In substance, the new thresholds are the same as the old. The minimum activity thresholds of major nuclear installations and the maximum activity thresholds of installations classified for environmental protection purposes have been fixed so that depending on the activity or nature of the substances used, one or other of the two administrative systems is applicable.

Under the 1963 Decree, as amended, a licensing decree based on a report by the Minister for Industry is required for the construction of major nuclear installations. This decree is issued following an inquiry procedure at central and local government levels.

Licensing applications are sent to the Directorate for the Safety of Nuclear Installations (*Direction de la sûreté des installations nucléaires* – DSIN) – answerable to the Minister for Industry and the Minister for Spatial Planning and the Environment – which conducts the inquiry. The DSIN informs the ministers concerned and submits the preliminary safety report supplied by the operator to the appropriate standing group of safety experts, which is assisted by the Institute for Protection and Nuclear Safety (*Institut de protection et de sûreté nucléaire* – IPSN).

At the same time, the Prefect concerned opens the public inquiry into the application, except where the installation has already been the subject of an inquiry prior to a declaration that the installation is in the public interest, and it has not undergone any changes.

The public inquiry opens as soon as the application is filed, and is widely publicised with organised discussion of opposing viewpoints, principally on the impact study. In fact, important major nuclear installations, such as *Électricité de France* (EDF) power plants, are subject to the declaration of public interest procedure, which is carried out by means of a public interest inquiry which follows the same rules as public inquiries. This procedure leads to a decree declaring the installation to be of public interest; however this decree does not exempt the future operator from compliance with the licensing procedure for construction of the nuclear installation by decree.

In all cases, the procedure laid down in Act No. 83-630 of 12 July 1983, as amended, on the Democratisation of Public Inquiries and Protection of the Environment must be followed. This Act provides for a public inquiry procedure for projects likely to affect the environment (inquiry to last at least a month, appointment of an inquiry commissioner by the Chairperson of the Administrative Tribunal, etc.). A Circular of 27 September 1985 defines the workings of the various decrees adopted in implementation of the 1983 Act (not all of which relate to the nuclear field):

- Decree No. 85-449 of 23 April 1985, as amended, provides that the procedure applies to major nuclear installations governed by Decree No. 63-1128 of 11 December 1963, and defines the thresholds and criteria involved. The classification of the major nuclear installations contained in the Annex of the Decree of 23 April 1985 was modified by Decree No. 96-198 of 11 March 1996 to bring it into line with the revised classification for the installations classified for the protection of the environment.

- Two other decrees deal with amendments to the provisions adopted in implementation of the Mining Code [Decree No. 85-448], and the conditions for safeguarding national defence secrets [Decree No. 85-693] respectively.

The purpose of these Decrees is to ensure that the provisions relating to public inquiries are incorporated within the existing procedures.

The Circular of 27 September 1985 also defines the scope of the Act of 12 July 1983, together with certain arrangements for the holding of the inquiry procedure.

Once the standing group has given its opinion, the results of the inquiry have been received and the ministers consulted have submitted their comments, the DSIN prepares a draft licensing decree and sends it for opinion to the Interministerial Commission for Nuclear Installations and to the Minister for Health for approval before submitting it to the Prime Minister for signature [Decree No. 63-1228 of 11 December 1963]. If approval is not given by the Minister for Health within three months, the decree may be adopted in the Council of Ministers.

The decree authorising construction fixes the perimeter of the installation, the conditions imposed on the operator and details of the commissioning procedure. Under the Ministerial Instruction of 27 March 1973, the start-up of a major nuclear installation is subject to approval by the Ministers for Industry and Research of the final safety report and the general operating rules.

The amendments to the 1963 Decree effected by Decree No. 90-78 of 19 January 1990 relate to the licensing procedure and are designed to harmonise the 1963 Decree with Act No. 87-565 of 22 July 1987, as amended, on the Organisation of Public Safety Measures, Forestry Protection against Fire and the Prevention of Major Risks. It provides that henceforth, licence application must also be

forwarded to the Minister for the Environment accompanied by a document describing, on the basis of the preliminary safety report, the measures necessary to address the particular risks which the installation presents and limit the consequences of any possible accident. As far as major nuclear installations are concerned, this document constitutes a risk analysis within the meaning of the Act of 1987. Licence applications must also specify the measures to be applied for dismantling the installation.

Decree No. 93-816 of 12 May 1993 amends the 1963 Decree as regards the licensing procedure for nuclear installations. The public inquiry procedure may now be extended by a further month (*i.e.* a total of three months maximum) by decree made following a report by the Ministers responsible for energy and for major technological risks.

Major nuclear installations are inspected by specialised nuclear energy inspectors who report to the Minister for Industry [Decree No. 63-1128 of 11 December 1963, as amended]. Safety is monitored by the DSIN, with the technical back-up of the Institute for Protection and Nuclear Safety (*Institut de protection et de sûreté nucléaire* – IPSN). The Board for Protection against Ionising Radiation (*Office de protection contre les rayonnements ionisants* – OPRI), created by Decree No. 94-604 of 19 July 1994 and successor to the Central Service for Protection against Ionising Radiation (*Service central de protection contre les rayonnements ionisants* – SCPRI), is the expert body responsible for ensuring protection of the public in that field. Its officials monitor discharge of radioactive effluents.

The Order and Circular of 10 August 1984 concern the design quality, construction and operation of major nuclear installations. Operators must ensure that the quality of the structures, equipment and operating conditions are commensurate with the importance of their functions from the viewpoint of the safety of the installation concerned [Order of 10 August 1984, Sections 1 and 2]. They must also exercise control over all suppliers of equipment and services. The Order prescribes the general principles to be applied for organising quality control, while the purpose of the Circular is to explain further the provisions of the Order.

These provisions were recently completed by the adoption on 31 December 1999 of an Order establishing the general technical regulations designed to warn against and limit any inconveniences or external risks resulting from the operation of major nuclear installations.

This Order was adopted in implementation of Section 10 bis of the Decree of 11 December 1963 on nuclear installations, which provides that "the general technical regulations governing the safety of major nuclear installations shall be adopted by order of the Ministry for Industrial and Scientific Development". It establishes the general technical regulations designed to warn against and limit any inconveniences and risks in relation to the general condition of the neighbourhood, public health, safety or hygiene, agriculture, protection of nature and the environment, the conservation of sites and monuments, which may result from the operation of major nuclear installations (INB) and major nuclear installations classified as secret (INBS).

This Order does not cover installations classified for environmental protection purposes situated within the perimeter of major nuclear installations; for such installations, the requirements established pursuant to Sections 7, 10 or 10(1) of the Act of 10 July 1976 apply.

The main provisions of this Order relate to the following areas:

- noises and vibrations;
- prevention of atmospheric pollution;

- prevention of water pollution;
- management of waste;
- prevention of other risks, in particular fire and nuclear risk.

The Order establishes transitional provisions for existing installations, to which the provisions of this text will apply two years after its publication.

ii) Major nuclear installations classified as secret (INBS)

Major nuclear installations classified as secret (*installations nucléaires de base classées secrètes* – INBS) by decision of the Prime Minister, upon proposal of the Minister for Defence and the Minister for Industry, are not subject to the provisions of the 1963 Decree, as amended.

They are regulated by Decree No. 99-873 of 11 October 1999 on major nuclear installations classified as secret. Based in particular on the Ordinance of 7 January 1959 on the general organisation of the defence, as amended, and on Section 8 of the Act of 2 August 1961 on the Control of Atmospheric Pollution and Odours, this Decree applies to installations under the responsibility of the Ministry for Industry and the Ministry for Defence.

Before the adoption of this Decree, although these installations complied in principle with the same technical rules and standards as the major civil nuclear installations, they were only subject to supervision and monitoring in the context of internal administrative procedures; which involved the High Commissioner for Atomic Energy for installations under the responsibility of the Minister for Industry, and both the High Commissioner and the services of the Ministry for Defence for major military nuclear installations classified as secret.

Technical criteria for the definition of major nuclear installations classified as secret are those used to define major civil nuclear installations [Decree of 11 December 1963, Section 2]. A major nuclear installation is classified as secret when special protection against nuclear proliferation, malicious actions or disclosure of information is justified.

The Decree extends and confirms the central role of the High Commissioner for Atomic Energy in respect of its own powers as well as those delegated from ministers concerned; major nuclear installations classified as secret now come under the jurisdiction of the Minister for Industry or the Minister for Defence. The High Commissioner is thus the nuclear safety authority for all major nuclear installations classified as secret.

Major nuclear installations classified as secret are subject to a regime of licensing, control and inspection, widely based on the Decree of 11 December 1963 (with the exception of measures related to information of the public). This regime is primarily implemented by the High Commissioner for Atomic Energy and under his authority. It should be noted that the supervision of discharge of effluents and the management of waste is carried out without prejudice to the supervision exercised by the bodies competent in the field of ionising radiation protection (namely OPRI).

iii) Non-major nuclear installations (ICPE)

Nuclear installations other than major ones are subject to the general regime for installations classified for environmental protection purposes (*installations classées pour la protection de*

l'environnement – ICPE) as established by Act No. 76-663 of 19 July 1976, which provides that a notification or licence is required for their construction, depending on the scale of the potential pollution or risk involved. These installations are under the jurisdiction of the Minister for the Environment.

Licences are issued by the Prefect following a public inquiry and consultation of the local government bodies concerned. Where hazards are likely to affect several *départements* or regions, the construction licence is granted by the Minister for the Environment, if necessary after obtaining the opinion of the Higher Council for Classified Installations (*Conseil supérieur des installations classées*).

Act No. 85-661 of 3 July 1985 both amends and supplements Act No. 76-663 of 19 July 1976 on Installations Classified for Environmental Protection Purposes. Its provisions increase the penalties prescribed in cases where classified installations are operated under illegal conditions.

Decree No. 77-1133 of 21 September 1977, which implemented the above-mentioned Act of 19 July 1976, was modified on several occasions. The last modification, introduced by Decree No. 96-18 of 5 January 1996, takes into account certain provisions of Act No. 92-3 of 3 January 1992 on Water, as amended, and of the Act of 2 February 1995 relating to Strengthening Environmental Protection. The 1977 Decree applies to all installations subject to the 1976 Act, but does not apply to installations belonging to government departments or agencies. Decree No. 86-1289 of 19 December 1986 amended the provisions governing installations subject to licensing, adding specifications as to the procedure; no changes were made, on the other hand, in respect of installations subject to notification.

Generally speaking, nuclear installations also require planning permission; for facilities intended for the production, transfer, distribution or storage of energy, including those using nuclear materials, planning permission is issued by the state [Town Planning Code/Act of 7 January 1983, as amended], unlike the situation under the ordinary law, when this task is given to the local mayor.

In 1994, a the International Nuclear Event Scale, used by the International Atomic Energy Agency (IAEA) to measure the severity of nuclear incidents and accidents, was adopted. This scale ranges from 1 to 7, in the same manner as that used to measure the severity of earthquakes: the more serious the accident, the higher the figure. It is intended to facilitate agreement and understanding both within the nuclear industry and for the general public.

Decree No. 96-197 of 11 March 1996 modifies headings 385 bis to six, and in doing so modifies the categorisation of installations classified for the purposes of the protection of the environment in relation to radioactive substances. This revision aims to make the headings of categories classifying installations for the protection of the environment more consistent with those of the radiation protection regulations. It provides, notably, that the classification of radionuclides by reference to their radiotoxicity will now result in there being four groups, rather than three as envisaged previously. In the same way, the classification of nuclear installations was modified by Decree No. 96-198 of 11 March 1996.

b) Emergency response

Act No. 87-565 of 22 July 1987 on the Organisation of Public Safety Measures, Forestry Protection against Fire and the Prevention of Major Risks, clarifies the previous system for organising assistance and emergency response, and introduces a new right to information about major risks. The Act thus deals with the conditions for preparing preventive action and for implementing necessary

measures in case of major risks or accidents. The preparation and organisation of assistance are determined within the framework of ORSEC and emergency plans.

Nuclear-related risks are included amongst technological risks. The Act provides that the public has a right to be informed about the risks to which they are exposed and about the preventive measures concerning them. Operators for whose installations a special action plan (*plan particulier d'intervention* – PPI) has been drawn up (see below), must help in providing the public with general information about measures taken in the vicinity of such installations. The Minister for the Interior draws up preventive measures and co-ordinates the assistance provided by the state, regional authorities and public bodies for France as a whole [Section 6].

Two Decrees have been adopted in implementation of the Act of 22 July 1987:

- Decree No. 88-622 of 6 May 1988, as amended, on emergency plans: this Decree contains provisions concerning emergency plans, including the category entitled "special action plans" (PPIs). Emergency plans are prepared by Prefects in liaison with the competent authorities, services and agencies, and adopted by them [Section 1]. Each emergency plan details the risks in relation to which it has been drawn up, specifies the intervention procedures and defines the tasks of government services, public agencies, regional authorities, etc. [Section 2]. The PPI includes a description of the installation concerned, a list of the communes on whose territory it applies, the measures for protecting and informing the public and diagrams for evacuation of local populations, including information on alternative accommodation [Section 7]. Also listed are the emergency measures for neighbouring populations to be taken by the operator before action is taken by or on behalf of the police authorities. Once a PPI has been finalised [Section 8], it is immediately brought to the attention of the mayors concerned and of the operator. A notice is placed in local or regional newspapers indicating the area to which it applies and places where it may be consulted [Section 9].

- Decree No. 90-918 of 11 October 1990, as amended, on the exercise of the right to information on major risks. This Decree specifies the content and type of information to which persons likely to be exposed to major risks must have access, in accordance with the Act of 22 July 1987. Its provisions apply in particular to communes for which a PPI has been prepared [Section 2]. The mayor prepares an information document containing a list of the preventive measures he has taken in respect of the risk on the territory of the commune concerned. The public is informed of the existence of this report by posters put up in the town hall, specifying that it may be freely consulted on the spot [Sections 3 and 6].

At the international level, France approved the 1986 Conventions on Early Notification of a Nuclear Accident and on Assistance in the Case of a Nuclear Accident or Radiological Emergency on 6 March 1989.

5. Trade in Nuclear Materials and Equipment

a) General provisions

Trade in nuclear techniques, materials and equipment is a highly sensitive area, and France has developed complex regulations in this respect. These aim on the one hand to establish strict control over the movement of materials and ensure the safety of these materials and the establishments in

which they are held (see Section 8 “Non-Proliferation and Physical Protection” *infra*), and on the other hand, to control exports and imports.

The export and import of nuclear materials and equipment involve general policy decisions taken at the highest level. Thus, the Council for Foreign Nuclear Policy, which was created in 1976 and is chaired by the President of the Republic, defines the different aspects of policy to be followed in respect of exports.

The French authorities exercise very strict control over the import and export of sensitive products, substances, materials and equipment. In this context, lists of sensitive products are published in the Official Journal in the form of a notice supplementing existing provisions, and are regularly updated: Notice of 12 August 1988 to exporters concerning products it is prohibited to export, supplementing and updating the provisions of the initial Notice published on 24 November 1964; Notice of 29 November 1990 to importers and exporters relating to the products and technology subject to final destination control, etc.

Act No. 80-572 of 25 July 1980 on the Protection and Control of Nuclear Material is the basic item of legislation in this field, and has been supplemented by Act No. 89-434 of 30 June 1989. It provides that the import, export, manufacture, possession, transfer, use and transport of nuclear materials are subject to prior licensing and control [Section 2]. The Act was followed by an implementing Decree No. 81-512 of 12 May 1981 on the protection and control of nuclear materials, Chapter II of which deals with import and export licences.

More generally, France has adopted the IAEA system of safeguards to ensure that the nuclear equipment it exports is not used for military purposes. Act No. 92-574 of 1 July 1992 authorised the accession of France to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons, which was approved on 2 August 1992.

b) Patents

In France, nuclear industrial property is subject to the normal legal rules set out in the Industrial Property Code [Act No. 92-597 of 1 July 1992, partially repealed].

The only nuclear legislation which deals with invention patents is Decree No. 72-1158 of 14 December 1972 relating to the Atomic Energy Commission (CEA), which states that invention patents arising from CEA activities are to be filed in its name [Section 7]. Inventors may receive an award, details of which are determined by the Administrator General, having regard to the opinion of the Atomic Energy Committee or in accordance with rules approved by it.

Special provisions exist for inventions relating to national defence or economic development, including those involving nuclear techniques. The state may, by decree, wholly or partially expropriate patents in return for payments to the inventor. Likewise, it may *ex officio* grant licences to certain bodies for patents related to national defence.

The French Nuclear Patent Management Company (BREVATOME), set up in 1958, is responsible for bringing together and managing French nuclear patents. For non-patentable knowledge, BREVATOME has organised know-how transfer through consultancy or co-operation agreements both for systems and for components. Manufacturing secrecy is protected by including clauses on classified information, secrecy or non-transfer of rights in these contracts, termed succession clauses.

6. Radiation Protection

Council Directive 80/836/Euratom of 15 July 1980 amending the Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionising radiation, as amended by Council Directive 84/467/Euratom of 3 September 1984, was replaced by Council Directive 96/29/Euratom of 13 May 1996. The Member States must ensure that their legislative and administrative provisions are in accordance with this Directive before 13 May 2000. Workers are now divided into two categories, A and B, which correspond respectively to the former categories of workers "directly assigned" and "indirectly assigned" to work involving radiation.

French provisions on the protection of workers and the public against the hazards of ionising radiation are currently to be found in the following legislative instruments:

- Decree No. 66-450 of 20 June 1966, as amended, on general principles for protection against ionising radiation; this Decree lays down the basic principles applicable to workers and the public;

- Decree No. 75-306 of 28 April 1975, as amended, on the protection of workers in major nuclear installations (*i.e.* reactors, facilities for the enrichment, reprocessing and manufacture of nuclear fuels and large nuclear research laboratories);

- Decree No. 86-1103 of 2 October 1986, as amended, concerning the protection of workers against the hazards of ionising radiation. This Decree covers all nuclear installations other than major ones [Section 1].

The purpose of the Decree of 2 October 1986 was to implement into French law Council Directive 80/836/Euratom of 15 July 1980, as amended, and to take account of developments in labour law and of new radiation protection techniques. At the technical level, it provides for individual dosimetry for workers in category A. At the medical level, controls are required for workers of both categories, with a higher degree of medical supervision for those in category A (special medical file and an individual medical card) [Sections 36-40]. Special provisions regulate the tasks of the Board for Protection against Ionising Radiation (*Office de protection contre les rayonnements ionisants* – OPRI) [Section 65]. OPRI is the national radiation protection agency and centralises the results of workers' radiation exposure monitoring.

Radionuclides are classified in four groups in accordance with their radiotoxicity (very high, high, moderate and low). The principle that exposure should be kept as low as possible is laid down [Decree of 20 June 1966, Section 6; Decree of 28 April 1975, Section 8; Decree of 2 October 1986, Section 4]. The operator is responsible for ensuring that persons working inside his installation as well as any other person required to enter his premises for whatever reason, are protected from ionising radiation. With respect to the members of the public outside the installation for which he is responsible, he must also take all necessary steps to ensure that there is no breach of the radiation protection requirements. The employer, irrespective of whether or not he is the operator, is responsible for taking steps regarding the protection and the individual monitoring of workers.

Several orders were adopted in implementation of Decree No. 86-1103 of 2 October 1986, in particular:

- the Order of 1 June 1990 defining methods of control pursuant to Decree No 86-1103 of 2 October 1986 on the Protection of Workers against the Dangers of Ionising Radiation;

- the Order of 1 October 1990 setting out conditions and methods of accreditation of bodies responsible for carrying out controls in relation to the protection of workers against the dangers of ionising radiation and the characteristics of the licence described in Section 29 of Decree No. 86-1103 of 2 October 1986;

- the Order of 2 October 1990 establishing rules on the frequency of controls on sealed sources, installations of electrical apparatus which emits ionising radiation and the protective measures set out in Decree No. 86-1103 of 2 October 1986 on the Protection of Workers against the Dangers of Ionising Radiation.

Decrees No. 98-1185 and No. 98-1186 of 24 December 1998 amended the above-mentioned Decrees No. 75-306 and No. 86-1103 on the Protection of Workers against the Dangers of Ionising Radiation. The first of these Decrees governs workers in major nuclear installations, whereas the second concerns workers based in other installations. Their adoption has allowed, *inter alia*, the implementation into French law of Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas, as well as the partial implementation, in advance, of Council Directive 96/29/Euratom of 13 May 1996.

One of the principal objectives of these Decrees is to introduce the concept of operational dosimetry. They provide that only the worker concerned (or his legal representatives), the in-house doctor and inspector, and those persons who are qualified in radioprotection and accredited to do so may have access to the individual results in respect of the radiation measures carried out. OPRI is entitled to use such individual results for statistical purposes or in the study of epidemiology. Furthermore, these Decrees set up a registration system to certify outside companies which carry out activities in controlled areas in a major nuclear installation, or which are involved in maintenance, repair work or operation of equipment which emits ionising radiation. These certification measures apply equally to temporary employment agencies whose employees participate in such work.

Two Orders implementing these Decrees were adopted on 23 March 1999. The first of these Orders, which establishes rules governing the external dosimetry of radiation workers, specifies that the control of dose equivalents received by workers in Category A, or those who work in a controlled zone and are subject to a risk of external exposure, is carried out using individual dosimeters which measure the exposure in real time (operational dosimetry) and at pre-determined times (passive dosimetry). It repeals the Order of 19 April 1968 establishing the conditions for use of individual dosimeters designed to monitor dose equivalents, which was adopted pursuant to the now-repealed Decree of 15 March 1967. The technical modes of implementation of the dosimetry, particularly operational, as well as the transfer of data involved, are set out in an Annex. The second Order, which lays down rules concerning the accreditation by OPRI of persons qualified in radiation protection, defines the method of accreditation of "persons qualified in radiation protection or from the service responsible for radiation protection" who have access to the individual results of the exposure of workers subject to this control, over a reference period which shall not be longer than the last twelve months.

Decree No. 97-137 of 13 February 1997 deals in particular with radiation protection of outside (contract) personnel who are working in major nuclear installations. It allows the medical service of the enterprise where the work is to be performed to carry out the medical supervision of these workers.

Furthermore, the regulatory regime governing medical control was completed by an Order of 28 August 1991 approving the terms of the recommendations made to in-house doctors responsible for the medical control of workers exposed to ionising radiation.

Following the adoption of the Decree of 2 October 1986, an Order of 25 August 1987 amended the Order of 9 July 1980 on radiation protection in units, services and establishments under the Ministry for Defence [in terms of which the Army Health Service discharges the duties normally assigned to OPRI (implementation of the regulations relating to radiological safety, technical monitoring of installations, medical surveillance, etc.), in conjunction with the latter].

In addition, an Order of 1 June 1990 defined the methods and procedures to be used in carrying out the controls provided for by the Decree of 2 October 1986.

An Order of 12 May 1998 amending the Order of 8 October 1990, as amended, which establishes a list of tasks which may not be performed by workers on fixed-term work contracts or by employees of a temporary employment agency. It further provides that such workers may not carry out activities in zones where the hourly dose rate is likely to be higher than 2 millisieverts.

The rules for the calculation and the transmission of statistical data on exposure to ionising radiation of personnel working in mines producing radioactive substances were laid down by an Order of 15 January 1990. This Order provides that operators mining radioactive substances must establish each year statistical data on exposure of mining personnel to ionising radiation [Section 1]. Once completed, the tables should be sent to the Regional Director for Industry and Research as well as to OPRI. The transmission of this data to OPRI is, however, unconnected with the communication of data which that Board centralises, uses and maintains, in implementation of Decree No. 66-450 of 20 June 1966, as amended in 1988.

Decree No. 90-222 of 9 March 1990, as amended, completing the general Regulations on extractive industries introduced by Decree No. 80-331 of 7 May 1980, as amended, implements Council Directive 80/836/Euratom, of 15 July 1980, as amended, into French law. This Decree inserts in the above-mentioned general Regulations, a Part 2 relating to environmental protection. Part 1, concerning the protection of workers, was introduced by Decree No. 86-1103 of 2 October 1986. The provisions of the 1990 Decree apply to surface facilities and workings of radioactive substances. They determine the annual admissible exposure limits to ionising radiation [Sections 5-7], and the monitoring of releases and of the environment [Sections 11-16]. It also specifies that work must be conducted in such a way as to ensure that its radiological impact on the environment is as low as possible [Section 3].

Lastly, the Order of 15 October 1992, on the qualifications of persons licensed to use unsealed sources for medical purposes, amended the previous provisions of the Order of 26 March 1974 on the topic, and added further conditions. Thus, users of such sources must henceforth hold the diploma of additional specialised studies in nuclear medicine as established by the Order of 26 July 1983, as amended, or the diploma of specialised studies in nuclear medicine as established by the Order of 23 May 1990, as amended, which sets out the list of diplomas for specialised medical studies, or the diploma of additional specialised radiopharmaceutical and radiobiological studies as established by Order of 29 April 1988, as amended.

It is primarily the responsibility of the specialised services of the Ministry for Health, in particular OPRI, to determine the conditions which must be met by nuclear activities in order to comply with radiation protection standards and to ensure that public health is not endangered.

7. Radioactive Waste Management

a) General Regulations

Under Act No. 75-633 of 15 July 1975, as amended, on Waste Disposal and the Recycling of Materials, "waste" means any residue from production, processing or use, any substance, material, product or more generally any personal property abandoned or which its owner intends to abandon.

The Act of 15 July 1975 requires any producer or possessor of waste to dispose of it in such a way as to avoid any harmful effects. It was amended by Act No. 92-646 of 13 July 1992, which organises transparency on waste disposal activities. Start-up of a waste storage facility is henceforth subject to the provision of financial guarantees by the owner or operator of the facility.

b) Radioactive Waste Regulations

Waste is packaged in a form preventing dispersal and the hazards of irradiation. The integrity of the package is calculated having regard to the nature of the waste and the concentration and half-life of the radionuclides present.

Radioactive waste management is based on the fundamental principle of safety, consisting of isolating the waste from the environment for as long as it represents a hazard.

Activities relating to radioactive waste require an official licence and are subject in particular to environmental protection and public health legislation as well as to the Labour Code.

Any nuclear installation, whether producing radioactive waste incidentally or intended for managing or storing such waste, requires a construction licence. Depending on the level of activity of the radioactive substances or waste produced or handled in the installation, the licence will be issued under Act No. 76-663 of 19 July 1976 or under Decree No. 63-1228 of 11 December 1963 relating to major nuclear installations. Licences are accompanied by technical conditions.

On 30 December 1991, Act No. 91-1381 relating to Research on Radioactive Waste Management was adopted. The Act provides that in the management of high-level long-lived radioactive waste, consideration should be given to protecting nature, the environment and health, account being taken of the rights of future generations [Section 1]. The Act establishes a programme of work and research in this respect. It supplements Act No. 76-663 of 19 July 1976 relating to Installations Classified for Environmental Protection Purposes as regards the underground storage of dangerous products.

Act No. 91-1381 also specifies the conditions for the construction and operation of underground laboratories for the study of deep geological formations in which high-level long-lived radioactive waste might be stored or kept [Sections 6-12].

The Act also provides that within a maximum period of 15 years from its adoption, the government must submit to Parliament an overall assessment of the research undertaken together with a bill authorising, where necessary, the establishment of a storage facility for high-level long-lived radioactive waste, and laying down the obligations attaching to such facility [Section 4].

Furthermore, the Act of 30 December 1991 establishes the National Radioactive Waste Management Agency (ANDRA) and defines its statute and duties.

Several Decrees have been adopted in implementation of the 1991 Act. These are as follows:

- Decree No. 92-1366 of 29 December 1992 concerning public interest groups set up under Section 12 of the Act which determines the conditions for creating public interest groups which may be constituted to provide assistance and to manage equipment for installing and operating each laboratory;

- Decree No. 92-1391 of 30 December 1992 on the National Radioactive Waste Management Agency;

- Decree No. 93-940 of 16 July 1993 deals with the construction and operating licence for underground laboratories for the study of the appropriateness of deep geological formations for the storage of radioactive waste (in this respect, by Decree of 3 August 1999, ANDRA was licensed to install and operate, on the territory of the Bure Commune (Meuse), an underground laboratory designed to study deep geological formations where radioactive waste could be stored);

- Decree No. 99-686 of 3 August 1999 implementing Section 14 of the 1991 Act, providing for the establishment, at the site of each underground laboratory, of a local information and monitoring committee;

- Decree No. 99-687 of 3 August 1999 implementing Section 6 of the 1991 Act, providing for the establishment of a collegiate mission responsible for organising preliminary consultations before a choice is made in relation to one or more granite sites where the initial work leading to the establishment of an underground laboratory could be carried out.

The Ministers for Industry, Research, Health, and the Environment all play a vital role in drawing up a coherent waste management policy and supervising waste-producing installations.

It is noteworthy that, at the international level, France ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter on 3 February 1977.

c) Discharge of effluents

Decree No. 95-540 of 4 May 1995 on liquid and gaseous discharges and on sampling of water from major nuclear installations establishes the procedure to be applied for liquid and gaseous discharges from major nuclear installations and from installations classified for purposes of environmental protection within the perimeter of a major nuclear installation.

Liquid radioactive effluent releases from major nuclear installations are subject to licensing, according to the classification contained in the Annex to Decree No. 93-743 of 29 March 1993. Gaseous radioactive effluent releases into the atmosphere are also subject to licensing when they are likely to cause atmospheric pollution or release odours as defined in Act No. 61-842 of 1961.

Radioactive releases from installations classified for purposes of environmental protection, within the perimeter of a major nuclear installation, are subject to the same procedure.

Decree No. 95-540 lays down two separate procedures depending on whether an activity is subject to licensing or to notification. Licensing applications as well as notifications must be sent to both the Minister for Industry and the Minister for the Environment. Furthermore, the licensing procedure provides for prior consultation of the Minister for Health and the Minister responsible for

public safety. The licence is granted after public inquiry by joint order of the Ministers for Industry, for the Environment and for Health [Section 11].

Under the Decree, the monitoring of radioactive effluents is carried out under the authority of the Minister for Health. When he notes any irregularities, he informs the Prefect and the head of the establishment concerned accordingly. The Ministers for Industry and for the Environment are also informed of the event.

A Circular of 20 May 1998 was adopted in order to establish the procedural requirements for licence applications. A receipt is provided to the sender of the notification by the competent ministers [Section 16].

The regime defined by the Decree of 4 May 1995 was complemented by an Order of 26 November 1999 laying down the general technical requirements related to the limits and modes of sampling and releases subject to licence, carried out by major nuclear installations. These requirements concern:

- limits and technical requirements of water sampling and liquid and gaseous releases;
- means of analysing, measuring and controlling licensed activities, as well as the monitoring of their impact on the environment;
- information of state authorities on sampling and releases carried out and their impact on the environment;
- controls carried out by OPRI and the state services; and
- public information.

Individual licence orders shall comply with these general requirements as a minimum. They may include more stringent requirements.

These new requirements apply to licences for sampling and discharges from major nuclear installations and classified installations within their perimeter, as well as to changes introduced into such licences after 5 January 2001.

The Order of 26 November 1999 provides for the repeal of seven Orders of 10 August 1976 which govern radioactive liquid and gaseous effluents from nuclear installations.

8. Non-Proliferation and Physical Protection

France has undertaken, notably through its ratification on 2 August 1998 of the 1968 Treaty on the Non-Proliferation of Nuclear Weapons, not to encourage the proliferation of nuclear weapons. France also ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 6 April 1998. This instrument is not yet in force. To this end, it has adopted measures to prevent and control the dissemination of nuclear materials and techniques.

The marketing of materials is regulated by Act No. 80-572 of 25 July 1980 on the Protection and Control of Nuclear Materials (already referred to in Section 5 “Trade in Nuclear Materials and Equipment” *supra*). It deals essentially with the safety of nuclear materials, and with protection

against any theft, diversion or loss. “Nuclear materials” are defined as those containing fusible, fissile or fertile elements (plutonium, uranium, thorium, deuterium, tritium, lithium 6), excluding ores.

The Act is based on a system of licensing and control in respect of the possession, import, export and transport of nuclear materials, the physical protection measures depending on the category to which the materials belong (these categories are in line with those contained in international agreements concerning the physical protection of nuclear materials).

Licences are issued by the Minister for Industry after consultation with the Minister for the Interior, and possibly the Minister for Foreign Affairs where nuclear materials are to be imported or exported, and with the Commission for the Protection of the Carriage of Nuclear Materials, where transport is involved, these authorities having 15 days in which to give their opinion. Should there be no reply, their opinion is assumed to be favourable.

Where the quantities of nuclear materials are below certain defined thresholds, a simple notification to the Minister for Industry is sufficient.

Licence holders are obliged:

- to keep accounts and records of nuclear materials;
- to ensure the physical protection of nuclear materials and of installations, buildings or facilities containing such materials;
- to ensure the protection of nuclear materials during transport.

The purpose of these regulations is to be able to obtain prompt information on quantities and location of materials and to protect against any risk of loss, theft, damage, dispersal, etc., regardless of the nature of the events leading to such risk (accident or deliberate interference).

The enforcement of these regulations is carried out by officials sworn to secrecy and appointed by the Minister for Industry, who is backed up by the Institute for Protection and Nuclear Safety (*Institut de protection et de sûreté nucléaire* – IPSN) on technical control aspects. The Minister thus checks records and accounts concerning nuclear materials drawn up by the possessor himself or stipulated by the Minister. Likewise, he receives prior notice of transport operations and approves, jointly with the Minister for the Interior, the conditions of carriage on the basis of an opinion from the Commission for the Protection of the Carriage of Nuclear Materials.

The Minister for Industry must be notified as soon as possible of any theft, loss or misappropriation of nuclear materials. Failure to notify is a criminal offence.

An Order of 14 March 1984 lays down measures for the follow-up, control and physical protection of nuclear materials subject to a notification requirement. This Order was promulgated in implementation of the above-mentioned Act of 25 July 1980 and of the Decree No. 81-512 of 12 May 1981 adopted under the Act. Notifications must be sent to IPSN which centralises the information and where necessary, prescribes the conditions to be complied with by the holder of the materials, in implementation of the Order.

The 1980 Act was amended by Act No. 89-434 of 30 June 1989, adopted at the same time as the Act approving the 1979 Convention on the Physical Protection of Nuclear Material [Act No. 89-433 of 30 June 1989], which was approved by France on 6 September 1991. The purpose of this Act was to

bring French law into line with the Convention and to extend the jurisdiction of French criminal courts to cover relevant offences committed abroad.

Compliance with the legislation on the protection and control of nuclear materials in no way exempts the parties concerned from complying with the other regulations in force (radiation protection, carriage of dangerous goods, classified information, etc.).

Research and work on protection are carried out within the CEA by IPSN, at the request of the ministerial departments concerned.

9. Transport

The basic law on transport is contained in Act No. 42-263 of 5 February 1942 relating to the Carriage of Dangerous Materials by Rail, Road or Inland Waterway.

The Act outlines the general legal framework, leaving detailed provisions to subsequent orders [Section 1] such as the Order of 15 April 1945 approving the Regulations on the Carriage of Dangerous Goods by Rail, Road and Inland Waterway. These provisions also apply to the transport and handling of dangerous materials in ports.

The 1945 Order has been supplemented and amended on several occasions:

- as regards radioactive materials, by an Order of 24 June 1974 relating to the carriage and handling of dangerous materials: transport of radioactive materials, Class VII(b);

- various Orders adopted in 1985 relating to the transport and handling of dangerous materials, and laying down certain technical requirements (labelling and warning signs, safety notices, alphabetical listings, etc.). These were followed by an additional Order bearing the same name and dated 5 November 1986, introducing wider-ranging amendments. Under this Order, it is now possible, by means of ministerial instructions, to define specific measures for implementing the 1945 Regulations concerning defence-related hazardous materials; and nuclear materials in Categories I and II (with the exception of spent fuel) as defined in the Table annexed to the Decree of 12 May 1981 on the protection and control of nuclear materials;

- lastly, the specific requirements under the 1945 Order for the overland transport of dangerous materials (road transport) were almost all repealed by the Order of 15 September 1992, as amended, [Section 1]. The provisions covering both overland transport and at least one of the other two modes of transport no longer apply to road transport, except for Appendix 6 which concerns flexible lead and equipment for pumping hydrocarbons. The repealed provisions have been replaced by provisions annexed to the 1992 Order, and include [Section 2]: Annex A concerning materials and their mode of transport; Annex B concerning transport equipment and transport; and an alphabetical list of the materials concerned. Radioactive materials are covered by both Annexes.

Sea transport is governed by the Order of 12 July 1954, as amended, regulating the carriage of dangerous goods by sea. Furthermore, an Instruction on measures to be taken by the state authorities in case of an accident during the maritime transport of radioactive materials was adopted on 7 September 1989. This Instruction, entitled "*Plan Nucmar*", defines the general principles for the organisation of measures to be taken by the state authorities in case of an accident occurring during the civilian maritime transport of radioactive materials (Class VII), entailing or possibly entailing damage

which could affect the health of man or the maritime environment. The Plan applies to any accident occurring within French territorial waters and beyond them when the coast and related interests are endangered, and provides for the formulation of specialised Nucmar emergency plans.

Air transport is governed by an Order of 31 July 1987 concerning protection and control of nuclear materials transported by air.

Consignments through the post are governed by an Order of 18 August 1972.

Pursuant to Act No. 80-572 of 25 July 1980 on the Protection and Control of Nuclear Materials [Section 1], Decree No. 81-512 of 12 May 1981 establishes a licensing procedure for the carriage of nuclear materials, whereby a licence is issued by the Minister for Industry following consultation with the Minister for the Interior and the Commission for the Protection of the Carriage of Nuclear Materials. The technical requirements for transport operations are set out in the Order of 26 March 1982 on the protection and control of nuclear materials in the course of carriage, as amended, *inter alia*, by an Order of 12 June 1986. This latter Order contains specific provisions on sub-contracting the transport of spent fuel and nuclear materials in Category III (the Category requiring the least stringent physical protection controls as provided for by the Decree of 12 May 1981). Thus, carriers of fuel and materials in that category may sub-contract their transport, provided that the sub-contractors concerned are approved by the Minister for Industry [Section 8].

Three orders have been adopted pursuant to the following items of legislation: the Act of 25 July 1980, the Decree of 12 May 1981 and the Order of 26 March 1982.

The Order of 12 June 1986 relates to the protection and control of spent fuel and nuclear materials carried by rail. As for the Order of 31 July 1987, it relates to the protection and control of nuclear materials carried by air, while the Order of 17 November 1988 concerns the protection and control of nuclear materials carried by sea. These Orders detail the conditions to be complied with by the approved carrier, namely the French carrier or foreign licence-holder as provided for by the above-mentioned Act of 25 July 1980. The approved carrier must in particular communicate certain information (planned dates, times and places of departure and arrival, nature and quantity of the nuclear materials) to the Transport Operational Service (*Échelon opérationnel des transports* – EOT), of the Institute for Protection and Nuclear Safety, the Civilian Protection Directorate of the Ministry for the Interior and to the consignee. Other provisions describe the conditions for transporting the materials and fuels covered by the said Orders, the protection measures to be applied during transport and the conditions for monitoring transport.

In the case of transport by rail, road or inland waterway, the National Civil Protection Service is kept informed of consignments of materials in nuclear safety Categories I, II and III [Orders of 12 July 1954, 22 August 1957 and 24 June 1974, as amended]. The Board for Protection against Ionising Radiation is kept informed of contamination checks which must be carried out on vehicles specialising in the carriage of radioactive materials. Approval certificates and licences for carriage by sea are granted by the Minister responsible for shipping. The Navigation Inspectorate issues licences for the shipping of nuclear cargoes. For air transport, licences are issued by the Secretary-General for Civil and Commercial Aviation. Such licences are not required for air freight operators complying with the recommendations of the International Air Transport Association (IATA).

In general, French legislation on the physical protection of radioactive materials is based on the 1973 Recommendations of the IAEA. Transport safety is based on the definition of criteria for classifying materials in accordance with certain risks (radiotoxicity, dispersal, criticality) and for selecting appropriate packaging.

As regards international transport, France has adhered to the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID) [Decrees No. 67-880 of 20 September 1967 and Order of 6 December 1996, as amended], the European Agreement concerning the international carriage of dangerous goods by road (ADR) [Decree No. 60-794 of 22 June 1960 and Order of 5 December 1996, as amended], and the Regulation on the carriage of dangerous substances on the Rhine (ADNR) [Decree No. 96-1056 of 3 December 1996].

Since the adoption of Decree No. 97-715 of 11 June 1997, the Minister for the Environment and the Minister for Industry jointly exercise responsibility for the drafting and implementation of nuclear safety policy, including aspects related to the transport of radioactive and fissile materials for civil purposes.

10. Nuclear Third Party Liability

French law on nuclear third party liability is based on the 1960 Paris Convention and the 1963 Brussels Supplementary Convention which France ratified on 9 March 1966 and 30 March 1966, respectively. French legislation supplements the provisions of these Conventions as regards matters under the jurisdiction of national governments. Act No. 90-397 of 11 May 1990 authorised ratification of the two Protocols of 16 November 1982 amending the Paris Convention and the Brussels Supplementary Convention, published in Decree No. 91-27 of 4 January 1991. Ratification took place on 6 July 1990. Furthermore, France ratified the 1971 Convention relating to Civil Liability in the Field of Maritime Carriage on 2 February 1973.

Act No. 68-943 of 30 October 1968, as amended by Act No. 90-488 of 16 June 1990, sets out measures left to the initiative of the Contracting Parties by the Paris and Brussels Conventions. It governs the third party liability of the operators of land-based nuclear installations. Its main provisions concern:

- the liability amount of the operators of nuclear installations which is fixed at FRF 600 million; this amount is reduced to FRF 150 million when only low-risk installations are operated on the same site. Decree No. 91-355 of 12 April 1991, adopted in implementation of the 1968 Act, as amended by the Act of 16 June 1990, lays down the definition of low-risk installations;

- the operator's maximum liability amount which is fixed at FRF 150 million for transport of radioactive substances regulated by the Paris Convention;

- compensation of damage in excess of the operator's liability amount: this compensation is paid by the state out of public funds under the conditions and within the limits specified in the Brussels Supplementary Convention (namely Special Drawing Rights (SDR) 300 million);

- compensation of nuclear damage caused by military installations, which is assumed by the state in the same manner as other installations;

- the *Tribunal de Grande Instance* of Paris has jurisdiction.

Decree No. 73-322 of 15 March 1973, as amended, on insurance and re-insurance of exceptional and nuclear risks, empowers the Central Re-Insurance Fund to cover, with state guarantee, the risks for which operators of land-based and mobile nuclear installations are liable and regarding which provision is made for state intervention.

Act No. 68-1045 of 29 November 1968 deals with the third party liability of the operators of nuclear ships. It was supplemented by Decree No. 69-690 of 19 June 1969. The liability regime is based on that of the Act of 30 October 1968, as amended. Another Act No. 88-1093 of 1 December 1988 lays down the liability rules for the operators of such ships assigned to public service. In the event of nuclear damage caused outside French territory, the amount of liability is determined by the law of the state on whose territory or within whose territorial waters the damage was caused. Should there be no limit under the legislation of this state, responsibility is then unlimited.

II. INSTITUTIONAL FRAMEWORK

After World War II, the French Government, which was then led by General de Gaulle, felt that there was a pressing need at national and international level to take steps to enable France to hold its own in the field of atomic energy research.

As a result, the Prime Minister was made personally responsible for atomic energy, and a specialised agency – the Atomic Energy Commission (*Commissariat à l'énergie atomique* – CEA) was set up directly under his authority for this purpose. Responsibility for atomic energy was later entrusted to a minister. Since 1969, this task has been carried out by the Minister for Industry.

When nuclear energy entered the industrial stage, it was necessary to reorganise existing structures. While defining their respective roles, it was decided to link up the Atomic Energy Commission (which remained the specialised agency for research and development, becoming the holding company for an industrial group specifically concerned with fuel cycle activities) and *Électricité de France* (EDF) (which, with a monopoly for the distribution of electricity, became the chief nuclear operator, with responsibility for constructing and operating nuclear power plants).

Meanwhile, it was decided to establish clear boundaries between the authorities responsible for supervising nuclear activities and operators.

In view of the implications of nuclear energy, the main ministries are active in their respective fields of jurisdiction and play a part in licensing and control procedures for nuclear activities, while numerous interministerial committees provide the necessary co-ordination between the various authorities.

1. Regulatory and Supervisory Authorities

a) President of the Republic

The President of the Republic is the guarantor of national independence, territorial integrity and observance of treaties.

Since it is vital to control exports of nuclear materials and equipment with a view to preventing the proliferation of nuclear weapons, a Council for Foreign Nuclear Policy has been set up. It is chaired by the President of the Republic [Decree No. 76-845 of 1 September 1976].

Council for Foreign Nuclear Policy

The Council was set up in 1976 to define the major principles of French foreign nuclear policy, especially with regard to the export of sensitive nuclear technology, equipment and products [Decree No. 76-845 of 1 September 1976, as amended by Decree No. 81-822 of 4 September 1981, Section 1].

The Council, chaired by the President of the Republic, includes, in addition to the Prime Minister, the Ministers for Industry, Research, Foreign Affairs and Defence, as well as the Administrator-General of the Atomic Energy Commission. Other ministers and certain senior civil servants or military officials may be invited to participate in the Council's work on matters falling within their province.

The General Secretary of the Office of the President of the Republic handles secretarial duties for the Council.

b) Prime Minister

The Prime Minister plays a prime role in the adoption of important decisions at governmental level and is also the chairperson of specialised committees in the nuclear field.

Interministerial Committee for Nuclear Safety (CISN)

This Committee (*Comité interministériel de la sécurité nucléaire* – CISN) is composed of the Ministers for Health, the Interior, Defence and Industry. Other ministers or heads of government departments, agencies or undertakings may be invited to participate in the Committee's work [Decrees of 4 August 1975 and 18 December 1978].

The CISN co-ordinates activities aimed at protecting persons and property against any hazards, nuisance or other disruption arising from the creation, operation or shutdown of nuclear installations or the storage, transfer, use or processing of natural or artificial radioactive substances.

The Committee's duties cover, in particular, the radiation protection of workers and the public, measures to be taken in the event of radiation incidents, release of radioactive or non-radioactive effluents from nuclear installations, the safety of nuclear installations, and the control and safety of nuclear materials including artificial radioelements and waste.

The CISN introduces or suggests general measures and co-ordinates resources available with the study and research programmes of ministerial departments and bodies under their supervision. It prepares government policy on nuclear safety in international negotiations, and decides and co-ordinates measures to inform the public.

The Committee's duties do not cover nuclear installations intended exclusively for defence purposes and classified as secret, or custom-made nuclear equipment for national defence.

The Secretary-General of the CISN is responsible, under the Prime Minister, for checking the application of measures to ensure nuclear safety and may, for this purpose, impose and follow up all such controls and inspections.

This general responsibility for inspection covers the organisation and operation of the ministry departments concerned and bodies answerable to them, as well as the implementation of control and surveillance directives relating to the application of nuclear safety measures.

Secretary-General for National Defence

The Secretary-General assists the Prime Minister in his duties relating to overall defence matters. He handles secretariat duties for defence boards and committees. He thus co-ordinates nuclear safety matters connected with defence installations.

Interministerial Technical Committee for Matters Relating to the Application of the Treaty Establishing the European Atomic Energy Community

Chaired either by the Prime Minister or the Minister responsible for atomic energy, this Committee (*Comité technique interministériel pour les questions relatives à l'application du Traité instituant la Communauté européenne de l'énergie atomique*) examines and implements directives and decisions connected with Euratom, under the authority of the Interministerial Committee for European Economic Co-operation Matters [Decree No. 58-344 of 3 April 1958].

The CEA provides secretariat facilities. The Interministerial Technical Committee is responsible for drawing up directives defining the French Government's position within the various bodies set up under the Euratom Treaty, and ensures that Community legislation is implemented.

Atomic Energy Committee

The existence of this Committee is mentioned here merely for the record, since it was set up under the CEA Statute and will therefore be dealt with later, in the section on the CEA.

The reform introduced by the Decree of 24 August 1982 amending the Decrees of 29 September 1970 and 14 December 1972 on the CEA means that the Atomic Energy Committee is now basically a select interministerial committee for this specific field.

The Committee is chaired by the Prime Minister or by a minister delegated by the Prime Minister for this purpose, failing which, by the Administrator-General of the CEA. It consists of the Administrator-General, the General Policy Director at the Ministry for Research, the Budget Director, the Chairperson of the National Scientific Research Centre, a person of standing selected by the Prime Minister, three persons selected by the Minister for Defence, and five experts in science and industry, one of whom acts as High Commissioner.

Apart from its CEA duties (deciding CEA programmes, adopting the CEA budget, and approving share acquisitions and sales), the Atomic Energy Committee may be asked to look into general nuclear policy matters.

c) Minister for Industry

The Minister for Industry is responsible for keeping abreast of all industrial or energy applications in the nuclear field. He is jointly responsible with the Minister for Spatial Planning and the Environment for drawing up and implementing nuclear safety policy, including the transport of radioactive and fissile materials for peaceful uses [Decree No. 97-710 of 11 June 1997 on the duties of the Minister for Economy, Finance and Industry]. The Prime Minister may request him to chair the Atomic Energy Committee of the CEA.

The main directorates of the Ministry for Industry involved in the nuclear energy field are the following [Decree No. 93-1272 of 1 December 1993; Decree No. 97-710 of 11 June 1997 on the duties of the Minister for Economy, Finance and Industry].

As regards industrial activities, nuclear energy is one of the responsibilities of the General Directorate for Energy and Raw Materials (*Direction générale de l'énergie et des matières premières* – DGEMP), which draws up and implements government policy in regard to energy and raw materials [Decree No. 93-1272 of 1 December 1993 on the organisation of the central administration of the Ministry for Industry, Post and Telecommunications and Foreign Trade]. It includes, *inter alia*, the Directorate for Gas, Electricity and Coal which monitors in particular the activities of *Électricité de France* and its subsidiaries, and a Nuclear Affairs Service.

The DGEMP follows the activities of, and has overall responsibility for the CEA, the General Company for Nuclear Materials *(Compagnie générale des matières nucléaires* – COGEMA*)*, the French Raw Materials Fund and the Environment and Energy Control Agency [set up by the Act of 19 December 1990]. The DGEMP is also responsible, within its jurisdiction and on behalf of the Minister, for relations with other countries and international authorities. It helps formulate the position of the French Government and takes part in the negotiation of international agreements.

As concerns nuclear safety, the Directorate for the Safety of Nuclear Installations (*Direction de la sûreté des installations nucléaires* – DSIN) is the main body responsible for studying, drawing up and implementing nuclear safety policy.

Consequently, the DSIN prepares technical regulations concerning nuclear safety, and arranges and carries out inspections of nuclear installations. In order to carry out its tasks, the DSIN relies on the facilities of the Minister for Industry in regard to nuclear safety, *i.e.* principally:

- standing groups of experts, which examine technical problems arising in regard to nuclear safety and the construction, commissioning, operation and shutdown of nuclear installations;

- the CEA Institute for Protection and Nuclear Safety, which looks into the technical aspects of safety matters and acts as *rapporteur* to the standing groups;

- the Higher Council for Nuclear Safety and Information.

Owing to the size of the French nuclear programme, the state authorities have decided to decentralise supervision of nuclear installations to the regional directorates for research and industry. These provide the natural link between operators and local authorities. Within the main regional directorates whose areas contain nuclear installations, special nuclear divisions have been set up in order to play a key role in the supervision of such installations.

Regarding the safety of nuclear materials, the Senior Defence official under the Minister for Industry assists the Minister in his defence duties [Decree No. 93-1272 of 1 December 1993 on the organisation of the central administration of the Ministry for Industry, Post and Telecommunications and Foreign Trade]. He is also responsible for security matters concerning the protection and transport of such materials. To this end, he chairs the Commission for the Protection of the Carriage of Nuclear Materials, which is consulted in the course of the licensing procedure for the transport of nuclear materials. This Commission also helps to draw up regulations relating to the physical protection and control of nuclear materials during transport.

A Nuclear Engineering Terminology and Neology Commission under the Minister for Industry has also been set up [Order of 23 May 1997]. This Commission is responsible for drawing up an inventory of the gaps in French nuclear engineering vocabulary, taking into account user needs, for proposing the necessary terms and for monitoring the harmonisation of terms between French-speaking countries.

d) Minister for the Environment

The Minister for the Environment has two major functions in the nuclear field:

- installations classified for environmental protection purposes are under his jurisdiction; in this respect he chairs the Higher Council for Classified Installations [Decree No. 76-323 of 29 December 1976];

- he plays a leading role in pollution and water control and is responsible for the water agencies.

He is co-signatory of the Decrees which authorise the construction of major nuclear installations. Lastly, the environmental impact studies accompanying licensing applications for nuclear installations are submitted to him.

The Minister for the Environment, together with the Minister for Industry and the Minister for Research, is also the supervisory authority for the National Radioactive Waste Management Agency [Decree No. 93-787 of 8 April 1993, Section 3(6)].

In relation to nuclear safety, the Minister for the Environment exercises, jointly with the Minister for Economy, Finance and Industry, responsibilities in respect of the definition and implementation of nuclear safety policy, including transport of radioactive and fissile materials for peaceful purposes; moreover, he exercises authority, in conjunction with the Minister for Economy, Finance and Industry, over the Nuclear Installations Safety Division [Decree No. 97-715 of 11 June 1997 on the duties of the Minister for Spatial Planning and the Environment].

e) Minister for Research

The Minister for Research is responsible for proposing and implementing government policy in the field of research and technology, in conjunction with the other ministers concerned. He is also responsible for technical and technological instruction in higher education establishments.

If necessary, he may call on the services of the General Directorate for Industry and the General Administrative Directorate of the Ministry for Industry, and the regional directorates for industry and research.

He may, if so requested by the Prime Minister, chair the Atomic Energy Committee of the CEA.

As far as research activities are concerned, naturally including nuclear research, funds for public bodies carrying out technological research and development activities come out of the budget of the Minister for Research.

The Scientific and Technical Unit advises the Minister on scientific and technical aspects of matters for which he is responsible.

The Directorate for Technology is responsible for developing means to use to best advantage the results of public research and technical co-operation with industry, to participate in the setting up of research and technological development programmes financed by the European Union and to follow their implementation.

The Directorate for Research draws up policy relating to research, training by research and scientific employment and ensures its implementation. Moreover, those research bodies which do not report to the Directorate for Technology come under its jurisdiction. This Directorate is also responsible for preparing the budget for civilian research and technological development, and its co-ordination.

f) Minister for Health (including OPRI)

The Minister for Health is responsible for protecting the health of the population.

Together with the Minister for Labour, he is the supervisory authority of the Office for Protection against Ionising Radiation (*Office de protection contre les rayonnements ionisants* – OPRI), a public body which was created by Decree No. 94-604 of 19 July 1994. Its task is to carry out any measurements or analytical work necessary to determine the level of radioactivity or ionising radiation in the various types of environment where it might lead to hazards for the health of individuals or of the population as a whole. It keeps a record of the results of the health monitoring of workers [Decree No. 86-1103 of 2 October 1986 and Decree No. 75-306 of 28 April 1975]. The Office is administered by a board of directors, the president of which is named by decree for a term of three years. Its resources derive largely from state subsidies and what it earns from services provided.

The Act of 2 August 1961 on the Control of Atmospheric Pollution and Odours explicitly requires OPRI to monitor all types of pollution caused by radioactive substances. The Water Act No. 92-3 of 3 January 1992 entrusts it with the same tasks in regard to water pollution. The amended 1963 Decree relating to nuclear installations requires OPRI inspectors to monitor the application of measures concerning the release of radioactive effluents. OPRI also provides technical support for the Minister for Employment in the application of decrees dealing with protection of workers against the hazards of ionising radiation, and adopted pursuant to Labour Code provisions concerning occupational health and safety.

OPRI undertakes measurements and analytical work to monitor the level of radioactivity in the various types of environment where it may lead to public health hazards. It defines standards, measurement methods and techniques for preventing radioactive contamination. It checks that protection measures are being applied and are effective.

In regard to atmospheric pollution, OPRI is responsible for carrying out checks through agents duly appointed and sworn in for this purpose.

OPRI co-ordinates and defines controls for the radiation protection of workers. It monitors the release of gaseous or liquid radioactive effluents from major nuclear installations and radiation levels in the surrounding areas.

In the medical field, OPRI's opinion is required prior to approval of medical or dental facilities using nuclear substances.

Lastly, OPRI is involved in ORSECRAD plans to be put into effect in the event of a radioactive incident.

g) Minister for Employment

The Minister for Employment has powers in the field of the safety, health and welfare of employees directly exposed to ionising radiation at work.

As mentioned above, he receives support from OPRI. He is also assisted by the Industrial Health Commission which gives opinions on all legislation concerning occupational health and safety. At local level, he has *département* labour offices. Labour inspectors are responsible for checking compliance with the legislation within firms.

h) Minister for the Interior

The Department of Defence and Public Safety

The Department of Defence and Public Safety (*Direction de la défense et de la sécurité civiles*) assists the Minister for the Interior in the exercise of his duties in relation to the preparation and implementation of defence measures within his own services as well as in other state services under his responsibility. The Defence and Public Safety Director, a senior civil servant in the defence field, has authority over all the departments and services of the Ministry for the Interior for the exercise of his duties in this field.

The duties of the Defence and Public Safety Director are set out as follows:

- he provides a permanent link with the Secretary-General for Defence, Prefects, chiefs of staff, as well as with senior civil servants in the defence field within different ministerial departments;

- he performs secretarial duties and organises the operations of the Standing Commission on Defence;

- he assists the Minister or represents him in the commissions, committees, working groups and meetings dealing with defence issues both at interministerial level and within the various ministries concerned;

- he co-ordinates the preparation and, where necessary, the implementation of defence plans, exercises and measures under the responsibility of the Minister for the Interior;

- he is responsible for implementing the provisions relating to defence safety and secrecy protection.

Under the authority of the Defence and Public Safety Director, the services of the Department of Defence and Public Safety include:

- Unit for Defence and Maintenance of National Services;
- Inspectorate for Public Safety;
- Sub-Directorate for Administration and Modernisation;
- Sub-Directorate for Preventive Measures and the Protection of the Population;
- Sub-Directorate for Emergency Services and the Fire Brigade;
- Sub-Directorate for Emergency Organisation and Civil Defence.

The Defence and Public Safety Director has ultimate authority over the military personnel of public safety services.

In the exercise of his tasks of defence and public safety, the Defence and Public Safety Director is assisted by members of personnel on secondment from central administration, the permanent professional staff of the Police Force and professionals from other services under the authority of the Ministry for the Interior. Military personnel may be seconded from the Ministry for Defence.

Act No. 87-565 of 22 July 1987 on the Organisation of Public Safety Measures, Forestry Protection against Fire and the Prevention of Major Risks states that public safety measures aim to prevent all types of risk and to protect persons, property and the environment against accidents, disasters and catastrophes [Section 1].

The preparation of preventive measures and the implementation of measures necessary to address major risks and catastrophes are addressed in the emergency plans, including the "Orsec plans".

The Minister for the Interior must intervene in order to organise emergency services in the event of an incident or to deal with any terrorist action.

Central Office for the Prevention of Illicit Trading in Weapons, Ammunition, Explosives and Biological and Chemical Nuclear Materials

This Office (*Office central pour la répression du trafic des armes, des munitions, des produits explosifs et des matières nucléaires biologiques et chimiques*) was set up within the Ministries for the Interior and for Rural Development (General Directorate for the National Police Force, Central Directorate for Criminal Investigation) [Decree No. 82-1050 of 13 December 1982].

It has the twofold task of preventing and prosecuting unlawful acts or offences concerning the possession of nuclear materials.

i) Minister for Transport and Housing

The Minister for Transport and Housing issues construction licences for nuclear installations [Act of 7 January 1983].

The *Interministerial Commission for the Carriage of Dangerous Goods* (*Commission interministérielle du transport des matières dangereuses*) was set up in 1941 to help develop regulations for the carriage of dangerous materials by rail, road, inland waterway or air and for handling of these materials in seaports [Decree No. 95-1029 of 13 September 1995 on the Interministerial Commission for the Carriage of Dangerous Goods, Orders of 15 April 1945 approving the Regulations on carriage of dangerous or infectious goods and 11 October 1948, Regulations of 1952 for the carriage of dangerous goods by sea]. Under transport Regulations, nuclear materials form part of the Commission's responsibilities [Class VII(b)]. The Commission has a membership of fifty and holds four plenary sessions per year.

The transport of dangerous goods by sea is dealt with by a commission under the authority of the General Directorate for Shipping. As far as air transport is concerned, IATA rules apply and therefore a Commission has not been set up.

2. Specialised Committees or Boards

In the previous section on the powers of the main ministries concerned with nuclear activities, the roles of the Interministerial Committee for Nuclear Safety, the Council for Foreign Nuclear Policy, the Interministerial Technical Committee for Matters Relating to the Implementation of the Euratom Treaty, and the Interministerial Transport Commission have already been described. The following is a brief description of the Interministerial Commission for Artificial Radioelements, the Interministerial Commission for Major Nuclear Installations and the Higher Council for Nuclear Safety and Information.

a) Interministerial Commission for Artificial Radioelements (CIREA)

This Interministerial Commission (*Commission interministérielle des radioéléments artificiels* – CIREA) was set up for the purpose of giving opinions on the problems raised by artificial radioelements [Act No. 52-844 of 19 July 1952]. The relevant regulations were incorporated in 1956 into the Public Health Code [Decree No. 56-1197 of 26 December 1956, Decree No. 79-175 of 26 February 1979]. At plenary sessions, the Commission formulates opinions or proposals on all general matters arising from the preparation and application of regulations relating to artificial radioelements.

The Commission is composed of two sections, one for medical applications and the other for non-medical uses.

It gives opinions on licensing applications for the transfer, use, manufacture and import of artificial radioelements: applications which are submitted to its chairperson for the authorisation of non-medical activities, and to the Ministry for Health for the authorisation of medical uses.

It is chaired by a Counsellor of State appointed by order of the Prime Minister. It is composed of eleven representatives of the ministries concerned, two CEA representatives, one CNRS representative, another from the National Institute for Health and Medical Research, and the Head of OPRI. A Permanent Secretary, who is entitled to vote, is appointed by order of the Prime Minister on a joint proposal from the CEA Administrator-General and the High Commissioner for Atomic Energy.

The CEA carries out secretarial duties for the Interministerial Commission. The Commission works in liaison with the Interministerial Committee for Nuclear Safety [Decree No. 78-1193 of 18 December 1978, Section 8].

b) Interministerial Commission for Major Nuclear Installations (CIINB)

This Commission (*Commission interministérielle des installations nucléaires de base* – CIINB) is asked for its opinion on licensing applications for setting up or modernising major nuclear installations and on specific provisions applicable to such installations. It is also consulted and makes proposals regarding the preparation and application of regulations relating to such installations [Decree No. 63-1228 of 11 December 1963, as amended by Decree No. 73-405 of 27 March 1973, Section 8]. Draft legislation on the safety and protection of workers is submitted to it.

The chairperson is a Counsellor of State, and the vice-chairperson, the CEA High-Commissioner [Section 7].

It has 29 full and 29 deputy members appointed for 5 years by order of the Prime Minister and representing the various ministries and bodies concerned.

A Permanent Secretary is appointed by the Prime Minister on the proposal of the Minister for Industry, and is entitled to vote [Section 9]. On the basis of the licensing applications for establishing nuclear installations received by him, he draws up the reports to be considered by the Commission.

When investigating a specific matter, the CIINB may call on experts from the scientific and technical fields.

The Commission holds at least one meeting a year at the request of its chairperson. Voting is by majority of the members present. If the votes are split equally, the chairperson has the casting vote.

The Commission has set up a select group within its structure, *i.e.* the Permanent Section, consisting of the chairperson, the vice-chairperson and the permanent secretary together with nine representatives of ministerial departments concerned, co-opted by the chairperson. The Permanent Section gives an opinion on licensing applications in cases of minor importance.

c) Higher Council for Nuclear Safety and Information

Created on 13 March 1973 under a slightly different name by Decree No. 73-278 and placed under the authority of the Minister for Industry, this Council (*Conseil supérieur de la sûreté et de l'information nucléaires*) was given its current name in 1987 along with new powers [Decree No. 87-137 of 2 March 1987 on the Higher Council for Nuclear Safety and Information].

The composition of the Council was broadened in order to include members belonging neither to the government nor to public services. At present, its members include the heads of ministerial departments and specialised agencies, members of Parliament, experts, representatives of trade unions and nature conservation and environmental protection associations.

The Council's activities cover [Section 1]:

- all matters relating to nuclear safety, defined as "all technical measures taken at the design, construction and operating stages to ensure normal operation, prevent incidents or reduce the impact of any incidents that might occur";

- all matters concerning the information of the public and the media and related to the safety of nuclear installations, or concerning information of the public in the event of an incident or accident occurring in a nuclear installation.

On the request of the Minister for Industry or if it deems it necessary, the Council may set up expert working groups to study specific scientific questions or to promote information [Section 4].

The Council has power to make recommendations on ways of improving nuclear safety.

3. Public and Semi-Public Agencies

a) Atomic Energy Commission (CEA)

In 1945, the provisional Government of the Republic presided by Général de Gaulle, foreseeing the potential applications of nuclear energy and their impact in economic, financial, political and military areas, became aware of the need to allow the state to take the initiative in the nuclear field. An Ordinance of 18 October 1945 created the Atomic Energy Commission (*Commissariat à l'énergie atomique* – CEA) [Ordinance No. 45-2563 of 18 October 1945, Corrigendum of 3 December 1945, as amended by Act No. 47-1497 of 13 August 1947 Allowing the Levy of Taxes, Duties, State Proceeds and Revenue, Establishing the General Budget for 1947 and on Miscellaneous Financial Provisions, Decree No. 70-878 of 29 September 1970 on the Atomic Energy Commission and Decree No. 78-662 of 22 June 1978 on the Atomic Energy Commission].

Decree No. 70-878 of 29 September 1970, as amended by Decree No. 82-734 of 24 August 1982 and Decree No. 74-584 of 14 June 1974 also concern the CEA.

i) Legal status

The CEA was given the status of a public scientific, technical and industrial establishment. It is an administratively and financially independent legal entity.

Following the Decree of 29 September 1970 reorganising the CEA, and the resulting creation of subsidiary companies (such as TECHNICATOME in 1972 and COGEMA in 1976), the CEA continues itself to carry out tasks in the field of fundamental and applied research, nuclear safety and military applications. In addition, through the intermediary of a holding company, it is a shareholder (sometimes majority, sometimes minority) in private law companies, and the companies in which it, directly or indirectly, owns more than 50% of the capital, form the CEA group.

The CEA is responsible for its own financial management and for submission of accounts in accordance with normal trade practice. In other words, it operates largely as a private enterprise [Decree No. 72-1158 of 4 February 1972, Section 8]. What is more, by derogation from the Decrees of 25 and 30 October 1935 and from the Ordinance of 13 November 1944, the CEA is exempt from a priori financial control applicable to state-owned independent public establishments. It is audited by an *ad hoc* audit team consisting of four officials belonging to each of the main state auditing bodies.

Originally answerable to the President of the Provisional Government and then to the President of the Council and afterwards to the Prime Minister, the CEA has since 1969 been placed under the authority of the Minister for Industry [Decree No. 93-1272 of 1 December 1993 relating to the organisation of the central administration of the Ministry for Industry, Post and Telecommunications and Foreign Trade].

ii) Responsibilities

The CEA's duties, as defined in the 1970 Decree and subsequently confirmed, can be classified under the following main headings.

Fundamental research: the CEA conducts scientific research into the nature of matter (atomic physics and particle physics) and applies the research opportunities offered by atomic or nuclear phenomena to a wide variety of fields such as biology, chemistry and astrophysics.

As regards nuclear legislation, under the General Secretariat of the Interministerial Committee for Nuclear Safety, the CEA helps to draw up regulations concerning the safety of nuclear materials both on-site and during transport.

The CEA works in co-operation with other fundamental research laboratories, both French – in particular the CNRS and its National Institute for Nuclear Physics and Particle Physics (IN2P3), the National Institute for Health and Medical Research (INSERM) and foreign or international laboratories (the Max Planck Institute, the University of Heidelberg, the Danish Space Research Institute, the DESY Laboratory in Hamburg, and the CERN in Geneva).

The *National Institute for Nuclear Science and Technology* (*Institut national des sciences et techniques nucléaires* – INSTN), set up in 1956 [Decree No. 56-614 of 18 June 1956], is a higher education establishment specialised in nuclear science with its headquarters at Saclay and supervised both by the Minister for Research and the Minister for Industry [Decrees No. 58-602 of 11 July 1958, No. 58-1045 of 30 October 1958, No. 66-266 of 26 April 1966 and No. 79-276 of 2 April 1979].

Through the INSTN, the CEA provides scientific training for top engineers and physicists in the field of atomic energy.

Protection and nuclear safety: The *Institute for Protection and Nuclear Safety* (*Institut de protection et de sûreté nucléaire* – IPSN), created in 1976 [Order of 2 November 1976] is responsible, on behalf of the CEA, for the protection of persons and property against the effects of nuclear energy. Its composition and duties were reorganised several times [Orders of 29 October 1981, 29 April 1983, 4 July 1983, 28 May 1990 and 20 August 1993].

On the basis of the general co-ordination measures adopted on the subject by the Interministerial Committee for Nuclear Safety, the Institute also undertakes, at the request of the ministerial departments and bodies concerned, studies, research or work on nuclear protection and safety. It may also undertake such research on behalf of outside enterprises [Order of 28 May 1990]. It provides technical back up to the Directorate for the Safety of Nuclear Installations.

The Institute's management consists of a director appointed by joint order of the Ministers for Industry and for the Environment on the joint proposal of the Administrator-General of the CEA and the High Commissioner for Atomic Energy, following consultation with the Secretary-General of the Interministerial Committee for Nuclear Safety. The Director of the Institute is assisted by a management board responsible for the choice of its activities and its budget. A Scientific Committee of ten members, chaired by the High Commissioner for Atomic Energy, is responsible for giving its opinion on the Institute's programme of work and for ensuring the coherence of its research policy [Order of 28 May 1990].

The IPSN has its own budget. Its income is mainly provided by appropriations under the budget of the Minister for Industry, granted after an opinion has been given by the Secretary-General of the

Interministerial Committee for Nuclear Safety. Its remaining funds consist of income from studies, research and work done for ministries or industry.

In the field of waste processing and storage, it carries out joint research with the National Radioactive Waste Management Agency on waste packaging processes.

Nuclear materials: the CEA ensures that users receive adequate supplies. It is empowered to prospect, produce, store and transport nuclear raw materials either directly or through enterprises in which it is a shareholder. Since it was set up in 1976, the CEA's fully-owned subsidiary COGEMA, which specialises in all kinds of industrial and commercial activities concerning the nuclear fuel cycle, has been responsible for industrial and commercial operations in that area.

Nuclear energy applications: to maintain and improve the reliability and safety of electronuclear facilities, on which France depends for its power supplies, the CEA provides technical support to the nuclear industry and to *Électricité de France* (EDF) for the development of new reactor fuels and fuel cycle processes.

Non-nuclear programmes: in accordance with government directives, the CEA has, on the basis of Decree No. 70-878 of 29 September 1970, developed a diversification policy in conjunction with the subsidiaries set up over the years, in order to promote research and development activities in the non-nuclear field.

Having acquired technological know-how through its work on nuclear energy, the CEA applies this knowledge to other sectors, thus meeting demand from industry or from public and private research bodies. It is thus involved in a wide variety of fields: electronics, components, scientific apparatus, biological and medical engineering, mechanical engineering, metallurgy, environmental protection, oceanology and radioelements in fields allied to the nuclear sector. Decree No. 82-734 of 24 August 1982 confirms this approach under which the CEA, through its various activities, contributes to the technological development of the regions.

Military applications: in national defence, the CEA is responsible for producing nuclear explosive devices and warheads as well as propulsion reactors for nuclear submarines. Matters relating to the carrying out of nuclear arms programmes are examined by a joint Defence-CEA Committee.

A joint Armed Forces-CEA Commission on Nuclear Security has been set up to report to the government authorities, and give its opinion on the security of weapons systems, nuclear-propelled ships and related equipment, from the design stage until withdrawal from service [Order of 3 July 1989 regulating the powers and organisation of the said Commission, Section 1]. However, the Commission is not empowered to monitor nuclear materials used for defence purposes [Section 11].

Information and the dissemination of know-how: in line with its primary involvement with nuclear activities, the CEA follows scientific, technical and economic developments in the nuclear field abroad, and takes an active part in the life of the scientific community in France and in other countries. The CEA is responsible for advising the government, especially in the course of the negotiation of international agreements.

iii) Structure

The CEA Statute provides for a number of central bodies.

Atomic Energy Committee

Under the chairmanship of the Prime Minister or a minister delegated to this effect by the latter, failing which under the chairmanship of the Administrator-General, this Committee is composed of:

- the Administrator-General;
- the Secretary-General of the Ministry for Foreign Affairs;
- the General Policy Director at the Ministry for Research;
- the Budget Director;
- the President of the National Centre for Scientific Research;
- a leading personality chosen by the Prime Minister;
- three leading personalities chosen by the Minister for Defence;
- five experts in the scientific and industrial fields, one of them acting as High Commissioner.

The High Commissioner and the *non-ex officio* members are appointed for three years by Decree of the Council of Ministers [Decree No. 76-951 of 19 October 1976].

The Atomic Energy Committee acts as a select interministerial committee in the nuclear field [Decree No. 72-1158 of 14 December 1972]. It also draws up the research and work programme of the CEA, approves the CEA budget and authorises share acquisitions and transfers.

The Committee must meet at least once a month. It is usually convened by its chairperson but in exceptional cases by the Administrator-General. Decisions are taken by majority vote of the members present, with the chairperson holding the casting vote if the votes are split equally.

Management Board

Under Decree No. 82-734 of 24 August 1982, some of the functions of the Atomic Energy Committee relating to management and general organisation, staff employment, adoption of the budget, the acquisition and transfer of shareholdings and the authorisation of loans were transferred to a tripartite management board.

Chaired by the Administrator-General, the board is composed of 18 members including government representatives, representatives of the staff of the CEA and its subsidiaries, and leading experts. Appointments are for a period of five years. The management board meets at least six times a year [Decree of 13 April 1984].

Administrator-General

The Administrator-General acts as head of the CEA. He is appointed by Decree of the Council of Ministers for a period of five years [Decree No. 70-878 of 29 September 1970, Section 4].

He has full powers to act within the terms of reference of the CEA, which he represents, except for powers delegated to the Atomic Energy Committee and the Management Board [Decree No. 72-1158 of 14 December 1972, Section 5]. He may delegate all or part of his powers to the High Commissioner or to one or more heads of department.

The Administrator-General may appoint a deputy.

High Commissioner

The High Commissioner is the technical and scientific adviser to the Administrator-General on CEA technical and scientific policy [Decree No. 70-878 of 29 September 1970, Section 5].

Selected from among leading scientists on the Atomic Energy Committee, he is consulted on all protection matters and may be given responsibilities in education.

The High Commissioner chairs a Scientific Board which assists him in the exercise of his duties [Decree of the Council of Ministers No. 82-734 of 24 August 1982 on the Atomic Energy Commission]. Apart from persons appointed on proposals by the Administrator-General and by ministers, the Scientific Board includes staff representatives appointed after consultation with the trade unions.

iv) Financing

The activities of the CEA are financed mainly by civilian or military grants from the government budget. Government grants are used to cover expenditure in applied research, nuclear power generation, the reprocessing of spent fuel and the manufacture of weapons. Furthermore, the industrial and commercial activities of CEA subsidiaries produce their own income. This outside income derives in particular from technical work and services, research contracts, sales of radioelements and energy, and fees for industrial property licences.

b) Électricité de France (EDF)

Under the Act of 8 April 1946 nationalising the production, transport, distribution and marketing of electricity, an industrial and commercial public establishment, *Électricité de France* (EDF) was made responsible for these activities.

EDF also produces nearly all the electricity distributed through the national grid. As such, EDF is the operator of almost all French nuclear power plants except for the fast breeders in service today.

In accordance with Decree No. 70-878 of 29 September 1970 [Section 2(5)], the CEA co-operates with EDF in the research sector and in the supply of nuclear fuels [Agreement of April 1967 and annexed Protocol of March 1968]. This co-operation consists of permanent exchanges of information, and the heads of the two bodies have adopted the practice of consulting one another on major issues.

EDF is run by a president appointed by decree of the Council of Ministers. It has a management board composed of fourteen members appointed by decree following an opinion by the Minister for Industry, and a chairperson appointed by decree of the Council of Ministers.

c) National Radioactive Waste Management Agency (ANDRA)

Initially, ANDRA (*Agence nationale pour la gestion des déchets radioactifs*), created within the CEA by Order of 7 November 1979, had no independent legal personality but did enjoy a certain budgetary autonomy. It was responsible for the long-term management of radioactive waste.

Act No. 91-1381 of 30 December 1991 on Research into Radioactive Waste Management replaced the former Agency by a new body with the same name. Decree No. 92-1391 of 30 December 1992, in implementation of the 1991 Act, laid down the new ANDRA statute, its new administrative structure and various other provisions relating to its operation.

i) Legal status

ANDRA is an industrial and commercial public establishment under the joint authority of the Minister for the Environment, the Minister for Industry and the Minister for Research [Act No. 91-1381 of 30 December 1991, Section 13; Decree No. 93-787 of 8 April 1993 relating to the powers of the Minister for the Environment].

ii) Responsibilities

ANDRA thus carries out the duties entrusted to it by Section 13 of Act No. 91-1381 of 30 December 1991 and by Section 1 of Decree No. 92-1391 of 30 December 1992. It is therefore responsible for operations concerning the long-term management of radioactive waste, and in particular for the following activities:

- in co-operation with the CEA, helping to define and contributing towards research and development programmes concerning the long-term management of radioactive waste;
- ensuring the management of long-term storage centres either directly or through the intermediary of a third party acting on its behalf;
- designing, selecting the site for and constructing new storage centres in the light of long-term forecasts for waste production and management, and carrying out all studies required for this purpose, in particular the construction and operation of underground laboratories to study deep geological formations;
- defining, in compliance with the safety rules, specifications for the treatment and storage of radioactive waste;
- recording the state and location of all radioactive waste on French territory.

Each year, ANDRA must submit to its ministerial supervisory authorities a report reviewing the work achieved and to be achieved. The Agency must also submit, no later than 31 December 2005 and after obtaining the opinion of the Scientific Board, a report analysing the results achieved together with, as the case may be, a project for an underground storage site for high-level, long-lived radioactive waste [Decree No. 92-1391 of 30 December 1992, Section 1].

iii) Structure

ANDRA is administered by a director-general, a management board, a financial committee and a scientific board.

The management board of the Agency includes [Section 2]:

- a Member of Parliament or a senator appointed by the Parliamentary Office for the Evaluation of Scientific and Technological Policies;
- six government representatives, appointed on proposal of the Ministers for Energy, Research, the Environment, the Budget, Defence, and Health, respectively;
- five persons of note representing economic circles concerned by the work of the Agency, one of whom should be proposed by the Minister for Health;
- two persons of note, qualified in fields within the competence of the Agency, one of whom should be proposed by the Minister for the Environment; and
- seven representatives of the staff of the Agency.

The members of the board are appointed for a term of five years.

The chairperson of the management board is selected from among its members, and appointed by decree following a joint report by the ministers responsible for the Agency.

The management board meets at least three times a year [Section 4]. Decisions are adopted by a majority of votes of the members present or represented. The management board settles the affairs of the Agency [general functioning, programme of work, forecasts of income and expenditure, loans, acquisitions, conclusion of contracts, etc.].

The Director-General for Energy and Raw Materials is the Government Commissioner for the Agency [Section 7] and acts as an intermediary between ANDRA and the government.

The Director-General of the Agency is appointed on the proposal of the chairperson of the board by decree made following a report of the ministers responsible. He manages the services of the Agency, prepares the meetings of the management board and implements its decisions [Section 8].

As for the Financial Committee, it is consulted on the conditions and price-levels for the services of ANDRA, and its investment programmes. For its part, the scientific board gives opinions on the research and development programmes carried out by the Agency.

iv) Financing

The resources of ANDRA include in particular [Section 11]:

- remuneration for services rendered;
- subsidies from the state, local governments and any other public or private, national or international bodies;

- proceeds from loans, etc.

The Agency is subject to economic and financial control by the government as provided by the Decrees of 29 August 1953 and 26 May 1955. Control of the financial management is carried out by a government auditor [Section 13].

d) National Institute for Nuclear Physics and Particle Physics (IN2P3)

Within the National Centre for Scientific Research (*Centre national de la recherche scientifique* – CNRS), the Institute includes experts on nuclear physics and on particle physics [Decree No. 84-667 of 17 July 1984, Section 3]. Its purpose is to prepare and co-ordinate research in the fields of nuclear physics and particle physics.

IN2P3 carries out its duties within bodies placed under the supervision of the Minister for Research, except for the CEA [Section 1].

The Institute is headed by a director appointed by order of the Minister for Research after an opinion by the Director-General of the CNRS and the Director-General of Higher Education and Research at the Ministry for Research. He is assisted by an administrative deputy director and by one or more scientific deputy directors appointed by the Director-General of the CNRS on a proposal by the Director of the Institute, after obtaining the opinion of the Director-General for Higher Education and Research with the Ministry for Research.

The Director of IN2P3 is, in addition, assisted by a management board and a scientific board.

The management board is composed of sixteen members including the CNRS Director-General, who acts as chairperson, members appointed from among ministerial representatives and leading scientists. It holds meetings at least twice a year, and on one such occasion it examines the budget. The Institute's budget is separate from that of the CNRS but is approved and amended in the same way as that of the CNRS. The management board decides on applications from laboratories and research centres to work in association with the Institute. In general, it fulfils the usual functions of management boards of public establishments.

The scientific board is consulted on the drawing up of research programmes, preparation of the plan and equipment programmes. It meets at least twice a year, and comprises representatives from different scientific bodies together with scientists and heads of laboratories, whether independent or associated with the Institute.

GERMANY

I. GENERAL REGULATORY REGIME

Information Note

The Government of the Federal Republic of Germany, newly elected in September 1998, decided to phase out the use of nuclear energy for electricity-generating purposes. This decision will lead to the introduction of substantial changes into German nuclear legislation. The necessary modifications mainly concern the 1959/1985 Atomic Energy Act as amended, but they will also involve the introduction of consequential amendments into implementing and complementing ordinances and other provisions. Work on re-drafting existing legislation is underway at the time of writing of this study (1999); but it is not yet possible to foresee in a precise manner the result of this exercise. In particular, a Draft Law to Amend the Atomic Energy Act has not yet been agreed upon among the Federal Ministries, which would provide a basis for re-drafting this chapter on Germany. For this reason, the editors decided to refrain from considering the minor legislative changes introduced in 1999 which essentially dealt with administrative issues. The text reproduced in this chapter reflects the situation at the end of 1998 which, with regard to all major issues of atomic energy law, is still the law applicable at the end of 1999.

1. Introduction

The legal basis for the regulation of the peaceful uses of nuclear energy in the Federal Republic of Germany was created in 1959 by an addition to the Basic Law (the Federal Constitution – *Grundgesetz*). Under Article 74 No. 11(a), the scope of the legislative power of the Federal State (*Bund*) was broadened to include the production and use of nuclear energy for peaceful purposes, the construction and operation of installations for such purposes, protection against hazards arising from the release of nuclear energy or from ionising radiation, and the disposal of radioactive substances. Article 87(c) of the Basic Law provides that laws promulgated under Article 74 No. 11(a) may, with the consent of the Federal Council (*Bundesrat*), which is composed of representatives of the *Länder* governments), stipulate that they are to be implemented by the *Länder* (states making up Germany) on behalf of the federal authorities (so-named *Bundesauftrags-verwaltung*) [Act of 23 December 1959 amending the Basic Law, BGBl[1] I, p. 813].

Against this background the Act on the peaceful use of atomic energy and protection against its hazards (Atomic Energy Act) became law on 23 December 1959.[2] In accordance with Article 87(c) of the Basic Law, the Atomic Energy Act provides that it is to be implemented by the federal authorities and the *Länder*. The *Länder* are subject to federal supervision of both the regularity and

1. BGBl: *Bundesgesetzblatt* = Federal Gazette.

2. Consolidated version published on 15 July 1985 [BGBl I, p.1565], last amended on 6 April 1998 [BGBl I, p.694].

appropriateness of measures taken by them to give effect to the Act (Basic Law, Article 85). For the purpose of exercising such supervision, the competent supreme federal authorities (*i.e.* in the case of nuclear safety and radiation protection the Federal Minister for the Environment, Nature Conservation and Nuclear Safety) may issue instructions [Atomic Energy Act, Section 24].

The Atomic Energy Act is intended to:

- promote nuclear research and the development and use of nuclear energy for peaceful purposes;

- protect lives, health and property from hazards associated with nuclear energy and from the harmful effects of ionising radiation and provide compensation for damage caused by nuclear energy or ionising radiation;

- prevent the domestic or external security of Germany from being endangered by reason of the use or release of nuclear energy;

- ensure fulfilment of the international obligations of Germany in the field of nuclear energy and radiation protection [Atomic Energy Act, Section 1].

The aim of affording protection, which underlies the Atomic Energy Act, is given practical effect through provisions dealing with licences, surveillance, liability and insurance cover, and in provisions relating to offences and penalties. In the event of a conflict concerning the purposes of the Act, the principle of protection against hazards and risks prevails, as the well-established case law of the Federal Administrative Court and other courts has shown.

The Atomic Energy Act empowers the Federal Government (in certain cases with the consent of the *Bundesrat*) to issue ordinances for the achievement of the objectives set out in the Act. So far the following matters have been dealt with:

- Ordinance on protection against damage caused by ionising radiation (*Strahlen-schutzverordnung* – Radiation Protection Ordinance) [consolidated version of 30 June 1989, as last amended on 18 August 1997 (BGBl I, p. 2113)];

- Ordinance of 14 October 1992 on persons responsible for nuclear safety and on the notification of safety-related events (*Atomrechtliche Sic-herheitsbeauftragten und Meldeverordnung* – Safety Officers and Notification Ordinance) [BGBl I, p. 1766];

- Ordinance of 8 January 1987, as amended, concerning protection from damage by X-rays (*Röntgenverordnung* – X-ray Ordinance) [BGBl 1987 I, p. 114; 1990 I, p. 607, 294 a; 1996 I, p. 1172];

- Ordinance of 18 February 1977, as amended in 1982 and 1994, concerning the procedure for licensing of installations pursuant to Section 7 of the Atomic Energy Act (*Atomrechtliche Verfahrensverordnung* – Nuclear Installations Ordinance) [BGBl I, p. 280; 1982 I, p. 411; 1994 I, pp. 3455, 3992; 1995 I, p. 180];

- Ordinance of 25 January 1977, as amended, concerning financial security pursuant to the Atomic Energy Act (*Atomrechtliche Deckungsvorsorgeverordnung* – Nuclear Financial Security Ordinance) [BGBl I, p. 220; 1990 I, p. 2106];

- Ordinance of 17 December 1981, as amended, concerning costs under the Atomic Energy Act (*Atomrechtliche Kostenverordnung* – Nuclear Costs Ordinance) [BGBl I, p. 1457; 1992 I, p. 2078];

- Ordinance of 28 April 1982, as amended, on advance contributions towards construction of federal installations for safe containment and final disposal of radioactive waste *(Endlagervorausleistungsverordnung* – Final Disposal Ordinance) [BGBl I, p. 562; 1990 I, p. 1418];

- Ordinance of 27 July 1998 on the Movement of Radioactive Waste into or out of the Territory of the Federal Republic of Germany [BGBl 1998 I, p. 1918].

It should be noted that, in accordance with Section 2(2) of the Act of 21 June 1990 bringing into force the regulations of the FRG in the GDR (so-called *Mantelgesetz*) [GBL I, p. 357], the Atomic Energy Act of the FRG entered into force in the GDR on 1 July 1990, with the status of GDR law. At the same time, the implementing Ordinances of the Act became valid, and the corresponding legislation of the GDR expired. Following the conclusion of the Treaty of 31 August 1990 between the FRG and the GDR on the establishment of the unity of Germany (Unification Treaty) [BGBl II, pp. 885, 889], federal law including the Atomic Energy Act, the Radiation Protection Ordinance, and all other implementing and complementing legal instruments entered into force on 3 October 1990 in the five new *Länder* in the territory of the former GDR.

The unification further brought about some minor amendments of the nuclear law in force. Thus the Atomic Energy Act was amended to provide for necessary transitional rules, *e.g.* concerning limited continuation of old licences [Section 57(a)]. The Radiation Protection Ordinance was also amended, to provide that in the new *Länder* the Ordinance would not be applicable to mining of radioactive minerals [Section 89(a)].

Nuclear and radiation protection law is not, however, to be found exclusively in the Atomic Energy Act and the above Ordinances. Another important piece of legislation is the Preventive Radiation Protection Act of 1986, as amended [BGBl 1986 I, p. 2610; 1990 I, p. 2106; 1994 I, p. 1416]. There are also numerous relevant provisions in other specialised fields. The principal ones are:

- national and international provisions on the transport of radioactive materials;

- provisions of water law dealing with protection and liability in regard to the disposal of radioactive sewage into surface waters;

- the Mining Act with regard to the search for radioactive minerals and the design of installations for the deep underground disposal of radioactive waste;

- provisions of the law relating to foodstuffs and medicine.

In addition, nuclear energy law in Germany is influenced by and, in part, directly subject to international treaties, particularly within the framework of Euratom, OECD and the IAEA.

2. Mining Regime

The search for radioactive minerals requires a permit and mining operations require a licence or a concession for the mine, in accordance with the provisions of the Federal Mining Act of 13 August 1980, as amended, which regulates such matters in detail [BGBl 1980 I, p. 1310; 1997 I, p. 1430, Sections 6-8]. A licence for handling radioactive materials under the Radiation Protection Ordinance is not required for activities to which the Federal Mining Act applies, but the radiation protection provisions of that Ordinance are applicable [Radiation Protection Ordinance, Section 3(1), Section 28 *et seq.*].

Two Ordinances of the former GDR remain valid for a transitional period, in accordance with the Unification Treaty [Article 9; Annex II, Chapter XII, Nos. 2 and 3] in relation to mining activities involving radioactive substances, especially when radon derivatives are present:

- the GDR Ordinance on Nuclear Safety and Radiation Protection of 1984 (*Verordung über die Gewährleistung von Atomsicherheit und Strahlenschutz* – VOAS) [GBL I, p. 341] and its implementing Regulation of 1984 [GBL I, p. 348; 1987, p. 196];

- the Order of 1980 on radiation protection in relation to slagheaps and industrial repositories [GBL I, p. 347].

It was decided that these two instruments should remain in force for a transitional period because they contained specific provisions for supervising activities which had not been developed in West Germany and therefore had not been covered adequately by FRG law.

The Radiation Protection Commission (*Strahlenschutzkommission* – SSK) in 1991 issued recommendations concerning the use of areas and material contaminated by the uranium mining activities of the former Soviet-German public limited company "Wismut" in the *Länder* of Saxony and Thüringen [BAnz[3] 1991, pp. 5461, 5684, 7858]. Wismut's activities were terminated following the unification of Germany in accordance with an Agreement between Germany and the USSR of 16 May 1991 [BGBl II, p. 1142].

3. Radioactive Substances, Nuclear Fuel and Equipment

Under the Atomic Energy Act, any person who constructs, operates or otherwise possesses any installation for the production, processing, treatment or fission of nuclear fuels or for the reprocessing of irradiated nuclear fuels, or who substantially alters any such installation or its operation, requires a licence from the highest competent authorities of the *Land* [Atomic Energy Act, Section 7].

The processing, treatment or other uses of nuclear fuels, other than in installations which require a licence under Section 7 of the Atomic Energy Act, are also subject to a licence [Section 9]. The same applies to any substantial deviation from the procedures for processing, treatment or other uses covered by the licence and to any change in the place of operation as defined in the licence.

3. BAnz: *Bundesanzeiger* = Federal Bulletin.

Any dealings (production, storage, processing, treatment, other utilisation and disposal) with other radioactive substances[4] require a licence from the competent authorities of the *Land* unless they are covered by a licence under the Atomic Energy Act [Radiation Protection Ordinance, Section 3].

A duty of notification exists in relation to low-level radioactive materials, specified appliances and equipment of approved design [Radiation Protection Ordinance, Section 4(1), Annexes II and VI].

Neither a licence nor notification is required for radioactive substances referred to in the Radiation Protection Ordinance which, by reason of their nature, quantity or activity, present no danger to individuals or the environment [Radiation Protection Ordinance, Sections 4(2) and 5, Annex III].

The construction and operation of installations for the production of ionising radiation (accelerators) which exceed a specified energy level require a licence. The operation of X-ray appliances is subject to the provisions of the X-ray Ordinance [Section 3].

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

Any person who constructs, operates or otherwise holds, or who substantially alters any installation for the production, processing or fission of nuclear fuel, or for the reprocessing of irradiated nuclear fuel must obtain a licence [Atomic Energy Act, Section 7]. A licence may be granted only if:

- there are no known facts giving rise to any doubts as to the reliability of the applicant or of the persons responsible for the construction and management of the installation and the control of its operation, and the latter persons possess the requisite specialised knowledge;
- the persons who are otherwise engaged in the operation of the installation possess the necessary knowledge concerning the safe operation of the installation, the possible hazards and the safety measures to be applied;
- every necessary precaution has been taken in the light of existing scientific knowledge and technology to prevent damage resulting from the construction and the operation of the installation;
- the necessary financial security has been provided to cover all legal liability to pay compensation for damage;

4. Section 2 of the Atomic Energy Act defines "other radioactive substances" as substances other than nuclear fuels which spontaneously emit ionising radiation. "Nuclear fuel" means special fissionable material in the form of plutonium-239, plutonium-241, uranium-233, enriched uranium, uranium and materials with a uranium content of natural isotopic mixture of such purity as to enable within an appropriate installation (reactor) a continuous self-sustaining chain reaction to be maintained. The term "radioactive substances" includes nuclear fuels and other radioactive substances and is used in this sense in the present study.

- all necessary protection is provided against disturbance or other interference by third parties;

- the choice of the site of the installation, in particular with respect to non-contamination of water, air and soil, is not contrary to overriding public interests.

Section 7 was amended by the Act to Amend the Atomic Energy Act and the Act on the Establishment of a Federal Office for Radiation Protection [BGBl 1998 I, p. 694], adopted on 6 April 1998, in order to facilitate safety improvements of existing nuclear installations. This amendment provides that in the future, the safety improvements of existing nuclear installations may be permitted even though they cannot fully satisfy the safety standards which are required in the licensing procedure for new nuclear installations. This provision is designed to encourage operators not to refrain from safety-orientated back-fitting measures even if such measures do not entirely comply with the latest standards in science and technology, as required for new installations.

In order to prevent risks to the general public, since 31 December 1993, an applicant for a licence for a nuclear power reactor must ensure, by the design and the operation of the installation, that in the event of a nuclear accident, it will not be necessary to take drastic measures (*e.g.* evacuation) outside the installation in order to protect the public against ionising radiation, even in exceptional circumstances [Atomic Energy Act, Section 7(2)(a)].

The licence is subject to strict conditions and is issued by the supreme *Land* authorities [Atomic Energy Act, Section 24]. The licensing procedure is laid down in the Nuclear Installations Ordinance.

The licensing procedure is conducted in several stages and involves consultation and intervention of the public and local authorities. Technical bodies are involved at the federal as well as at the *Land* level. When the application is filed, the licensing authority of the *Land* concerned forwards copies of the request for the licence to the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, which is advised on licensing questions by the Reactor Safety Commission and the Radiation Protection Commission. After consultations with the Commissions have been concluded, the Ministry informs the *Land* authorities of the findings and issues the relevant instructions. In addition, the *Land* authorities request expert opinions from independent experts.

As regards the different stages of the licensing procedure, provisional site approval is not a mandatory step within this procedure: it is at the discretion of the applicant whether he applies for that approval or not. Such approval is limited to the question of whether a given site is suitable for construction and operation of a nuclear installation, but it does however provide the opportunity to settle certain questions which would be likely to cause public controversy. This provisional site approval is binding in nature, but it will become invalid if the applicant does not apply for the final licence within two years from the date on which this approval is no longer subject to appeal.

A new Section 7(c) of the Atomic Energy Act, introduced by the 1998 amendment [BGBl 1998 I, p. 694], introduced a procedure which aims to promote the development of new reactor types with advanced safety technology. This provision allows the assessment of the individual elements of the necessary safety requirements, irrespective of the actual site of the installation. The competent authority in this case is not the competent Minister of the *Land* in question, but rather the Federal Office for Radiation Protection. The procedure aims to give the Federal Office the opportunity to influence new safety concepts during the development phase. Consequently, the licensing authority competent for the final procedure is not bound by the results of the preliminary assessment, the results of which are to be published in the *Bundesanzeiger*.

The construction permit may be and is normally granted in several stages: a partial construction permit concerning, *inter alia*, a specified construction volume, the site and the basic safety design of the installation. Principles to be taken into account in the design of nuclear power plants are contained in the Safety Criteria for Nuclear Power Plants of 21 October 1977 (BAnz 1977, No. 206).

The operating licence may also be applied for and granted in several stages. Before issuing an operating licence, the licensing authority must be certain that other provisions of public law, such as those relating to buildings and zoning, water and environmental protection, trade and nuisance control, have been observed and the requisite permits and licences have been granted by the appropriate (*Bund*, *Land* or local) authorities.

Costs connected with decisions and rulings and with the official custody of nuclear fuels, or other official acts by the competent authorities under the Atomic Energy Act are dealt with in accordance with the relevant provisions of the Act, or in the Nuclear Costs Ordinance made under it and in the Administrative Costs Act *(Verwaltungskostengesetz*) [Atomic Energy Act, Sections 21, 21(a), 21(b); Ordinance of 17 December 1981, BGBl I, p. 1457; 1992 I, p. 2078].

Finally, the construction, operation and possession of nuclear installations are subject to continuous government supervision [Atomic Energy Act, Section 19]. The supreme authorities of the *Länder* are responsible for exercising supervisory and control functions, which they may delegate to subordinate agencies in individual cases.

The holder of a licence to operate an installation referred to in Section 7(1) of the Atomic Energy Act must appoint a person to be responsible for nuclear safety (*kerntechnische Sicherheitsbeauftragter* – Safety Officer). This person must supervise and assess the measures aiming at guaranteeing nuclear safety in the installation, including, *inter alia*, assessing safety-related events, elaborating measures to improve nuclear safety, and informing the operator on deficiencies in the nuclear safety of the installation. The operator must support the safety officer in fulfilling his tasks and, in particular, must provide the necessary personnel for his assistance. [Safety Officers and Notification Ordinance of 14 October 1992, BGBl I, p. 176].

It is relevant in this context to note that Germany ratified the 1994 Convention on Nuclear Safety on 20 January 1997 [Act of 7 January 1997 on the Convention on Nuclear Safety, BGBl 1997 II, p. 130].

b) Protection of the environment against radiation effects

Where a licence or land planning permission is required for a nuclear installation or waste disposal facility, an environmental impact assessment must be included in the procedure leading to a decision. [Atomic Energy Act, Sections 7 and 9(b); Act on Environmental Impact Assessment of 12 February 1990, as amended (BGBl 1990 I, p. 205; 1997 I, pp. 2081, 2111). This Act was originally promulgated as Article 1 of the Act of 12 February 1990 to implement Council Directive 85/337/EEC of 27 June 1985 on the assessment of the impact of projects on the environment, [BGBl 1990 I, p. 205].

The person responsible for radiation protection (the operator) is required to plan the technical design and operation of his installation or equipment so that exposure of humans to radiation caused by the release of radioactive substances into air or water does not exceed certain specified limits. Such exposure to radiation must be calculated with regard to the most unfavourable points of impact (*i.e.* the worst possible scenario) taking into account all relevant exposure pathways including food chains

[Radiation Protection Ordinance, Section 45, Annex X]. See also General Administrative Regulation (*Allgemeine Verwaltungsvorschrift*) concerning Section 45 of the Radiation Protection Ordinance, namely "Identification of the radiation exposure caused by the release of radioactive substances from nuclear installations" issued by the Federal Government on 21 February 1990 [BAnz 31 March 1990, No. 64(a)].

Where the operation of nuclear installations or installations for the production of ionising radiation, or the handling of radioactive substances, involves the possibility of the release of radioactive substances into the air, water or soil, then steps must be taken to ensure that:

- there is no uncontrolled release;
- the radioactivity released is kept as low as possible and in any case does not exceed the limit fixed by the Radiation Protection Ordinance;
- release of radioactivity is monitored and the results notified at least once a year to the competent authorities [Section 46].

To meet the requirements of the Radiation Protection Ordinance, the Guidelines for the Surveillance of Releases from Nuclear Installations (*Richtlinie zur Emissionen-und Immission-süberwachung kerntechnischen Anlagen*) were drawn up in a circular of 30 June 1993 issued by the Federal Minister for the Environment, Nature Conservation and Nuclear Safety.

The Penal Code, as amended by two Acts Concerning Criminal Acts Against the Environment [Act of 28 March 1980, BGBl I, p. 373 and Act of 27 June 1994, BGBl I, p. 1440], covers offences committed in connection with the use of nuclear energy or ionising radiation, as well as non-compliance with licence conditions or an order of the authorities.

c) Emergency response

The operator is obliged to notify accidents, incidents and other safety-related events to the competent authority. The criteria for a notifiable event are laid down in detail in Annexes 1 and 2 of the Safety Officers and Notification Ordinance which also provides for a formal notification procedure. The safety officer must supervise the notification by the operator to check that it is correct and complete [BGBl 1992 I, p. 1766, Chapter 3].

The Act on Preventive Protection of the Public against Radiation (Preventive Radiation Protection Act) of 19 December 1986, as amended, [BGBl 1986 I, p. 2610; 1994 I, p. 1416] sets out the respective administrative responsibilities of the *Bund* and the *Länder* in relation to monitoring radioactivity and taking protective measures following an incident [Sections 2 and 3]. It also establishes a federal information system on "Radioactivity in the Environment" [Section 4]. The Federal Minister for the Environment, Nature Conservation and Nuclear Safety has the power to fix acceptable dose levels [Section 6]. These dose levels may be implemented by ordinances prescribing restrictions on trade in, and use of, foodstuffs, tobacco products and drugs [Sections 7 and 8]. Border police and customs officers have special powers for controlling transborder traffic and trade with regard to radioactive contamination.

Four Ordinances to implement the Preventive Radiation Protection Act were adopted in 1989, 1991, 1997 and 1998 [Ordinances of 3 August 1989, 31 July 1991, 16 October 1997 and 30 July 1998

to assign competence for measurements and evaluations in accordance with the Preventive Radiation Protection Act (BGBl 1989 I, p. 1582; 1991 I, p. 1768; 1997 I, p. 2474; 1998 I, p. 2009)].

The Federal Minister for the Environment, Nature Conservation and Nuclear Safety has the exclusive power to issue recommendations to the population as to the conduct they should adopt in order to protect themselves [Section 9]. The Radiation Protection Ordinance was amended on 18 August 1997 [BGBl I, p. 2113] to implement Council Directive 89/618/Euratom of 27 November 1989 informing the general public about health protection in the event of a radiological emergency.

Furthermore, at the international level Germany ratified both the 1986 Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency and the 1986 Convention on Early Notification of a Nuclear Accident on 14 September 1989.

5. Trade in Nuclear Materials and Equipment

Nuclear trade in general (both domestic and foreign) is subject to the provisions of the Atomic Energy Act and its implementing ordinances. Therefore, the applicable norms concerning licensing and supervision, radiation protection, financial security and physical protection must be observed. In addition, the international obligations of Germany must be respected, notably European Union legislation, international transport agreements, the nuclear third-party liability conventions and the Treaty on the Non-Proliferation of Nuclear Weapons.

Foreign trade in nuclear material is subject also to the general foreign trade legislation contained in the Foreign Trade Act (*Außentwirtschaftgesetz*) of 28 April 1961 [BGBl I, p. 481] as amended, as implemented by the Foreign Trade Ordinance (*Außentwirtschaftsverordnung)* of 22 November 1993 [BGBl 1993 I, p. 2493], last amended in 1998 [*Bundesanzeiger* 1998 p. 985; 1998 Attachments Nos. 105, 139, 162 and 174]. The Foreign Trade Act lays down the principle that all economic transactions with other countries are unrestricted, subject to the limitations provided for by the Act itself, other laws and international agreements. The Act allows restrictions to be prescribed by ordinance and the Foreign Trade Ordinance specifies such restrictions in relation to trade in nuclear material, installations and equipment. The Foreign Trade Ordinance also incorporates the restrictions on nuclear trade imposed by the recommendations of the Nuclear Suppliers' Group (London Club) and by the so-named Trigger List. The Import and Export Lists annexed to the Foreign Trade Ordinance were last revised in 1998 [*Bundesanzeiger* 1998 Attachment No. 88].

The import and export of nuclear fuel or radioactive substances require either a licence or a declaration, depending on the substances involved [Atomic Energy Act, Section 3; Radiation Protection Ordinance, Sections 11 and 12, Annexes V, VI and VII]. Exemptions from these requirements are made for radioactive substances which are exempted from a handling licence and for other radioactive substances which are imported/exported by the Armed Forces [Radiation Protection Ordinance, Sections 11(3) and 13]. Both the Atomic Energy Act and the Radiation Protection Ordinance expressly stipulate that other legal provisions on import and export remain unaffected. In this respect, the Foreign Trade Act and the Foreign Trade Ordinance are of particular relevance, as are the Import List and the Export List which are annexed to them, respectively. The Export List comprises a Nuclear Energy List, which enumerates nuclear material, installations and equipment which are subject to a special regime under the Foreign Trade Act and Ordinance, while both lists provide country lists which provide details on countries with which trade has been liberalised and those which are subject to restrictions.

6. Radiation Protection

Part 3 of the Radiation Protection Ordinance contains provisions dealing with protection against damage due to ionising radiation. These provisions apply to all activities connected with radioactive substances (nuclear fuels and other radioactive substances) [Radiation Protection Ordinance, Sections 28-80].

The basic rules laid down by the Radiation Protection Ordinance require any person who undertakes or proposes to undertake activities specified in the Atomic Energy Act or in the Ordinance itself:

- to avoid all unnecessary radiation exposure or contamination of persons, property or the environment;

- to keep as low as possible any exposure to radiation or contamination of persons, property or the environment, even below the limits set out in the Radiation Protection Ordinance, having regard to the existing state of scientific and technical knowledge and in the light of all the circumstances of each case [Section 28].

In addition, in planning protective measures against incidents at a nuclear power plant, in the most unfavourable case, exposure in the vicinity of the installation must not be more than certain prescribed annual limits for various parts of the body [Sections 28 and 45, Annex X]. The licensing authorities may, in particular, accept that sufficient precautions have been taken against certain incidents where the applicant has based the design of the installation on the safety criteria which the Federal Minister for the Environment, Nature Conservation and Nuclear Safety has laid down with respect to the prevention of such incidents.

Any person pursuing an activity requiring a licence or subject to notification under the Atomic Energy Act or the Radiation Protection Ordinance is responsible for ensuring compliance with the radiation protection principles and rules. For this purpose he must appoint an adequate number of staff to be responsible for compliance with the various protection requirements [Radiation Protection Ordinance, Sections 29 and 31].

To implement the above-mentioned provisions on protection against damage caused by ionising radiation, the Radiation Protection Ordinance deals specifically with:

- the various radiation protection areas [Part 3, Chapter 4];

- measures and means for the physical monitoring of radiation levels [Part 3, Chapter 5];

- medical surveillance [Part 3, Chapter 6];

- radiation measurement apparatus [Part 3, Chapter 7].

a) Protection of workers

The special provisions relating to the protection of occupationally exposed persons fix maximum permissible doses; exposure in excess of these limits is only permissible to deal as a matter of urgency with the consequences of an incident or to remove danger to individuals. The protection of

occupationally exposed persons is to be ensured through permanent devices such as shielding. To achieve this end activities may be prohibited or restricted [Sections 49 et seq., Annexes IV and X].

The effective occupational life exposure is limited to 400 millisievert [Radiation Protection Ordinance, Section 49].

A register has been established at the Federal Office for Radiation Protection (*Bundesamt für Strahlenschutz* – BFS) to collect and record the doses of radiation of professionally exposed persons and the dates of exposure [Atomic Energy Act, Section 12(c); Radiation Protection Ordinance, Section 63(a)].

Ordinances also exist to protect particular groups of workers against the harmful effects of radiation, such as the Ordinance of 21 December 1990 on maternity protection of female soldiers [Consolidation of 23 December 1993, BGBl 1994 I, p. 50], and the Ordinance of 11 January 1991 on maternity protection of female civil servants [BGBl I, p. 125].

The Ordinance of 25 July 1996 [BGBl I, p. 1172] amended both the Radiation Protection Ordinance of 1989 and the X-Ray Ordinance of 1987, to extend the transitional provisions permitting continued employment of certain categories of occupationally exposed workers. The deadline has now been extended to 31 December 2000.

b) Protection of the public

Special provisions apply to the use of radioactive substances in medical research, medical treatment and dentistry [Radiation Protection Ordinance, Sections 41-43].

The operation of X-ray apparatus is governed by the radiation protection provisions in the X-ray Ordinance of 8 January 1987 as amended. These are intended to ensure that radiation absorbed by patients during X-ray examination and treatment is kept as low as possible.

To ensure safety in the use of medicines it is unlawful to market radioactive medicines or medicines produced with the aid of ionising radiation save where the regulations so permit. These provisions are contained in the Medicines Act of 24 August 1976 [Sections 1 and 7, BGBl I, p. 2445] and the Ordinance on Radioactive and Irradiated Medicines of 28 January 1987 as amended [BGBl I, p. 502].

Under Section 13 of the Foodstuffs and Consumer Goods Act, the treatment of foodstuffs with ultraviolet and ionising radiation and the marketing of irradiated foodstuffs for commercial purposes are prohibited [consolidated version of 8 July 1993, [BGBl I, p. 1169]. Exceptions are set out in the Food Irradiation Ordinance [Ordinance of 16 May 1975, BGBl I, pp. 1281, 1859].

Such prohibited foodstuffs must not be introduced into Germany [Section 47], but this does not apply to the introduction of products which were brought lawfully into circulation in the territory of a Member State of the European Union [Section 47(a)]. After the entry into force on 1 January 1994 of the Agreement of 2 May 1992 between the European Union states and the European Free Trade Association states on the European Economic Area, the exemption was extended to goods from the other states of this Area [BGBl 1994 II, p. 5151].

The Federal Minister for the Environment, Nature Conservation and Nuclear Safety, in consultation with other ministers, may issue ordinances to forbid or limit the sale of foodstuffs affected by radioactive contamination of the environment [Section 9(4)].

Drinking water must not contain radioactive substances in such concentration as to be capable of affecting human health [Ordinance of 5 December 1990, BGBl I, p. 2612, BGBl 1991 I, p. 227 corrigendum].

7. Radioactive Waste Management

The Atomic Energy Act uses the term "radioactive waste" in different places, but contains no actual definition. It appears that from Section 9(a) of the Act, radioactive wastes are such radioactive residues or such decommissioned parts of a nuclear installation which the licence holder decides to dispose of, and not to re-use. The Radiation Protection Ordinance also refers to radioactive waste within the meaning of the Atomic Energy Act [Section 2(1), Annex I].

Any person in possession of radioactive waste must normally hand it over to installations of the *Länder* or the *Bund*. The surrender requirement does not apply in cases where the disposal of the waste does not require a licence, or is permitted under the Ordinance or has been otherwise ordered or approved [Atomic Energy Act, Section 9(a)(2) and (3); Radiation Protection Ordinance, Sections 81-86].

For this purpose the *Länder* are to establish collection points for interim storage. The construction and operation of these facilities require a licence from the competent *Land* authorities [Atomic Energy Act, Sections 9(a)(3) and 9(c)].

The federal authorities are responsible for the establishment of facilities for the safe containment and final disposal of radioactive waste. The construction and operation of these facilities, which are the responsibility of the Federal Office for Radiation Protection must be approved in the context of a land-use planning procedure by the *Land* in which the facility is situated [Atomic Energy Act, Sections 9(b) and 23]. In 1996, Section 9(b) of the Atomic Energy Act was amended to simplify and speed up the licensing procedure for a federal radiation waste disposal facility [Licensing Procedures Expedition Act of 12 September 1996, BGBl I, p. 1354]. Under the new procedure the competent authority may issue a simple licence, provided the applicant requires only a modification of an existing facility and the modification is not prejudicial to the environment.

Operators of nuclear installations and research centres are responsible for the interim storage of the waste they produce until a federal waste disposal facility is in operation [Radiation Protection Ordinance, Section 86]. The federal authorities and the *Länder* may call upon the services of third parties to meet their obligations in regard to waste disposal. In particular, the Federal Office for Radiation Protection has made arrangements with a private company, the Company for the Construction and Operation of Disposal Facilities (*Deutsche Gesellschaft zum Bau und Betrieb von Endlagern für Abfallstoffe mbh* – DBE) concerning the design and setting up of facilities for the safekeeping and disposal of radioactive waste. Any arrangements with third parties do not affect the responsibility of the federal authorities or the Länder with respect to the management of radioactive waste. On 6 April 1998, an Act was issued to amend the Atomic Energy Act and to amend the Act on the Establishment of a Federal Office for Radiation Protection [BGBl 1998 I, p 694]. Section 9(a)(3) of the Atomic Energy Act was amended to allow for the possibility of a full transfer of these functions to third parties. This is envisaged in two steps, the second of which still has to be elaborated under the Act.

Which radioactive wastes have to be delivered to the *Land* collection points and which to the federal facilities is determined by the Radiation Protection Ordinance [Atomic Energy Act, Section 12(1) Nos. 8 and 9; Radiation Protection Ordinance Sections 81 and 82]. The authorities may order that the wastes be treated in a certain way before surrender [Radiation Protection Ordinance, Section 85].

In addition to the provisions of the Atomic Energy Act, the construction and operation of an installation for the storage, safe containment or final disposal of radioactive waste is also subject to numerous provisions of the Federal Mining Act of 13 August 1980 if it is of a type suitable for underground disposal without containment [Section 126(3)].

The Ordinance of 13 July 1990 on the assessment of the effects of mining projects on the environment [BGBl I, p. 1420] provides that certain projects, including subsoil installations for the safe containment or final disposal of radioactive waste, are subject to prior assessment of their possible environmental effects. Information concerning projects must be submitted to the competent authorities under the Federal Mining Act (and under other laws such as the Waste Act, the Construction Act and the Nature Conservation Act) and must also be transmitted to the authorities of European Union Member States. Consultations with those authorities must be held with due regard to the principles of reciprocity and equivalent treatment.

In accordance with the Ordinance on advance contributions towards construction of federal installations for safe containment and final disposal of radioactive waste (*Endlagervorausleistungs-verordnung* – Final Disposal Ordinance), the Federal Office for Radiation Protection may levy costs for intermediate and final storage pursuant to the Atomic Energy Act [Section 21(b)].

The amending Act of 6 April 1998 (see *supra*) empowered the Federal Government to implement EC Directive 92/3/Euratom of 3 February 1992 on the Supervision and Control of Transboundary Movements of Radioactive Waste (EC OJ No. L 35, p. 24). On the basis of this authorisation, the government issued the Ordinance of 27 July 1998 on the Movement of Radioactive Waste into or out of the Territory of the Federal Republic of Germany (BGBl 1998 I, p. 1918). This Ordinance creates a licence requirement and contains the necessary administrative procedures in accordance with the Directive. The Ordinance entered into force on 1 August 1998.

The Federal Minister for the Economy, with the concurrence of the Federal Ministers for Labour and Social Affairs, and the Federal Minister for Transport issued the General Mining Ordinance on 23 October 1995 [BGBl 1995 I, p. 1466] which concerns all aspects of mining activities and which constitutes the national implementation mechanism for several EC Directives (89/391/EC of 12 June 1989, 89/655/EC and 89/656/EC of 30 November 1989; 92/58/EC of 24 January 1992; 92/91/EC of 3 November 1992 and 92/104/EC of 3 December 1992). The Ordinance establishes a framework for safety and health protection with regard to mining activities, including underground storage. It therefore applies directly to underground radioactive waste repositories.

At the international level, Germany has been a Party to the 1972 Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter since 8 November 1977, and it ratified its 1996 Protocol by an Act of 9 June 1998 [BGBl 1998 II, p. 1345]. Following the ratification of the 1996 Protocol, an Act was adopted on 25 August 1998 to implement it [BGBl 1998 I, p. 2455]. This Act prohibits the dumping and incineration of waste and other matter into the high sea.

Furthermore, Germany ratified the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 13 October 1998 [BGBl 1998 II, p. 1752].

8. Non-Proliferation and Physical Protection

By Acts of 4 June 1974, the Federal Republic of Germany approved:

- the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (ratification took effect on 2 May 1975) [BGBl 1974 II, p. 785];

- the Agreement of 5 April 1973 between Belgium, Denmark, the Federal Republic of Germany, Ireland, Italy, Luxembourg, the Netherlands, Euratom and the IAEA in implementation of Article III(1)(4) of the Treaty on the Non-Proliferation of Nuclear Weapons (Verification Agreement) [BGBl 1974 II, p. 794].

The Agreement of 5 April 1973 was given effect in the Federal Republic of Germany by an Act containing detailed provisions regarding the safeguarding of fissionable materials. Alongside Commission Regulation (Euratom) No. 3227/76 of 19 October 1976 concerning the application of the provisions on Euratom safeguards (OJ EC No. L 363, 1976) there exists extensive regulations to give effect to the Non-Proliferation Treaty and the Euratom Treaty [Act of 7 January 1980, BGBl II, p. 165].

The Act on Control of Military Weapons of 22 November 1990, as amended, forbids development, production, import and export (including transit), trade in or possession of nuclear weapons [BGBl I, p. 2506; 1997 I, p. 1059] In order to enhance control over foreign trade and to prevent proliferation of atomic, biological and chemical weapons, the Federal Minister for the Environment, Nature Conservation and Nuclear Safety may inform the appropriate authorities of any facts which become known to him in connection with nuclear licensing procedures which arouse suspicion of an infringement of the Foreign Trade Act [Atomic Energy Act, Sections 19(1) and 24(a)]. The Foreign Trade Act (*Außenwirtschaftsgesetz*) of 28 April 1961 [BGBl I, p. 481] and the Foreign Trade Ordinance (*Außenwirtschaftsverordnung*) of 22 November 1993 [BGBl I, pp. 1934, 2493] were repeatedly amended in order to improve supervision and control of the export and transit of sensitive material and equipment, including nuclear material, goods and technology [See *e.g.* BGBl I, pp. 1457, 1460 and recently: *Bundesanzeiger* 1997 Attachment No. 242; 1998, p. 985; 1998 Attachments Nos. 105, 139, 162 and 174].

Pursuant to the Act of 9 July 1998 [BGBl 1998 II, p. 1210], Germany ratified the 1996 Comprehensive Nuclear Test-Ban Treaty on 20 August 1998, and on 23 July 1998, the Parliament adopted an Act to implement this Treaty [BGBl 1998 I, p. 1882]. This Act provides for the necessary legal framework to carry out inspections under Article IV of the Treaty. With the exception of two Sections, this Act will enter into force when the Treaty itself enters into force.

An essential precondition for the licensing of nuclear installations, and for the handling and transport of radioactive substances is the provision of the necessary protection against interference or other action by third parties (physical protection) [Atomic Energy Act, Sections 4(2) No. 5, 6(2) No. 4, 7(2) No. 5, 9(2) No. 5, 12(1) No. 10, 12(b); Radiation Protection Ordinance, Sections 6(1) No. 7 and 10(1) No. 6].

Germany ratified the 1979 Convention on the Physical Protection of Nuclear Material on 6 September 1991, and has given effect to it through provisions in the Penal Code [Law on the Convention on the Physical Protection of Nuclear Material, of 24 April 1990, BGBl II, p. 326, as amended by the Second Act Concerning Criminal Acts Against the Environment of 27 June 1994, BGBl 1994 I, p. 1440].

9. Transport

The transport of radioactive substances is subject not merely to the provisions of the Atomic Energy Act and the Radiation Protection Ordinance, but also to the provisions applicable to each type of carrier (Ordinances on the Transport of Dangerous Goods by Road, Rail, Sea and Inland Waterways), which are based on the Act on the Transport of Dangerous Goods (*Gesetz über die Beförderung gefährlicher Güter*) of 6 August 1975 as amended [BGBl I, p. 2121; 1996 I, p. 1019; 1998 I, p. 2037]. This Act does not however apply to carriage on the sites of installations where dangerous goods are produced, stored, used or disposed of. Furthermore, the Act does not apply to the transboundary shipment of dangerous goods to the extent that regulations of the European Union or international agreements apply to that carriage, and it does not apply to transportation by mountain railway. The provisions relating to the transport of radioactive substances follow the IAEA Regulations for the Safe Transport of Radioactive Materials.

Germany is a party to the following international agreements concerning the transport of dangerous goods:

- European Agreement of 30 September 1957 concerning the International Carriage of Dangerous Goods by Road (ADR) [BGBl 1969 II, p. 1489];

- Regulations for the Transport of Dangerous Goods on the Rhine (ADNR) [BGBl 1994 II, p. 3830; Special annex volume to BGBl 1997 II, No. 48];

- Agreement of 9 May 1980 (COTIF) [BGBl 1985 II, p. 130] including the Protocol of 17 February 1984 [BGBl 1985 II, p. 666] and including the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID) [Annex B Attachment No. 1 as amended; Special annex volumes to BGBl 1985 II, No. 18; 1997 II, No. 51].

The transport of radioactive materials requires a licence, available in the case of nuclear fuel and major sources of radiation from the Federal Office for Radiation Protection, and in the case of other radioactive substances from the competent authorities of the *Länder* [Atomic Energy Act, Sections 4, 23 and 24; Radiation Protection Ordinance, Sections 8 and 9].

Specific exemptions apply for certain low level radioactive substances and articles containing small quantities of radioactive substances [Radiation Protection Ordinance, Section 9, Annexes II and III].

As regards the domestic transport of radioactive substances, carriers are subject to a large number of instruments, which are in conformity with international agreements and recommendations.[5] There also exists a Dangerous Goods (exceptions) Ordinance which is revised regularly, and which lists in a comprehensive annex the respective exceptions for the regime of dangerous goods [annex volume to BGBl I, No. 41 of 27 June 1997].

5. These may be found in a loose-leaf collection: Eberhard Ziegler (ed.), *Bestimmungen über die Beförderung radioaktiver Stoffe* (Provisions applicable to the transport of radioactive substances), NOMOS Publ., Baden-Baden.

10. Nuclear Third Party Liability

The operator of a nuclear installation is liable under the 1960 Paris Convention, ratified by Germany on 30 September 1975, and the 1963 Brussels Supplementary Convention, ratified on 1 October 1975, as supplemented by the provisions of the Atomic Energy Act [Atomic Energy Act, Section 25]. Germany has also been party to the 1971 Convention relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material since 1 October 1975.

A catch-all clause covers all other cases of liability; this clause is particularly relevant in the case of handling of radioisotopes and particle accelerators as well as for nuclear material not covered by the Paris Convention, *e.g.* transit through German territory of nuclear fuel being transported from the United States to Austria [Section 26].

The liability of the operator of a nuclear installation for damage occurring within Germany is unlimited, unless the incident was due to war, insurrection or a grave natural disaster, in which case liability is limited to the amount of the state guarantee, which is set at German deutsche marks (DEM) 1 billion. The maximum in the case of damage occurring abroad is determined in accordance with the principle of reciprocity. If the state in which the damage occurs does not have equivalent compensation arrangements in relation to Germany, a maximum of Special Drawing Rights (SDRs) 300 million applies if it is a Party to the Brussels Supplementary Convention, and SDRs 15 million in other cases [Section 31].

The licensing authorities are responsible for defining the nature, extent and amount of cover necessary to meet the legal liability for compensation (financial security), which is not to exceed DEM 500 million for nuclear installations or DEM 50 million for the transport of nuclear materials. These amounts must be covered by the operator liable through private financial security. Details are set out in the Financial Security Ordinance [Section 8(4)] pursuant to the Atomic Energy Act [Section 13].

The maximum amount of financial security of DEM 500 million is provided by a system consisting of two layers. Up to DEM 200 million is covered by third party liability insurance taken out by each operator. Between this amount and DEM 500 million, it is provided in the framework of a contract jointly subscribed to by all nuclear power plant operators in Germany.

For the purpose of implementing the second layer, the electricity generating companies operating nuclear power plants have set up a partnership under civil law. The partnership concluded a co-operative agreement and, on the basis of the latter, a contract with the six leading insurance companies in the Federal Republic of Germany to cover the remaining DEM 300 million. The operators have to pay an annual advance fee and a deferred premium. The advance fee is calculated on the basis of the nominal thermal power of the nuclear power reactors covered by the contract and distributed among the operators according to a scale fixed by the partnership agreement. The deferred premium (up to a total of DEM 300 million) falls due if compensation for nuclear damage has to be paid in excess of DEM 200 million and up to DEM 500 million. The deferred premium has to be paid by the operators (partners) according to the scale specified in the partnership agreement. Thus, the operators act as their own reinsurers.

The operator of a nuclear installation will be indemnified against claims for damages of up to DEM 1 billion to the extent that they are not covered by private financial security or cannot be paid out of such security. Such indemnification is borne as to 75% by the federal authorities and as to 25% by the *Land* within which the installation is situated [Atomic Energy Act, Sections 34 and 36].

In certain circumstances, the state will pay compensation for damage suffered in Germany following a nuclear incident in another country, if adequate compensation is not obtainable under the law of that country [Atomic Energy Act, Section 38]. Following the Chernobyl accident in 1986, guidelines were issued concerning the compensation to be paid to persons who had suffered damage [Equity Guidelines of 2 June 1986, BAnz 12 June 1986, No. 105, p. 7237; Guidelines of 21 May 1986, BAnz 27 May 1986, No. 95, p. 6417; Equity Guidelines of 24 July 1986, BAnz 2 August 1986, No. 140, p. 10388].

An Act which, *inter alia*, amends Annex 1 to the Atomic Energy Act was adopted on 6 April 1998 [BGBl 1998 I, p. 694]. This Annex, which contains the definitions applying to the liability chapter of the Act, is identical to Article 1(a) of the Paris Convention. Following the NEA Steering Committee's decision of 11 April 1984 [NE/M (84) 1], "installations for the disposal of nuclear substances" are included in the list and are now "nuclear installations" governed by the Paris Convention.

On 22 October 1986, an Agreement on Third Party Liability in the Nuclear Field was concluded between Germany and Switzerland to expressly declare reciprocity in regard to the amount of compensation and to provide for greater uniformity in the compensation regimes in the two countries [BGBl 1988, p. 598]. It entered into force on 21 September 1988.

Non-nuclear damage resulting from activities involving certain nuclear installations is covered by the Act on Liability for Damage to the Environment of 10 December 1990 [BGBl I, p. 2634] and by general tort law.

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities

Germany's federal structure plays a crucial role in implementing nuclear and radiation protection. As mentioned above, an amendment to the Constitution gave the *Bund* concurrent legislative power in the field of the peaceful use of atomic energy. Due to the special safety needs in this field, the *Länder* are responsible for enforcing existing federal legislation not on their own behalf but as agents for the *Bund* to the extent that the *Bund* has not established its own agencies for this purpose [Basic Law, Article 87(c) and Atomic Energy Act, Section 24(1)].

Implementation of the Atomic Energy Act and of ordinances to give effect to it by the *Länder* on behalf of the *Bund* has the following consequences:

- the establishment of the appropriate agencies remains the responsibility of the *Länder* except where federal legislation otherwise provides;

- the Federal Government, with the approval of the Federal Council can regulate general administration and the standardised training of officials and other employees;

- the *Land* authorities must comply with the directions of the supreme federal authorities (Federal Ministries), such directions to be addressed as a general rule to the supreme authorities of the *Länder*;

- federal supervision covers the legality and appropriateness of measures taken by the *Länder*; for this purpose the Federal Government may require the submission of reports and may inspect documents [Basic Law, Article 85].

The Atomic Energy Act defines the distribution of the administrative duties between the federal authorities and those of the *Länder* [Atomic Energy Act, Sections 22-24].

A. Federal Authorities

a) Federal Minister for the Environment, Nature Conservation and Nuclear Safety

The Federal Minister for the Environment, Nature Conservation and Nuclear Safety is responsible for nuclear safety and radiation protection pursuant to the Atomic Energy Act. He has the power to issue directions in this field and he supervises the legality and appropriateness of the acts of authorities responsible for enforcing the Atomic Energy Act and the Radiation Protection Ordinance [Basic Law, Article 85(3)].

The Federal Minister for the Environment, Nature Conservation and Nuclear Safety and the authorities of the *Länder* responsible for enforcing the Atomic Energy Act work together within the *Länder* Committee for Nuclear Energy (*Länderausschuß für Atomkernenergie*) [BAnz 1977, No. 206].

In carrying out his duties the Minister is advised by two commissions, namely the Reactor Safety Commission (*Reaktor Sicherheitskommission* – RSK) and the Radiation Protection Commission (*Strahlenschutzkommission* – SSK). The Nuclear Technology Committee (*Kerntechnischer Ausschuß* – KTA) was also set up to develop standards in the nuclear field. Its members represent all groups active in the nuclear field (nuclear operators, industry, etc.) and its Secretariat is part of the Federal Office for Radiation Protection which is under the authority of the Ministry for the Environment, Nature Conservation and Nuclear Safety.

Under the Act on Preventive Protection of the Public against Radiation (Preventive Radiation Protection Act) of 19 December 1986 [BGBl I, p. 2610], the Minister for the Environment, Nature Conservation and Nuclear Safety has power to fix dose levels, which may be implemented by ordinances jointly issued with other interested federal ministers [Sections 6 and 7]. The Minister also has exclusive power to issue recommendations to the population as to the conduct they should adopt following a nuclear incident, but must do so in close contact with other competent authorities of the *Bund* or *Länder* [Section 9].

In 1994, the Minister for the Environment, Nature Conservation and Nuclear Safety published a comprehensive list of the authorities which are competent in the field of nuclear licensing and nuclear surveillance in Germany, covering both federal authorities and authorities of the *Länder* [*Gemeinsame Ministerialblatt* 1994 No. 28, p. 838]. This list provides precise information about the powers of each authority and indicates the respective legal bases of those powers.

b) Federal Minister for Education, Science, Research and Technology

The Federal Minister for Education, Science, Research and Technology is responsible for nuclear research and for international co-operation in the nuclear field (with the IAEA, OECD/NEA and Euratom). He shares responsibility for nuclear liability matters with the Minister for the Environment, Nature Conservation and Nuclear Safety.

c) Federal Minister for Finance

The Federal Minister for Finance and the customs authorities answerable to him are responsible for supervising the import and export of nuclear fuels and other radioactive substances [Atomic Energy Act, Section 22(2), as amended by the Excise Duty and Single Market Act of 21 December 1992, Section 22].

d) Federal Minister for Transport

The German railway authorities designated by the Federal Minister for Transport are responsible for the supervision of the transport of radioactive substances by rail and by boat within Germany [Atomic Energy Act, Section 24(1)].

e) Federal Minister for Defence

The Federal Minister for Defence has the competence to license and supervise nuclear activities within the army, the navy and the airforce. As Germany does not have any nuclear weapons, these activities largely comprise the use of radioisotopes in the military field. The Minister for Defence acts in all cases in agreement with the Federal Minister for the Environment, Nature Conservation and Nuclear Safety [Atomic Energy Act, Section 24(3)].

f) Federal Office for Radiation Protection (BFS)

The Federal Office for Radiation Protection (*Bundesamt für Strahlenschutz* – BFS) is an independent federal authority (*selbständige Bundesoberbehörde*) within the portfolio of the Federal Minister for the Environment, Nature Conservation and Nuclear Safety [Law of 9 October 1989, as amended, BGBl I, p. 1830; 1998 I, pp. 694, 698]. It is responsible for:

- the official custody of nuclear fuels;
- the construction and operation of federal installations for the safe containment and final disposal of radioactive waste, including the transfer of these functions to third parties and their supervision;
- land-use planning decisions with regard to disposal facilities and their inspection after the function of final disposal of radioactive waste has been transferred to a corporate body in accordance with Section 9(a), paragraph 3, sentence 3 of the Atomic Energy Act;

- the licensing of the transport of nuclear fuels and other radioactive substances whose activity exceeds limits specified by the law, including withdrawal and revocation of such licences;

- performing of test procedures pursuant to Section 7(c) of the Atomic Energy Act;

- the licensing of the storage of nuclear fuels outside official custody;

- the establishment and maintenance of the Radiation Protection Register [Atomic Energy Act, Section 23(1)].

It also has administrative responsibilities, and undertakes scientific research in the fields of radiation protection, nuclear safety, transport of radioactive substances and radioactive waste management.

g) Federal Export Office

This body (*Bundesausfuhramt*), which is an independent federal authority (*selbständige Bundesoberbehörde*) within the portfolio of the Federal Minister for Economy, is responsible for the issue of import and export licences for nuclear material. In carrying out this function, it is bound by the technical instructions issued by the federal minister responsible for nuclear safety and radiation protection (the Minister for the Environment, Nature Conservation and Nuclear Safety) [Atomic Energy Act, Section 22(1); Act on the establishment of a Federal Export Office of 28 February 1992, BGBl I, p. 376].

B. Authorities of the *Länder*

Administrative duties (licensing and supervision) under nuclear and radiation protection law not performed by the federal authorities are exercised by the *Länder* on behalf of the *Bund,* subject to technical and legal supervision by the Federal Minister for the Environment, Nature Conservation and Nuclear Safety [Basic Law, Article 87(c) and Atomic Energy Act, Sections 19 and 24(2)].

For the purpose of enforcing nuclear and radiation protection law the *Länder* designate their authorities responsible in accordance with their own rules for determining competence. The *Länder* can make administrative regulations for the implementation of nuclear and radiation protection law; in practice, however, the guidelines and recommendations adopted by the *Länder* Committee for Nuclear Energy serve as the basis for decisions by the *Land* authorities.

The main duty of the authorities designated by the *Länder* is the issue of licences for the construction and operation of nuclear installations, notably power reactors. The licensing procedure however involves the participation of all competent federal, *Land* and local authorities. In the event of differences of opinion between the licensing authorities of the *Land* and a federal agency, the licensing authority must obtain directions from the Federal Minister for the Environment, Nature Conservation and Nuclear Safety [Atomic Energy Act, Section 7(4)].

2. Advisory Bodies

As part of the supervision by the Federal Minister for the Environment, Nature Conservation and Nuclear Safety of the legality and appropriateness of action by subordinate authorities, advisory bodies have been set up within the Ministry for that purpose.

a) Reactor Safety Commission (RSK)

i) Legal status

A Reactor Safety Commission (*Reaktor Sicherheitskommission* – RSK*)* was set up within the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and consists of some twelve members representing all specialist fields involved in nuclear safety [Notification of 22 December 1998, BAnz. 9 January 1999, p. 201].

ii) Responsibilities

The Commission is responsible for advising the Federal Minister for the Environment, Nature Conservation and Nuclear Safety on all matters concerning the safety of nuclear installations and related issues as well as in the field of radioactive waste management. The Commission thereby backs up the Federal Minister for the Environment, Nature Conservation and Nuclear Safety in exercising federal supervision over the *Länder* as regards the performance of tasks delegated to them by the *Bund*.

As a result of its deliberations the Commission issues recommendations and opinions, which require a majority of two-thirds of its members in the case of recommendations and opinions relating to the siting, design and commissioning of nuclear installations or to intermediate storage facilities for spent fuel elements. The Reactor Safety Commission has set out the safety requirements for the design, construction and operation of nuclear power plants equipped with pressurised water reactors in the form of guidelines. The latter are used as a basis for deliberations and recommendations in individual cases.

iii) Structure

The Federal Minister for the Environment, Nature Conservation and Nuclear Safety normally appoints the members of the Reactor Safety Commission for a period of three years, usually renewable for one further three-year term. Membership is a personal honorary office and as such cannot be delegated. Members are independent and may not receive instructions from any higher authority. In the event of bias the member concerned will be excluded from the deliberations of the Commission. In order to ensure that the Commission provides well-balanced advice, its members should represent the entire spectrum of views (*Brandbreite*) on the state of science and technology. The Minister has entrusted the Federal Office for Radiation Protection with the operation of the Secretariat of the Commission. This Secretariat functions independently from the Office.

iv) Financing

The Federal Minister for the Environment, Nature Conservation and Nuclear Safety is responsible for the financing of the Reactor Safety Commission and for reimbursement of the expenses of its members.

b) Radiation Protection Commission (SSK)

i) Legal status

A Radiation Protection Commission (*Strahlenschutzkommission* – SSK) has been set up within the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and is comprised as a rule of 14 well-known and experienced specialists from the fields of radiation biology, radiation genetics, radiation protection medicine, radiation protection technology, radiation physics, biophysics, radiochemistry and radioecology [Notification of 22 December 1998, BAnz 9 January 1999, p. 202]. In the same manner as the RSK, its members should represent the entire spectrum of views (*Brandbreite*) on the state of science and technology.

ii) Responsibilities

The Radiation Protection Commission is responsible for advising the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety on all major issues of radiation protection. It does not cover matters dealt with by the Reactor Safety Commission. The Radiation Protection Commission has six committees and specialist groups which help in the preparation of opinions and recommendations. The Commission was consulted with regard to the preparation of the Radiation Protection Ordinance of 13 October 1976 and subsequent amendments and has also in recent years issued a series of significant recommendations on basic radiation protection matters. It also gives its views via its Committee on Radiation Protection in Nuclear Installations on questions arising in connection with the licensing of nuclear installations.

iii) Structure

As for the SSK, the Federal Minister for the Environment, Nature Conservation and Nuclear Safety appoints the members of the Radiation Protection Commission for a period of three years. Reappointment for a consecutive period is possible only once. Membership is a personal honorary office. Members are independent and may not receive instructions from any higher authority. The Secretariat of the Commission, which is subject to instructions from the Minister, is provided by the Federal Office for Radiation Protection.

iv) Financing

The Federal Minister for the Environment, Nature Conservation and Nuclear Safety is responsible for the financing of the Commission and for reimbursement of the expenses of its members.

c) Nuclear Technology Committee (KTA)

The general reference in nuclear law to the state of science and technology means that the relevant rules and guidelines for deciding what that state is, are of decisive importance. Private associations and organisations, with objectives independent of those of the authorities, concern themselves with the definition of technical and scientific rules and guidelines.

i) Legal status

In 1972, in view of the multiplicity of existing bodies, a Nuclear Technology Committee (*Kerntechnischer Ausschuß* – KTA) comprised of experts reflecting the interests concerned was set up within the Federal Ministry for the Interior and is now attached to the Ministry for the Environment, Nature Conservation and Nuclear Safety. [Notification of 20 July 1990, BAnz 1990, No. 144; Procedural Rules of the KTA: BAnz 1986, No. 183].

ii) Responsibilities

The Committee is responsible in areas of nuclear technology where, on the basis of experience, specialists working for manufacturers, constructors and operators of nuclear installations, experts and the authorities consensually agree to prepare technical safety rules and to promote their application. Rules adopted by the Committee are published by the Federal Minister for the Environment, Nature Conservation and Nuclear Safety in the *Federal Bulletin*; proposed rules are published in the Bulletin before being adopted so as to give the public an opportunity to present their views.

iii) Structure

The Committee consists of fifty expert members in the following proportions:

- ten represent manufacturers and constructors of nuclear installations;
- ten represent operators of nuclear installations;
- ten represent the competent authorities of the *Länder* and of the Federal Minister for the Environment, Nature Conservation and Nuclear Safety;
- ten represent expert advisory bodies;
- ten represent various specified authorities, organisations and other bodies.

Members and their deputies are designated by the agencies they represent and appointed by the Federal Minister for the Environment, Nature Conservation and Reactor Safety for a period of four years. The office of member or deputy member is an honorary one. The Committee is led by a board and its business is conducted by a secretariat established within the Company for Nuclear Safety and run by a manager acting on the instructions of the board. The Committee establishes its own rules of procedure. The adoption of technical safety rules by the Committee requires a majority of five-sixths of its members. The rules must be published by the Federal Minister for the Environment, Nature Conservation and Nuclear Safety in the *Federal Bulletin.*

iv) Financing

Responsibility for the expenses of the Committee is borne in accordance with a general agreement between the Federal Minister for the Environment, Nature Conservation and Nuclear Safety and the three private interest groups.

3. Public and Semi-Public Agencies

a) Technological Surveillance Associations (TÜV)

The Technological Surveillance Associations (*Technische Überwachungsvereine* – TÜV) are autonomous economic bodies in the form of private registered associations. They exist in all the *Länder* and may be entrusted by the competent official bodies to act on their behalf with respect to the implementation of nearly all control and surveillance measures required by law in relation to technical equipment and installations. In the nuclear technology field the licensing authorities also as a rule entrust the Technological Surveillance Associations with the implementation of detailed safety inspections and the preparation of opinions and reports.

The Technological Surveillance Associations all belong to the private Union of Technological Surveillance Associations (*Vereinigung der technischen Überwachungsvereine eV*), and the latter body has in turn set up a central unit for nuclear technology (*Leitstelle Kerntechnik*). This unit issues instructions to ensure uniformity of controls and technological standards. Where there is disagreement on the application of these instructions, the *Länder* Committee for Nuclear Energy is responsible for ensuring uniformity of practice among licensing authorities in the *Länder*.

b) Company for Reactor Safety (GRS)

The Company for Reactor Safety *(Gesellschaft für Anlagen und Reaktorsicherheit mbH* – GRS*)*, whose headquarters are in Cologne, originated from the Institute for Reactor Safety of the Technological Surveillance Associations. Its founding members were the Federal Republic of Germany, the *Länder* of Bavaria and North-Rhine-Westphalia, several technological surveillance associations and *Germanischer Lloyd* Company. The Company for Reactor Safety has the prime duty of advising the Federal Minister for the Environment, Nature Conservation and Nuclear Safety in the performance of his supervisory duties over the *Länder* in implementation of the Atomic Energy Act. It is also responsible for collecting and evaluating knowledge on nuclear safety matters and participating in an expert capacity in nuclear licensing and supervisory proceedings.

c) Karlsruhe Research Centre for Technology and Environment

The Karlsruhe Research Centre (*Kernforschungszentrum Karlsruhe fur Technik und Umwelt GmbH*) was created in 1956 with the participation of the federal authorities, the *Land* of Baden-Württemberg and German industry. Following the transfer of the shareholding of industry to the federal authorities and the *Land* in 1963, the federal share has since 1972 been 90% and that of the *Land* of Baden-Württemberg 10%.

The Centre makes an important contribution to the development of German nuclear research and nuclear technology in co-operation with nearby universities and industry.

The main concerns of the Centre in the nuclear field are the technological development of heavy water reactors, fast breeders, uranium enrichment, reprocessing, final disposal of radioactive substances, and basic and safety research into fusion reactor technology.

d) Jülich Research Centre

The Jülich Research Centre (*Forschungzentrum Jülich GmbH*) was founded in 1967 by the federal authorities and the *Land* of North-Rhine-Westphalia. The Centre originated from a nuclear physics research establishment of the *Land* of North-Rhine-Westphalia set up in 1956. The federal authorities now have a 90% share in the company and the *Land* 10%.

The Centre's main concerns include the development of high temperature reactors, nuclear fusion, basic nuclear research and solid state physics.

e) GKSS Research Centre Geesthacht

The GKSS Research Centre Geesthacht (*Forschungszentrum Geesthacht GmbH*) was established in 1956 as the Centre for the exploitation of nuclear energy in shipbuilding and shipping (*Gesellschaft für Kernenergieverwertung in Schiffbau und Schiffahrt mbH* – GKSS).

The *Bund* have a 90% share in the company and the *Länder* of Schleswig-Holstein, Lower Saxony, Bremen and Hamburg a 10% share.

The GKSS began its work with the testing of engines for nuclear-powered ships, leading to the operation of the nuclear-powered research and trading vessel Otto Hahn from 1968 to 1979. Today the research and development programme of the GKSS covers the exploitation of the sea and the coasts as well as the use of nuclear energy. The nuclear side of its activities covers projects in the field of reactor safety and forms part of the reactor safety programme of the Federal Minister for Education, Science, Research and Technology.

f) Hahn-Meitner Nuclear Research Institute in Berlin (HMI)

The Institute (*Hahn-Meitner-Institut für Kernforschung Berlin GmbH* – HMI) began its scientific work in 1959 and since 1971 has become a major research establishment of the *Bund* and the *Land* of Berlin, which have 90% and 10% holdings respectively.

The Institute's research is directed mainly to heavy ion nuclear physics, nuclear solid state research, radiation and photochemistry, nuclear chemistry, and data processing and electronics.

g) The Electron-Synchrotron in Hamburg (DESY)

This Synchrotron (*Deutsches Elektronen-Synchrotron* – DESY) was set up in 1959 as a private law foundation. The *Bund* provides 90% of its financing, with the balance being provided by the *Land* of Hamburg.

DESY is mainly concerned with high-energy physics and elementary particle physics.

h) Max-Planck Institute for Plasma Physics at Garching/Munich (IPP)

The Institute (*Max-Planck-lnstitut für Plasmaphysik* – IPP) was established in 1960 and receives 90% of its financing from the *Bund* and 10% from the *Land* of Bavaria.

It deals mainly with plasma physics and controlled nuclear fusion.

i) Company for Heavy Ion Research (GSI)

The Company for Heavy Ion Research (*Gesellschaft für Schwerionen-forschung mbH* – GSI) was established in 1969 with headquarters in Darmstadt and receives 90% of its financing from the *Bund* and 10% from the *Land* of Hesse.

The GSI carries out research work on heavy ions in the fields of nuclear physics, nuclear chemistry and solid state physics.

j) Rossendorf Association for Nuclear Technology and Analysis

This Association (*Verein für Kernverfahrenstechnik und Analytik Rossendorf eV* – VKTA) is an establishment entirely financed by the Free State of Saxony. It disposes of waste from the nuclear facilities and nuclear material located at the Rossendorf research station, and undertakes practically oriented research on the disposal of radioactive waste and fissile material, as well as on the technology of processing radioactive substances. It also undertakes basic research on the environmental restoration of old waste disposal sites.

The VKTA runs the *Land*'s collection point for radioactive waste and the official intake measurement centre of Saxony.

HUNGARY

I. GENERAL REGULATORY REGIME

1. Introduction

At present there is one nuclear power station in Hungary, located at Paks, which is operated by Hungarian Power Companies Ltd. (*Magyar Villamos Müvek Reszvenytarsag*, formerly MVM, now MVM Rt.). The station's four units have a capacity of 1 840 MWe, generating about 40% of the country's domestic electricity production. The first Atomic Energy Act was promulgated in 1980 at the time of construction of this power station to ensure regulation of the industry. The four units at Paks came into service between 1983 and 1987 and have been subjected to what amounts to a continuous process of upgrading.

The legal regime applicable to nuclear activities in Hungary was previously governed by the Atomic Energy Act of 1980. On 10 December 1996, the Hungarian Parliament adopted a new Atomic Energy Act, which replaced the 1980 Act. The Atomic Energy Act of 1996 (hereinafter referred to as "the Act"), while preserving the basic principles of the 1980 Act, aims to conform to recent international rules and recommendations as promulgated by the International Atomic Energy Agency (IAEA) and the OECD Nuclear Energy Agency (OECD/NEA). It entered into force six months after its promulgation *i.e.* on 1 June 1997, with the exception of Sections 62-64 (concerning the Central Nuclear Financial Fund), which entered into force on 1 January 1998. As with the 1980 Act, different ministers are responsible for implementing the Act in their respective fields of jurisdiction by means of separate legal regulations. Until new regulations are brought into effect, the existing regulations continue to apply, with some exceptions where new regulations came into force on the same day as the Act itself. Thus, activities involving radioactive material continue to be regulated in detail by Ordinance No. 7 of 20 July 1988, adopted pursuant to the 1980 Act, although new regulations are under preparation.

The aim of the Act is not only to modernise Hungarian nuclear law, but also to harmonise Hungarian national law with international treaties to which Hungary is a party. The basic principles of the Act are to protect the population and the environment against the hazards generated by the peaceful uses of nuclear energy, and to improve the safety of all nuclear activities.

The Act provides that nuclear energy may only be used in the manner set out in legal regulations and under regular control by the authorities. The regulatory authorities are required under the Act to be independent from organisations having an interest in the promotion and development of the uses of nuclear energy [Section 5(2)].

The powers to implement the government's responsibility under the Act for the control and supervision of the safe utilisation of nuclear energy are vested in the Hungarian Atomic Energy Commission – HAEC (*Országos Atamenergia Bizottság*) and the Hungarian Atomic Energy Authority – HAEA (*Országos Atomenergia Hivatal*), as well as the ministers concerned

[Section 6(2)]. The HAEC is concerned with the development of policy, as well as the overall co-ordination and monitoring of activities in the nuclear field. Its members are comprised of senior officials of the ministries and public organisations performing regulatory tasks under the Act [Section 8]. The HAEA, on the other hand, is an authority and, as such, co-ordinates or performs the particular regulatory tasks necessary to ensure the safe application of nuclear energy [Section 17]. The responsibilities of the HAEA and HAEC are established in Government Decree No. 87/1997 (V.28) Korm.,[1] on Duties and Scope of Authority of the HAEC and on the Scope of Duty, Authority, and Jurisdiction for Imposing Penalties, of the HAEA. The Decree came into effect on 1 June 1997.

Various ministers and other authorities are responsible for enforcing those aspects of any particular licence granted by the HAEA which fall within their jurisdiction. These ministers and authorities and their relevant areas of competency for enforcement under the Act [Sections 19(2), 21-28 and 68] are described, *infra*, in Part II of this study "Institutional Framework", Section 1 "Regulatory and Supervisory Authorities".

2. Mining Regime

No radioactive ores are mined in Hungary and, accordingly, there is no legislation dealing specifically with the prospecting for and mining of such ores. General mining legislation would, therefore, apply (Act No. XLVIII of 1993, as amended by Act No. XII of 1997).

Under the Atomic Energy Act of 1996, the President of the Hungarian Mining Authority (*Magyar Bányászati Hivatal*) is empowered to enforce technical and safety aspects of mining, in so far as they relate to the activities licensed by the HAEA [Section 19(2)(h)] or licensed by the Minister for Health [Section 21(1)(g)].

3. Radioactive Substances, Nuclear Fuel and Equipment

The Act states, as a general principle, that the user of nuclear energy is responsible for its safe application and compliance with safety standards [Section 10(1)]. Furthermore, the user is expressly obliged to provide the resources required for the safe use of nuclear energy [Section 10(2)].

To ensure that the user properly carries out this responsibility, a general regime of licensing is provided for under Chapter III of the Act. Where not regulated by this Act, the provisions of Act No. IV of 1957 on the General Rules of State Administration Procedures apply to the use of nuclear energy [Section 12(1)].

As regards the general regime under the Act, the HAEA has a co-ordinating role in regulating nuclear activities [Section 17(1)]. It has general responsibility for activities such as accountancy and control of nuclear materials, licensing the transport of radioactive materials as well as approval and inspection of transport packaging, co-ordination of research and development related to the safe use of nuclear energy and co-ordination of international co-operation related to the use of nuclear energy [Section 17(2)].

As will be discussed below in more detail (see, *infra*, Section 4 "Nuclear Installations"), the HAEA has particular responsibility for licensing and supervision of nuclear facilities

1. "Korm." is the abbreviation of the Hungarian word for "government".

[Section 17(2)(a)] and nuclear equipment. It also monitors the existence of a quality assurance system as prescribed in Section 11(2) of the Act.

The Minister for Health has responsibility for the licensing and monitoring of a wide variety of other nuclear activities. These include the ownership, manufacture, possession, storage, use and distribution of radioactive materials, as well as, *inter alia*, the ownership and use of facilities and equipment generating ionising radiation [Section 20(1)(a) and (c)]. As will be discussed below in more detail (see, *infra*, Section 6 "Radiation Protection" and Section 7 "Radioactive Waste Management"), this Minister has particular responsibility for radiation hygiene and for radioactive waste disposal facilities [Section 20(1)(d)-(h)].

The Act does not apply to activities related to radioactive materials, nor to equipment which – due to the character and extent of ionising radiation that it can produce – does not qualify as hazardous to human life and health, or to the animate and inanimate environment [Governmental Decree No. 124/1997 (VII.18) Korm. on radioactive materials and equipment generating ionising radiation exempted from the scope of the Atomic Energy Act No. CXVI of 1996; Order of the Minister responsible for health No. 23/1997 (VII.18.) NM defining the exemption levels (activity concentrations and activities) of radionuclides].

In respect of both the licences issued by the HAEA and the licences issued by the Minister for Health, certain other ministers and authorities are empowered to enforce those aspects of the licence which fall within their jurisdiction. Similarly, there are provisions in the Act which give nominated ministers and authorities, some of which are the same as those nominated in the licensing provisions, the specific power to conduct inspections of or otherwise regulate those aspects of nuclear activities which fall within their jurisdiction. These various other ministers and authorities, and their respective areas of responsibility, are described in Sections 19(2), 21-28 and 68 of the Act.

In Hungary there is an itemised national accounting scheme, beginning with the production of radioactive materials, through to their disposal as radioactive waste. Under the executive orders of the Act, the Department of Nuclear and Radioactive Materials of the HAEA is responsible for the Central Registry of radioactive material as well as for the State System of Accountancy and Control of nuclear material through which the national accounting systems are maintained [Decree No. 25/1997 (VI.18) Korm.; Decree No. 39/1997 (VII.1) Korm.].

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

In the definition section of the Act, a nuclear facility is defined as including a nuclear power plant, a nuclear district heating plant and a nuclear reactor for research and training [Section 2(g)]. Parliament's preliminary approval is required to initiate activities for the construction of a new nuclear facility, or the addition of a further unit to an existing power plant [Section 7(2)].

Under the general regime of licensing, the HAEA is the regulatory body responsible for licensing the siting, construction, enlargement, commissioning, operation, modification, shutting down and decommissioning of a nuclear facility [Section 17(2)(a)]. In addition, the HAEA is the regulatory authority for licensing of structures connected to nuclear facilities [Section 17(2)(c)]. The processing period for each of these licences should not exceed six months [Section 12(2)].

The Act leaves many of the details of the regulatory scheme to be governed by separate regulations. Thus, a government decree was adopted to deal with nuclear safety and the procedures the HAEA should follow to ensure compliance with the legislation [Decree No. 108/1997 (VI.25) Korm.]. Under this decree, the Nuclear Safety Directorate (NSD) of the HAEA is nominated as the nuclear safety regulatory body, which makes decisions in the first instance in licensing, inspection and enforcement matters.

In respect of nuclear facilities, a permit from the NSD is required for: siting, construction (or enlargement), commissioning, operation, modification, permanent shutdown and decommissioning.

In respect of the equipment and nuclear fuel used in nuclear facilities, the NSD grants a general or specific permit for: manufacturing, importation, installation, commissioning (and operation), modification and decommissioning.

The NSD also grants permits for the construction, commissioning, maintenance, remodelling, rehabilitation, modification, expansion, use (other than for its original function) and demolition of nuclear buildings and structures.

In the interests of ensuring nuclear safety, the NSD is required, in all phases during the life cycle of nuclear facilities, to routinely inspect the following:

- the observance of provisions prescribed in applicable laws and regulations, including the quality assurance system of the nuclear facility;
- the fulfilment of conditions attached to licences; and
- the execution of instructions issued by the NSD.

The following nuclear safety regulations are set out in a five-volume appendix to the Decree, which describes the mandatory safety requirements for nuclear facilities:

- Regulatory Procedures of Nuclear Power Plants;
- Quality Assurance of Nuclear Power Plants;
- Design Requirements of Nuclear Power Plants;
- Operation Requirements of Nuclear Power Plants;
- Regulation of Research Reactors.

Under the Act, a licence may be granted for a limited or an unlimited period of time and may be issued subject to conditions. A licence granted for a limited period may be extended upon request. A licence becomes void if it expires, if the conditions set out in the licence are not complied with, or if the nuclear equipment or facility is continuously out of operation beyond a period specified in the licence. The HAEA may withdraw a licence or limit its period of validity if the Authority determines that there has been a change in the safety conditions and level of risk which had served as the basis for issuing the licence in the first instance. Similarly, the HAEA may withdraw a licence, or limit its period of validity, if modifications to a nuclear facility or to nuclear equipment or systems are in breach of the licence to undertake the modifications [Section 14]. It should also be noted that the area surrounding a nuclear facility may be designated an exclusion zone, with restrictions on mining, land

use and water usage [Sections 34-37]. Governmental Decree No. 213/1997 (XII. 1) Korm. on the exclusion zone of a nuclear facility and a radioactive waste disposal facility contains detailed provisions on this matter.

In addition to the enforcement powers set out above, the HAEA is obliged to monitor compliance with licence conditions and with safety regulations, keep records of inspections and, in the event of violations, may impose fines as prescribed by separate regulations [Section 15(1)-(4)]. The Act provides that no fine can be imposed beyond six months from the date the HAEA learns of the breach, or beyond two years from the date when the licensee should have complied with its obligations [Section 15(5)].

As part of the HAEA's licensing process, other relevant administrative bodies are authorised to participate within the scope of their responsibility as defined by separate regulations [Section 17(3)]. Some of the more important ministers and bodies involved in this process are expressly provided for, with reference in the Act to their areas of competence [Section 19(2)]. For details of their responsibilities see, *infra*, Part II of this Study "Institutional Framework", Section 1 "Regulatory and Supervisory Authorities". The applicant is obliged to attach the other prescribed regulatory licences and approvals to the licence application [Section 19(3)].

The Act also provides that the HAEA is responsible for the nuclear safety inspection of nuclear facilities [Section 17(2)(b)]. As with the licensing function, this is intended to be supplemented by inspection and regulatory powers granted under the Act to other specified ministers and administrative bodies with particular areas of interest, most of whom are referred to in the previous paragraph [Sections 22-26]. The details of these inspection powers are as determined in separate legal regulations.

In addition, it is necessary under the Act to obtain the relevant licence from the Hungarian Energy Office (*Magyar Energia Hivatal*), pursuant to Act No. XLVIII of 1994 on the Production, Transport and Supply of Electric Energy, for the construction and lawful operation of a nuclear power plant [Section 33].

Operators at the Paks nuclear plant receive between two and three years of classroom and on-the-job training. Operators must also successfully complete five weeks of simulator training on the plant's full-scope simulator before taking the qualifying examination. Once qualified, the operators receive a day of refresher training every five weeks and about 80 hours of simulator training every year. The regulatory requirements for education, training and retraining of employees is set out by Joint Ordinance No. 49 of 2 June 1998 of the Minister for Industry, Trade and Tourism and the Minister for Culture and Public Education.

Hungary was the first Eastern European country to request an Operational Safety Review Mission of its nuclear plant organised by the IAEA, which was followed by other international review missions *e.g.* on safety upgrading, independent peer review of probabilistic safety assessment etc. The general judgement was that the design of the Paks nuclear power plant is up to the safety level of other western nuclear power plants constructed at the same time and that it is operated in a safe manner.

At the international level, Hungary ratified the 1994 Convention on Nuclear Safety on 18 March 1996, and it concluded bilateral agreements with: Austria on the Regulation of Issues of Common Interest regarding Nuclear Facilities (25 August 1987), the Czech Republic and the Slovak Republic on Nuclear Safety and Radiation Protection (15 May 1991), as well as a multilateral agreement with Bulgaria, the Czech Republic, Finland, Poland, Russia and the Slovak Republic on Research on Reactor Safety (30 November 1990).

b) Emergency response

Chapter IV of the Act deals with measures for the prevention of abnormal events and the elimination of their consequences. The user of nuclear energy is obliged to take immediate appropriate measures if an abnormal event occurs in the course of its activities and the level of ionising radiation released is or may be higher than the level permitted by the authorities [Section 42].

The termination of an abnormal event, the investigation of its causes, and the execution of measures necessary to prevent its repeated occurrence are primarily the responsibility of the user of nuclear energy. In order to prevent the occurrence of a nuclear emergency, to respond to or limit the consequences of an event that has occurred, as well as to restore the situation, the user of nuclear energy is obliged to:

- prepare a plan for emergency preparedness and have it approved by the relevant authorities;
- establish the required conditions and verify the suitability of those conditions from time to time for an efficient emergency response; and
- co-operate with the relevant authorities to ensure adequate external assistance if the need arises [Section 43].

To the extent that the capabilities of the user of nuclear energy are exceeded in the event of a nuclear emergency, the necessary response measures become the responsibility of the authorities identified in the emergency preparedness and response plan [Sections 44 and 46].

Government Decree No. 135/1989 (XII.20) MT[2] establishes the National System for Nuclear Emergency Preparedness (hereinafter referred to as the "NSNEP"). The NSNEP is under the direction of the Government Commission for Nuclear Emergency Preparedness (hereinafter referred to as the "GCNEP"). For details, see, *infra*, Part II of this Study "Institutional Framework", Section 1 "Regulatory and Supervisory Authorities".

Under the Act, the user of nuclear energy is obliged to report all abnormal events, or any accident resulting in personal injury, to the mayor with jurisdiction over the area, or the county or Budapest office of the State Public Health and Medical Officer's Service (*Állami Népegészségügyi és Tisztiorvosi Szolgálat* – SPHMOS) with jurisdiction over the area, the police and the HAEA [Section 45]. The HAEA may stipulate further reporting obligations applying to nuclear facilities [Section 45(3)]. If the environment is contaminated there are additional authorities which must be notified [Section 45(1) and (2)].

The Act lays down the obligations of the State Public Health and Medical Officer's Service in the event of an emergency, to prevent the proliferation of radioactive contamination and to avoid radiation injury [Section 47].

Hungary is a party to the following conventions in the field of nuclear emergencies:

- 1986 Convention on Early Notification of a Nuclear Accident, ratified on 10 March 1987;

2 . "MT" is the abbreviation of the Hungarian word for "Council of Ministers".

- 1986 Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency, ratified on 10 March 1987;

- bilateral agreement with Germany on Early Notification of a Nuclear Accident (7 February 1991), and Slovenia on Early Notification of Radiological Emergencies (15 February 1996); similar agreements concluded with Romania and Ukraine entered into force on 24 February 1998 and on 25 February 1999 respectively. An Agreement on Early Notification of a Nuclear Accident was signed with Croatia.

5. Trade in Nuclear Materials and Equipment

Hungarian controls over the export and import of nuclear materials are in line with the provisions of the Treaty on the Non-Proliferation of Nuclear Weapons. The governmental decree on nuclear exports and imports [Decree No. 121/1997 (VII.17) Korm.] updates the previous Decree of 1986. It includes the requirements and the trigger list of the Nuclear Suppliers Group ("London Club"), as well as the list of materials and equipment covered by the Non-Proliferation Treaty ("Zangger Committee List"). It also takes into account the regulations of the European Union. The HAEA is responsible for the licensing of nuclear exports and imports [Section 17(2)(h)]. For details on licensing of transport and approval of packaging, see, *infra*, Section 9 "Transport".

6. Radiation Protection

The HAEA has responsibility for licensing nuclear equipment with regard to ionising radiation protection requirements, as well as for monitoring the quality assurance system prescribed under the Act [Section 17(2)(d) and (e) of the Act]. This function is performed by the Nuclear Safety Directorate of the HAEA, which is entitled to conduct inspections at licensees and suppliers premises [Decree No. 108/1997 (VI.25) Korm.].

The Minister for Health has responsibility for enforcing the health and radiation protection considerations arising from the activities licensed by the HAEA [Section 19(2)(f) of the Act]. In addition, through the State Public Health and Medical Officers Service, the Minister, as part of the radiation safety procedures, carries out:

- licensing and monitoring of all activities with radioactive materials; and

- licensing and inspection of non-nuclear facilities in which ionising radiation or radioactive material is utilised (including radioactive waste repositories) [Section 20(1)(a)-(d)].

The Minister also oversees radiation protection services established in facilities utilising nuclear energy, compliance with occupational safety requirements in the field of radiation protection and data collection and evaluation relating to the national radiation situation [Section 20(1)(e)-(h)].

The area surrounding a nuclear installation may be designated an exclusion zone, comprising restrictions on mining, and on land and water usage [Sections 34-37]

Ordinance No. 7/1988 (VII.20) SZEM of the Minister responsible for health of 20 July 1988 on radioprotection prescribes the health requirements and radiation protection standards applicable to all activities involving the use of atomic energy, in order to protect workers and the general public against the harmful effects of ionising radiation. The persons in charge of an establishment using atomic

energy are required to draw up internal rules on radiation protection [Section 9]. Such an establishment is required to have access to a radiation protection service [Section 10].

Maximum permissible doses of ionising radiation are set out for workers and certain members of the public [Section 5 and Annex 1]. Training of staff engaged in activities involving the use of atomic energy is also provided for [Section 7].

The 1988 Ordinance is under revision at the time of writing (1999).

7. Radioactive Waste Management

Under the Act, the Parliament's preliminary approval is required for the establishment of a new radioactive waste disposal facility [Section 7(2)].

The Minister for Health, through the State Public Health and Medical Officer Service, is responsible for licensing and monitoring the siting, construction, commissioning, operation, modification and closing of radioactive waste disposal facilities [Section 20(1)(d)]. Pursuant to Section 21 of the Act, other ministers and authorities are responsible for enforcing specified aspects associated with the licensing of the waste disposal facility. For details, see, *infra*, Part II of this Study "Institutional Framework", Section 1 "Regulatory and Supervisory Authorities".

A licence for the application of nuclear energy will only be granted if the safe interim storage or final disposal of the radioactive waste or spent fuel can be assured in accordance with the most recent scientific knowledge and experience [Section 38(1)]. Under the Act, the interim storage and final disposal of radioactive waste and spent fuel shall be considered safe if (a) the protection of human health and the environment is ensured during the whole period of these activities, and (b) the effect on human health and the environment is not higher beyond the country's borders than that accepted within the country [Section 38(2)].

Facilities for the interim storage or final disposal of spent fuel are nuclear facilities and the Nuclear Safety Direction (NSD) of the HAEA may regulate their operation. The interim storage of radioactive waste and spent fuel is licensed only for a limited period of time [Section 39]. In recognition of the importance of this issue on the national scale, the Act provides that the performance of tasks related to the final disposal of radioactive waste, as well as the interim storage and final disposal of spent fuel and decommissioning of a nuclear facility, will be restricted to an organisation designated by the government [Section 40].

The licensee is liable to cover the costs of the final disposal of radioactive waste, as well as the interim storage and final disposal of spent fuel (or, in the case of organisations funded by the national budget, the costs will be funded by the budget) [Sections 41 and 63(1)]. For this purpose the Central Nuclear Financial Fund (*Központi Nukleáris Pénzügyi Alap*) was established (as of 1 January 1998). The fund is managed by the HAEA and is a separate state fund pursuant to Act XXXVIII of 1992 on Public Finance, exclusively earmarked for financing the construction and operation of facilities for the final disposal of radioactive waste, as well as for the interim storage and final disposal of spent fuel, and the decommissioning of nuclear facilities [Section 62]. Payments into the fund by licensees of nuclear facilities will be determined in such a way that the fund fully covers all the costs arising from the waste management, interim storage and final disposal of spent fuel, both during the operation of the facility and at the time of its decommissioning [Section 63(2)]. In the case of a nuclear power plant, payments made by the licensees to the fund should be taken into account when pricing electricity [Section 63(4)].

Governmental Resolution No. 2414/1997 (XII.17) Korm. authorises the Director-General of HAEA to establish the Public Agency for Radioactive Waste Management (PURAM). In accordance with the relevant government decrees and resolutions [see Governmental Decree No. 240/1997 (XII.18) Korm. on establishment of the organisation designated for implementing radioactive waste disposal and spent fuel, as well as decommissioning of nuclear installations, and on the financial resources necessary to perform these tasks], the PURAM attends to the planning, construction and management duties associated with the storage and disposal of radioactive waste and spent fuel. It is also responsible for activities related to the decommissioning of nuclear facilities, as well as for the operation of the Püspökszilágy Radioactive Waste Treatment and Disposal Facility and the Interim Storage Facility for Spent Fuel located at the Paks Nuclear Power Plant. The PURAM's duties include preparation of the annual, intermediate and long-range plans for the Central Nuclear Financial Fund.

Detailed regulations for radioactive waste management are contained in Ordinance No. 7 of 20 July 1988 of the Minister responsible for health. A revision of this Ordinance was, at the time of writing (1999), under preparation. Some special geological aspects are regulated by the Order of the Minister of Industry, Trade and Tourism No. 62/1997 (XI.26) IKIM on the Geological and Mining Requirements for the Siting and Planning of Nuclear Facilities and Radioactive Waste Disposal Facilities.

In the past, spent fuel from the Paks plant was sent back to Russia for reprocessing. In 1992, however, Russia passed legislation prohibiting the import of foreign radioactive waste, and since that time the reshipment has required lengthy, case by case, negotiation. At the same time Ukraine became a transit state and a trilateral governmental agreement was concluded between the Russian Federation, Ukraine and Hungary to provide an appropriate legal framework for the shipments. With storage space in its spent fuel pools running low, and future acceptance of spent fuel by Russia uncertain, the Paks plant awarded a contract to GEC Alsthom Engineering Systems in 1992 for the construction of a modular vault dry storage system. The HAEC issued a licence for the commissioning of the facility in February 1997. The first fuel assemblies were received by the facility in September 1997. The operational licence was issued – in accordance with the changes in the licensing regime – by the HAEA for the first three modules in 1998.

In 1993, a national project was launched to select a site for the disposal of low and intermediate level waste from the nuclear power plant, and exploratory work is now under way to identify a site for detailed research. A site for a high-level waste repository in the Mecsek Mountains is also under preliminary study.

On 2 June 1998, Hungary ratified the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. It has also been a Party to the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter since 6 March 1976, following its ratification on 5 February 1976.

8. Non-Proliferation and Physical Protection

Hungary ratified both the 1968 Treaty on the Non-Proliferation of Nuclear Weapons, on 27 May 1969, and the 1996 Comprehensive Nuclear Test Ban Treaty, on 13 July 1999. It also ratified the 1979 Convention on the Physical Protection of Nuclear Material on 4 May 1984.

As a non-nuclear weapon state it has subjected all of its nuclear activities to the provisions of the safeguards agreement, which it signed with the IAEA on 30 March 1972, and obliged itself to keep strict accountancy and control of all nuclear materials. The Act and its executive orders make the

Director-General of the HAEA responsible for these actions. The General Nuclear Directorate (more precisely, the Department of Nuclear and Radioactive Materials) of the HAEA runs the State System of Accountancy and Control.

Hungary also contributes to the international control of nuclear materials through its export and import controls, which include the requirements and the trigger list of the Nuclear Suppliers Group, as well as the Zangger Committee list. It also takes into account similar regulations and controls of the European Union. Pursuant to Decree No. 121/1997. (VII.17) Korm issued under the Act, in the case of nuclear exports or imports, the prior approval of the Department of Nuclear and Radioactive Materials of the HAEA is required in the general licensing procedure for internationally controlled goods and technologies carried out by the Export Control Office of the Ministry for Economic Affairs.

Express provision is made in the Act for the guarding and protection of nuclear facilities. This is stated to be the responsibility of the licensee, as required in separate regulations, through the use of armed security guards [Section 30(1)]. In addition, the Act provides for the possibility of protection of nuclear facilities, pursuant to separate legislative provisions, by the national security services [Section 30(2)]. The Act empowers the police to monitor compliance with regulations relevant to public security and domestic order [Section 30(3)]. The police, pursuant to separate regulations, are also responsible for issuing an approval, as a special authority, for nuclear facilities and facilities used for the final disposal of radioactive waste [Section 30(4)]. Similarly, the police, under separate regulations, issue licences for transporting fresh and spent nuclear fuel within Hungary and across its borders [Section 30(5)]. Further details are governed by separate regulations, namely Order No. 47/1997. (VIII.26) BM of the Minister for the Interior on the tasks of the police in connection with the use of atomic energy.

9. Transport

The HAEA is responsible under the Act for the licensing of nuclear exports and imports, transport of radioactive materials in accordance with the regulations for the transport of dangerous goods, and for the approval and inspection of packaging of radioactive materials [Section 17(2)(h)-(j)]. The approval of the packaging and the notification of their transport are performed by the Department of Nuclear and Radioactive Materials of the HAEA, with the expert support of the Institute of Isotopes and the Surface Chemistry Research Centre of the Hungarian Academy of Sciences.

There are a number of relevant international transport regulations in force, implemented by the following:

- Ordinance No. 20/1979 (IX.18) of the Minister for Transport, Communication and Water Management, which implements the provisions of the European Agreement concerning the International Carriage of Dangerous Goods by Road;

- Ordinance No. 2/1982. (II.22) of the Minister for Transport, Communication and Water Management, which implements the provisions of the draft European Agreement on the International Carriage of Dangerous Goods by Inland Waterway; and

- Ordinance No. 12/1990. (IV.30) of the Minister for Transport, Communication and Water Management, which implements the provisions of the International Regulations concerning the Carriage of Dangerous Goods by Rail.

Further Ordinances by the Minister for Transport, Communication and Water Management include:

- No. 13/1997 (IX.3) KHVM on promulgation of the regulation on the safe transport by railway of spent nuclear fuel;

- No. 14/1997 (IX.3) KHVM on transport, carriage and packaging of radioactive material.

10. Nuclear Third Party Liability

Hungary was the first Eastern European State to become a Party to the 1963 Vienna Convention on Civil Liability for Nuclear Damage (accession on 28 July 1989) and to the 1988 Joint Protocol on the Application of the Vienna Convention and the Paris Convention (approved on 26 March 1990).

Chapter V of the Act implements these international obligations. Thus, there is strict liability, channelled to the licensee (operator) of the nuclear facility, for all nuclear damage, except as provided for by the Act [Sections 48(1) and 51]. In the case of international carriage, the location where the liability is transferred is required to be stated in the contract [Section 48(2)]. Exemptions from liability are limited to external causes (armed conflict, war, civil war, armed uprising or a grave natural disaster of an extraordinary character) or if the damage suffered by the injured party was caused by the injured party's gross negligence, or is the consequence of a wilful and unavoidable act or omission of the injured party which was expressly aimed at creating the danger [Section 49].

The liability of the licensee is limited to Special Drawing Rights (SDR) 100 million per nuclear accident arising in a nuclear facility, and SDR 5 million per accident arising during the transport or storage of nuclear fuel. Nuclear damage in excess of this amount will be compensated by the state, provided the total amount does not exceed SDR 300 million. Compensation will be paid in Hungarian currency, based on the official exchange rate with SDR [Section 52].

Where damage is caused by another event jointly with the nuclear accident, and the two cannot be separated, the damage caused by the other event will be classed as nuclear damage. Two or more nuclear facilities operated at the same site by the licensee will be treated as one nuclear facility for the purposes of compensation [Section 53(4)].

If there is nuclear damage falling outside the scope of the Act, the person responsible for the release of ionising radiation is liable therefor under Section 345 of the Civil Code [Section 53(1)].

The licensee is obliged to provide for insurance or another form of financial security up to the amount of compensation specified in Section 52 of the Act [Section 54(1)]. The insurer or financial guarantor is not permitted to suspend or cancel the insurance or financial security without giving at least two months notice in writing to the HAEA and the licensee [Section 54(2)], or in the case of carriage of nuclear materials, it may not be cancelled or suspended during the period of carriage [Section 54(3)].

The amount of liability under Section 52 of the Act does not include the interest and costs associated with the nuclear damage, as determined by the relevant court [Section 56(1)]. If the amount available for compensation is not enough to satisfy the entitlements of the injured parties, then the amount due to each of them will be reduced proportionately [Section 56(3)].

Injured parties may claim their right to compensation within a three year limitation period, commencing on the date when the injured party learned or could have learned of the occurrence of the damage and the identity of the licensee responsible; the licensee shall not be liable for damage after ten years from the date of the occurrence of the nuclear accident [Section 57(1) and (2)]. If the nuclear damage was caused by an abnormal event resulting from nuclear material which was stolen, lost, jettisoned or abandoned at the time of the abnormal event, the period of limitation shall commence from the date of the abnormal event, but shall not exceed twenty years from the date of the events listed [Section 57(3)].

No compensation is due to any party that has received full compensation for the same nuclear damage under any other cause of action [Section 59]. The Municipal Court of Budapest has exclusive jurisdiction to judge compensation claims under the Act [Section 65(1)] Governmental Decree No. 227/1997 (XII.10) Korm. on the features, conditions and amounts of the insurance or other financial security related to liability for nuclear damage provides for further details.

As regards insurance against nuclear liability claims, eleven Hungarian Insurers representing the vast majority of the Hungarian insurance market's non-life capacity, established the Hungarian Nuclear Insurance Pool at the end of 1996, the so-called "Hungarian Atomic Pool". The Pool is based on the fundamental principles common to all nuclear pools and is organised and managed by the Hungaria Insurance Co., the largest of such companies. The Hungarian Pool provides third party liability coverage for the Paks nuclear power plant in accordance with the Act. Property insurance is expected to be provided in the future as well. The Paks nuclear power plant is the first Russian designed plant to have third party liability insurance cover.

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities[3]

a) Hungarian Atomic Energy Commission (HAEC)

Under the Act, the Hungarian Atomic Energy Commission – HAEC (*Országos Atomenergia Bizottság*) as a governmental committee has various roles which are described in broad terms [Section 8(2)]. In its policy role, it is obliged to take a position on government proposals and programmes involving the use of nuclear energy and on issues of national and international significance related to regulating the use of nuclear energy, nuclear safety and radiation protection. It is also required to monitor international trends in the field of nuclear energy and make proposals to the

3. In addition to the ministers and authorities specifically listed, the building authority responsible for the area concerned is responsible for enforcing the general considerations related to regional planning and building. [Sections 19(2)(g) and 21(f)].

government for corresponding domestic measures [Section 8(2)(a)]. It co-ordinates activities related to the safe use of nuclear energy which fall within the scope of authority of the government, the HAEA and other bodies stipulated in the Act [Section 8(2)(b)]. Finally, in its role as controller, it monitors in particular the enforcement of regulations related to the use of nuclear energy, and, based on the findings arising out of its inspections, it initiates actions and makes proposals for amendment of the applicable legislation or draws up new draft legislation [Section 8(2)(c)].

The President of the HAEC is appointed by the Prime Minister. The members of the HAEC are senior officials of the Ministries and central public administration organisations performing regulatory tasks pursuant to the Act. They are appointed by the ministers and directors of the organisations concerned, with the agreement of the President of the HAEC [Section 8(1)]. The President of the HAEC presents an annual report to the National Assembly on the safety use of nuclear energy [Section 8(7)]. Presently, the President of the HAEC is the Minister for Economic Affairs, who performs this task independently of his responsibilities as minister.

b) Hungarian Atomic Energy Authority (HAEA)

The Hungarian Atomic Energy Authority – HAEA (*Országos Atomenergia Hivatal*) plays a central role in the regulation of the use of nuclear energy in Hungary [Section 6]. Pursuant to the Act, it regulates certain activities (in particular, the licensing of nuclear facilities) and co-ordinates the regulation of other activities by Ministries and administrative bodies specified under the Act and regulations [Sections 17 and 19].

The Director-General and the Deputies of the HAEA are appointed by the Prime Minister. The government exercises supervision over the HAEA through the President of the HAEC [Section 8(6)], who is one of the members of the government [Section 8(l)].

Within the HAEA, the Nuclear Safety Directorate (NSD) makes decisions in the first instance on licensing and enforcement matters. The Director-General of the HAEA is the decision maker in the event of an appeal against the decision of the NSD and there is the further possibility of a final appeal to the administrative court.

NSD established a multipurpose centre for emergency response, training and analysis (CERTA) equipped with hardware and software tools for independent analysis of abnormal events and accidents, giving estimations on duration of the incident and possible escalation of the consequences of accident scenarios by calculation of source term. The centre also serves for the training of regulatory staff members using simulators as well as providing them with Probabilistic Safety Assessment (PSA) based tools to assist in their everyday decision-making work.

The General Nuclear Directorate of the HAEA, through its Department of Nuclear and Radioactive Materials, runs the State System of Accountancy and Control of nuclear materials and the Central Registry of radioactive materials from their production to their disposal as radioactive waste.

The Division of Research and Development of the HAEA co-ordinates and supervises research and development in all fields of nuclear safety. It is also responsible for financing the scientific and technical work as support for the regulatory and nuclear emergency preparedness tasks.

c) Minister for Health

The Minister for Health has responsibility for the licensing and monitoring of a number of nuclear activities specified in the Act [Section 20]. These include the ownership, production, possession, storage, use, and distribution of radioactive materials, as well as, *inter alia*, the ownership and use of equipment generating ionising radiation [Section 20(1)(a) and (c)]. Of particular importance is the Minister's power to licence and monitor radioactive waste disposal facilities [Section 20(1)(d)] and to supervise occupational radiation protection services and other matters related to radiation hygiene [Section 20(1)(e)-(h)].

d) Minister for the Interior

The Minister for the Interior, through the offices of the National Police Force and the Fire Protection and Civil Defence Service, enforces those licensing aspects of nuclear facilities, nuclear equipment, radioactive materials and radioactive waste disposal facilities relating to public and domestic order, fire protection, physical protection, security, civil defence and nuclear emergency management [Sections 19(2)(a), 21(a) and 22].

e) Minister for Agriculture and Regional Development

The Minister for Agriculture and Regional Development, through the offices of the Animal Health and Food Control Stations, enforces those licensing aspects of nuclear facilities, nuclear equipment, radioactive materials and radioactive waste disposal facilities associated with the use of nuclear energy relating to food, plant and animal hygiene, as well as soil protection [Sections 19(2)(b), 21(b) and 23].

f) Minister for Economic Affairs

The Minister for Economic Affairs, through the Hungarian Geological Survey, enforces those licensing aspects of nuclear facilities, nuclear equipment, radioactive materials and radioactive waste disposal facilities relating to geology [Sections 19(2)(c) and 21(c)] and generally is responsible for the inspection of radioactivity of raw materials used or imported for the production of building materials [Section 24].

g) Minister for Transport, Communication and Water Management

The Minister for Transport, Communication and Water Management, in respect of HAEA licences, enforces those licensing aspects of nuclear facilities and nuclear equipment and radioactive materials associated with water utilisation, protection of ground water and mitigation of water damage [Section 19(2)(d)] and, in respect of licences issued by the Minister for Health, including licences issued for radioactive waste disposal facilities, enforces those aspects related to traffic and transport as well as the previously mentioned matters relating to water supplies [Section 21(e)].

h) Minister for the Environment

The Minister for the Environment, in respect of licences issued by the HAEA and by the Minister for Health, enforces those licensing aspects of nuclear facilities, nuclear equipment, radioactive materials and radioactive waste disposal facilities relating to environment protection, nature conservation and water quality protection [Sections 19(2)(e) and 21(d)] and is generally responsible for the inspection of the radioactive contamination of the air, land and water environments [Section 25].

i) Minister for Defence

The Minister for Defence, as detailed in separate regulations, is responsible in defence matters for the control of handling of radioactive materials, as well as for the construction, operation and closing down of military facilities and equipment which fall within the scope of the Act. In respect of the Hungarian Army, the Medical Officer's Service of the Army performs the same tasks handled by the Minister for Health in the civilian context under Section 20 of the Act, other than in respect of radioactive waste disposal facilities or the central collection and processing of data relating to a national radiation situation [Section 26].

j) Minister for Education

The Minister for Education is responsible for integrating into the National Master Curriculum the requirement to provide education on the scientific, technical and radiation protection aspects of the use of nuclear energy. The Minister also regulates higher and postgraduate education in the field of the application of nuclear energy in co-operation with the relevant professional institutions and ministers [Section 28].

k) President of the Hungarian Mining Authority

The President of the Hungarian Mining Authority (*Magyar Bányászati Hivatal*) is responsible for enforcing the technical and safety considerations relating to mining under the licence regime administered by the HAEA [Section 19(2)(h)] and the licensing regime administered by the Minister for Health [Section 21(g)].

l) President of the National Measurement Authority

The President of the National Measurement Authority (*Országos Mérésügyi Hivatal*), as determined in separate regulations, is required to perform the regulatory tasks related to measuring instruments in connection with the use of nuclear energy [Section 27].

m) Government Commission for Nuclear Emergency Preparedness (GCNEP)

The President of the GCNEP is the Minister for the Interior, the vice-presidents are the Minister for Defence and the Director-General of the HAEA, with the remainder of the membership comprised of other ministers and heads of organisations with national responsibilities in emergency preparedness. The constituent parts of the GCNEP are the Operative Staff, the Technical Scientific Advisory Board

and the Secretariat. Decision making is supported by the Emergency Information Centre of the GCNEP, by the National Environmental Radiation Monitoring System and by the Centre of Emergency Response, Training and Analysis (CERTA) of the HAEA. The HAEA also serves as the International Contact Point.

2. Advisory Bodies

Scientific Board

The Scientific Board is the advisory body of the HAEC and the HAEA on all matters of importance concerning the safe use of nuclear energy. It consists of prominent members of the Hungarian Academy of Sciences, research institutions and universities. It is convened two or three times a year under the chairmanship of the Director-General of the HAEA and formulates directives on current issues.

3. Public and Semi-Public Agencies

a) Institute for Electric Power Research (VEIKI)

VEIKI was established in 1964. It has been functioning as a company with share capital since 1 January 1993, with its shares being fully owned by the state. The capital of the company is Hungarian Forint (HUF) 330 million.

VEIKI is responsible for solving the operational problems of power plants (both conventional and nuclear). In the nuclear field its main duty is the independent evaluation of safety of VVER-type nuclear power plants, as well as the development of methods necessary for the evaluations. VEIKI acts as one of the technical support organisations of the HAEA**.**

About 10% of VEIKI's annual income comes from the state budget, with the major part of the remainder coming from contracts with domestic industry. Less than 10% of its budget is derived from international projects (PHARE, US DOE, IAEA, bilateral contracts).

b) Atomic Energy Research Institute (AEKI)

AEKI is one of the research institutes of the Hungarian Academy of Sciences. It is responsible for independent nuclear safety research in Hungary and for the operation of the Budapest Research Reactor. An additional responsibility of AEKI is to act as the technical support organisation of the HAEA.

The Institute is financed from multiple sources. The state budget provides about half of the income, with the other half coming from European projects (PHARE, etc.) and from commercial sources.

c) Hungarian Power Companies Ltd. (MVM Rt.)

The MVM company was restructured as part of the country's move towards a market economy. It became a company with share capital on 1 January 1992, with the government holding all the shares. MVM Rt. was a holding company with its subsidiaries consisting of eight generating corporations, six regional distribution corporations and one transmission system corporation. In April 1994, the Hungarian Parliament adopted a new electricity law, clearing the way for the sale of MVM Rt.'s non-nuclear subsidiaries.

In the last four years there were significant changes in the Hungarian power system and in the environment determining its operation. The system has been operating according to a new regulation since 1995. The first phase of privatisation, which concerned each of the six regional power distribution companies and six of the eight power plant companies, has been finished. The majority of these companies have become the property of trade investors. The nuclear power station (Paks Nuclear Power Plant Ltd.) and the transmission system company (National Power Line Company Ltd.) are almost 100% owned by MVM Rt. The new regulations and the privatisation created the necessary conditions for operating the electricity industry in a competitive environment. The transformation of the industry was performed without jeopardising the security of the consumers' supply.

According to the regulations in force, the basic role of MVM Rt. is to control the operation of the national power system, as well as electricity transmission and wholesale. This includes *inter alia* electricity export and import. MVM. Rt. purchases electricity from the power plants or import sources, and sells it to the distribution companies. During its operation, MVM Rt. must ensure the optimal utilisation of the power plants and the national grid, at the lowest possible cost.

ICELAND

I. GENERAL REGULATORY REGIME

1. Introduction

Bearing in mind that there are no nuclear power-generating installations in Iceland, activities involving the use of ionising radiation in this country are presently governed by two basic legal texts. The first is Radiation Protection Act No. 117/1985 (hereinafter referred to as the "Act") and the second text, based on the first, is entitled Regulations No. 356/1986 relating to safety measures against ionising radiation (hereinafter referred to as the "Regulations").

2. Mining Regime

There are no specific provisions governing uranium mining in Iceland.

3. Radioactive Substances and Equipment

It is not permitted to produce or import, own or sell, handle or deliver radioactive materials, (whether they are pure, mixed with other substances or built into equipment), or equipment capable of producing ionising radiation, without a permit [Article 10 of the Act]. Similarly, it is not allowed to commence or alter activities where radioactive materials or radiological equipment are used without a permit from the Icelandic Radiation Protection Institute (hereinafter referred to as the "Institute") [Article 19 of the Act and Article 17 of the Regulations].

The Minister of Health and Social Security is authorised to issue permits under Article 10 of the Act, and may, by regulations, also authorise such permits to be issued by the Institute. Applications for permits must be made using the special forms prepared by the Institute [Article 11 of the Act]. Article 2(2) of the Regulations authorises the Institute to issue such permits, but stipulates that the approval of the Minister must first be sought before granting a permit for a new technique or new use of radioactive materials and radiological equipment.

Before a permit is granted under the Act, the Institute must investigate whether the safety arrangements and the intended use of the relevant equipment and materials are in accordance with the Act, the Regulations or other rules based on these texts [Articles 4 and 18 of the Regulations].

Those who have been granted a permit are only allowed to sell, hire out, lend or transfer by any other means the relevant equipment and materials to parties who have acquired a permit from the Institute to use them. The transfer of the equipment and materials must be reported to the Institute immediately [Articles 5 and 17 of the Regulations].

Article 12 of the Act provides that a permit is not required for:

- radioluminous watches, pocket compasses, meters and other equipment of that nature containing a slight quantity of radioactive material;

- radar, television sets, electron microscopes and other equipment of that nature, provided that the equipment is not intended for the purpose of producing ionising radiation.

Radiological equipment and radioactive materials used for diagnostic or therapeutic purposes are to be owned by recognised health, research or educational establishments, or by physicians, dentists and veterinary surgeons [Article 13 of the Act]. The owner bears responsibility for the use of radioactive materials and radiological equipment. When used for diagnosis or treatment they shall be operated under the supervision and under the professional responsibility of a physician, veterinary surgeon or dentist [Article 20 of the Act and Article 19 of the Regulations]. The professionally responsible person, or another person designated by him/her, shall ensure that the operation and use of the materials and equipment are in accordance with the legislation [Article 20 of the Regulations].

Only those persons who have the necessary knowledge and experience, in the view of the Institute, are permitted to carry out repairs and install or make changes to radiological equipment [Article 6 of the Regulations]. Those who carry out such activities shall ensure that legal safety requirements for the equipment have been met, and shall immediately report to the Institute if this is not the case [Article 7 of the Regulations]. Those who intend to install or make changes to radiological equipment must submit a proposal on the prescribed form to the Institute, and may not proceed with the work until approval has been obtained [Article 14 of the Act and Article 8 of the Regulations].

Similarly, any person intending to commence or alter an activity where radioactive materials and radiological equipment are used shall send an application for a permit to the Institute, together with plans for the proposed operation or alterations with detailed information. When radioactive materials and radiological equipment are taken out of use, the Institute must be notified without delay [Article 19 of the Act and Article 17 of the Regulations].

For further details of the Institute's control over radiological equipment and radioactive materials, see Section 6 "Radiation Protection", *infra.*

4. Nuclear Installations

There are no nuclear installations in Iceland, and no legislation in this respect.

5. Trade in Nuclear Materials and Equipment

The Institute is empowered to control the import, packing and customs inspection of radioactive materials [Article 2(5) of the Regulations]. Customs inspections of consignments containing radioactive materials are to be undertaken in the presence of a qualified person from the Institute, if requested by the Director of Customs or his representative [Article 13 of the Regulations].

6. Radiation Protection

The Institute exercises control over radiological equipment and radioactive materials through general periodic inspections of the equipment and materials and of the factors (such as use of lead aprons at X-ray departments of hospitals) that influence the safety of personnel, patients and others that might be exposed to ionising radiation. For this purpose the personnel of the Institute have unlimited access to any place where such equipment and materials are used or stored. This control is aimed at keeping exposures as low as reasonably achievable. This control is also exercised through education and training on radiation protection and on the use of equipment and substances. The owner of equipment or materials may request an extra inspection without charge [Article 15 of the Act and Article 9 of the Regulations]. Registered owners of equipment or materials subject to inspection must pay a special fee to defray the cost of the inspection.

The owners of radiological equipment and radioactive material are required to carry out any adjustments deemed to be necessary by the Institute. If the adjustments are not made within the required time, the Institute may forbid any further use of the equipment or materials until such adjustments have been carried out [Article 16 of the Act and Article 10 of the Regulations]. Similarly, if safety arrangements are so insufficient that they can lead to danger, the Institute may forbid any further use of the equipment and materials until the situation has been remedied [Article 17 of the Act and Article 11 of the Regulations].

During the design and construction of a building or facilities where radioactive materials or radiological equipment are to be used, the Institute must be consulted as to whether the proposed building, facilities or other equipment satisfies the requirements relating to radiation protection [Article 21 of the Act and Article 22 of the Regulations]. All places where radioactive materials and radiological equipment are used shall be clearly marked with warning signs in accordance with instructions from the Institute [Article 23 of the Regulations].

Only those who are suitably qualified and experienced, in accordance with the requirements of the Institute, are allowed to work or supervise work with radioactive materials and radiological equipment [Articles 21 and 24 of the Regulations].

The Institute is authorised to control and undertake research into the doses received by personnel, patients and the public arising from the use of ionising radiation [Article 7(2) of the Act and Article 2(3) of the Regulations]. In co-operation with the Director General of Health, the Institute is required to lay down rules on the medical examination of employees working with ionising radiation [Article 26 of the Regulations]. As a preventive safety measure, the Institute is also authorised to provide training in radiation protection for personnel exposed to ionising radiation, and to supply information to the public and the media [Article 7(1) of the Act and Article 2(7) of the Regulations].

The Institute participates in a European emergency procedure which guarantees mutual notification in the event of a radiation hazard [Article 2(10) of the Regulations]. Similarly, it participates in Nordic and international co-operation in the sphere of radiation protection [Article 2(12) of the Regulations].

Iceland ratified the 1986 Convention on Early Notification of a Nuclear Accident on 27 September 1989.

7. Radioactive Waste Management

Under the Regulations, the Institute is empowered to control, *inter alia*, the removal and disposal of radioactive materials [Article 2(5) of the Regulations]. The Institute must be consulted on such activities, and its rules and Instructions must be followed [Article 16 of the Regulations].

The Icelandic rules regarding radioactive waste are based on the Nordic document entitled "Application in the Nordic Countries of International Radioactive Waste Recommendations" (published by the Radiation Protection Institutes in Denmark, Finland, Iceland, Norway and Sweden in 1986).

Iceland ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter on 24 May 1973.

8. Non-Proliferation and Physical Protection

Iceland became a party to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (NPT) on 18 July 1969.

Radioactive materials must always be stored in a reliable and safe place. The Institute is empowered to lay down further rules concerning the construction and equipment of these storage facilities. Places where radioactive materials or equipment that makes use of ionising radiation are stored must carry warning signs as specified by the Institute [Article 15 of the Regulations].

9. Transport

During transport, radioactive materials must be kept in reliable containers in order to ensure that such materials are not emitted into the environment, even if the container suffers damage. Radiation doses emitted during transport must conform to the recommendations of the International Commission on Radiological Protection. Consignments must indicate the chemical form and quantity of the radioactive substance, together with the names and addresses of the consignor and consignee. All documents relating to transport must specify that the consignment contains radioactive materials [Article 14 of the Regulations].

10. Nuclear Third Party Liability

There are no specific provisions in Icelandic legislation governing nuclear third party liability.

II. INSTITUTIONAL FRAMEWORK

Regulatory and Supervisory Authorities

a) Minister of Health and Social Security

The Minister of Health and Social Security is primarily responsible for radiation protection in Iceland. This responsibility is carried out directly, through the issue of permits under the Act, and indirectly through the Icelandic Radiation Protection Institute. The Minister has the power to request the Institute to address particular problems in this field, and the power to regulate the implementation of the Act, the operation of the Institute and the control exercised by the Institute.

b) Icelandic Radiation Protection Institute

The Icelandic Radiation Protection Institute (*Geislavarnir ríkisins*) is an independent entity under the authority of the Minister of Health and Social Security. The Institute is responsible for the establishment of safety measures to protect against the hazards of ionising radiation which may be emitted from radioactive materials and radiological equipment.

The Minister of Health and Social Security appoints a board of governors, which consists of three persons who hold special qualifications relating to the duties of the Institute. The Minister appoints the chairperson among the three members of the board of governors. The board is appointed for a period of four years. The Minister also appoints the director of the Institute on the recommendation of the board of governors.

Both the Act and the Regulations set out in some detail the responsibilities of the Institute. They include:

- training in radiation protection for personnel exposed to ionising radiation, as well as the supply of information to the public and the media;
- control of and research into doses received by personnel, patients and the public arising from the use of ionising radiation;
- control of the installation and modification of X-ray equipment and other radiological equipment;
- control of import, packing, customs inspection, removal and disposal of radioactive materials;
- control of and research into environmental radioactivity, radioactivity in food and related fields;
- research in the field of radiation protection;

- participation in a European emergency procedure in the event of a radiation hazard, as well as in international co-operation in the field of radiation protection; and

- other tasks as decided by the Minister.

c) Civil Defence Authority

This is a regulatory authority which is responsible for taking appropriate action when life or property is threatened in an acute manner, including in the case of radiological emergencies.

d) Food Agency

This authority is empowered to issue rules with regard to acceptable levels of radioactivity in food. It co-operates closely with the Institute.

IRELAND

I. GENERAL REGULATORY REGIME

1. Introduction

The framework legislation governing the nuclear and radiation protection sectors in Ireland is the Radiological Protection Act of 11 May 1991 [No. 9 of 1991]. This Act repealed the Nuclear Energy Act, 1971.

The Radiological Protection Act, 1991 was amended by Section 26 of the Energy (Miscellaneous Provisions) Act, 1995 and by Section 65 of the Food Safety Authority of Ireland Act, 1998. References in this study to the Radiological Protection Act, 1991 should be construed as references to the Radiological Protection Act, 1991, as amended. Sections of the 1991 Act referred to in this study which were amended by the 1995 and 1998 Acts are identified accordingly.

Before 1991, the Nuclear Energy Act, 1971 [No. 12 of 1971] was the central piece of legislation on nuclear matters, giving major responsibility to the then Minister for Industry and Energy, who was advised and assisted by the then Nuclear Energy Board. Under the Radiological Protection Act, 1991, as amended, the Minister for Public Enterprise has the major ministerial role in relation to nuclear and radiological protection matters. The Radiological Protection Institute of Ireland established under that Act, and which replaced the Nuclear Energy Board, is the national expert body responsible for, *inter alia*, advising the Minister and the government on nuclear safety and radiological protection matters and for regulating, in particular through advance licensing, the custody, use, manufacture, transportation, disposal etc. of radioactive substances, irradiating apparatus and other sources of ionising radiation.

The Radiological Protection Act, 1991, as amended, sets out the functions of the Radiological Protection Institute of Ireland as well as the functions of the Minister for Public Enterprise. It also sets out specific responsibilities of other government ministers and the functions of the Food Safety Authority, essentially in regard to the protection of individuals from radiological hazards in food.

The Radiological Protection Act, 1991, as amended, would apply to nuclear installations as well as radioactive substances and irradiating apparatus [Section 2]. However, Section 18(6) of the Electricity Regulation Act, 1999 prohibits the construction of a nuclear power plant in Ireland and there are no nuclear installations in this country at the present time.

The other legislation directly relating to or impinging on nuclear matters and radiological protection is as follows:

- Health Act, 1953 [No. 26 of 1953];
- Safety Health & Welfare at Work Act, 1989;

- Dumping at Sea Act, 1996;
- Harbours Act, 1996;
- Electricity Regulation Act, 1999;
- European Communities (Medical Ionising Radiation) Regulations, 1988 [S.I.[1] No. 189 of 1988] and the European Communities (Ionising Radiation) Regulations, 1991 [S.I. No. 43 of 1991];
- European Communities (Vocational Training for Drivers of Vehicles Carrying Dangerous Goods) Regulations, 1992 [S.I. No. 204 of 1992];
- European Communities (Protection of outside workers from Ionising Radiation) Regulations, 1994 [S.I. No. 144 of 1994];
- European Communities (Supervision and control of certain shipments of radioactive waste) Regulations, 1994 [S.I. No. 276 of 1994];
- European Communities (Radiological and Nuclear Medicine Installations) Regulations, 1998 [S.I. No. 250 of 1998];
- European Communities (Minimum requirements for vessels carrying dangerous or polluting goods) (Amendment) Regulations, 1998 [S.I. No. 3 of 1998];
- European Communities (Minimum requirements for vessels carrying dangerous or polluting goods) (Amendment) Regulations, 1999 [S.I. No. 96 of 1999];
- Radiological Protection Act, 1991 (General Control of Fissile Fuels, Radioactive Substances and Irradiating Apparatus) Order, 1993 [S.I. No. 151 of 1993].

2. Mining Regime

There are no specific provisions governing uranium mining in Ireland.

3. Radioactive Substances, Nuclear Fuel and Equipment

The Radiological Protection Act, 1991, as amended, provides that the Minister for Public Enterprise may, after consultation with the ministers concerned, make orders regulating the use of radioactive substances and equipment [Section 30]. At present, the main legislation dealing with these matters is the Radiological Protection Act, 1991 (General Control of Fissile Fuels, Radioactive Substances and Irradiating Apparatus) Order, 1993 [S.I. No. 151 of 1993]. The Order provides that the custody, use, manufacture, import, export, distribution, transport or other activity involving fissile fuels, radioactive substances and devices, and irradiating apparatus is permitted only under a licence issued by the Radiological Protection Institute of Ireland. The Institute may attach to any licence under

1. S.I.: Statutory Instrument.

this Order any conditions it considers necessary, and may do so either at the time of issue of the licence or later.

Applications for a licence, which must be made to the Institute, must contain the particulars required on the planned activity so as to enable the Institute to assess the application. It may ask for additional information relating to the suitability of the applicant in the safe use and handing of the fuel, substance or device that is the subject of the application.

The Institute may, at its discretion, refuse or revoke a licence if, in its opinion, this is necessary to ensure the protection of persons or property against hazards arising from fissile fuels, radioactive substances, devices, or irradiating apparatus.

Products (except toys, foodstuffs, household products, medicinal products, cosmetics, etc.) whose activity level do not exceed certain limits as provided by the Order, are excluded from the scope of the Order.

Section 26 of the Energy (Miscellaneous Provisions) Act, 1991 amends Section 7 of the Radiological Protection Act, 1991 dealing with the general functions of the Radiological Protection Institute of Ireland. It removes the restrictions imposed on the functions of the Institute on the use of ionising radiation for medical purposes.

At the international level, Ireland ratified the 1994 Convention on Nuclear Safety on 11 July 1996.

4. Nuclear Installations

There are no nuclear installations in Ireland.

5. Radiation Protection

a) Radiation protection standards

Legislative provisions relating to the protection of workers and the public from radiation are contained in a number of different Acts and Regulations. The most important of these are the Radiological Protection Act, 1991, as amended, and the following Regulations; the European Communities (Medical Ionising Radiation) Regulations, 1988 [S.I. No. 189 of 1988]; the European Communities (Ionising Radiation) Regulations, 1991 [S.I. No. 43 of 1991]; and the European Communities (Radiological and Nuclear Medicine Installations) Regulations, 1998 [S.I. No. 250 of 1998]. Other relevant provisions that deal more generally with health and safety are to be found in the Safety, Health and Welfare at Work Act, 1989 and the Health Act, 1953.

The Radiological Protection Act, 1991, as amended, confers extensive powers in relation to the protection of agriculture, livestock, fisheries and water supplies. Under Section 31 of the Act, as amended by Section 65 of the Food Safety Authority of Ireland Act, 1998, the Minister for Public Enterprise may prescribe acceptable levels of radioactivity in respect of animals, fauna, poultry, eggs, crops, fish etc. intended for human consumption or any food. For the purpose of protecting individuals from the risk of radioactivity contained in food in circumstances where specified levels of activity are, or are likely to have been exceeded, the Minister for Agriculture, Food and Rural Development, the

Minister for the Marine and Natural Resources, the Minister for Health and Children and the Minister for Finance in co-operation with the Food Safety Authority of Ireland are given wide regulation-making powers in respect of the harvesting and movement of crops, slaughter of animals, taking of fish, sale and export of food, and taking and sale of fauna [Section 32, as amended by Section 65 of the Food Safety Authority of Ireland Act]. The responsible ministers are empowered to order the slaughter of animals and destruction of food products where the prescribed levels of activity have been exceeded [Section 32, as amended]. These provisions are designed to protect individuals and the public in general from radiological hazards.

Another element in the legislative framework of protection of the public is the power of the Institute, the Food Safety Authority of Ireland and specified ministers to appoint inspectors [Section 28 of the Radiological Protection Act, 1991, as amended] authorised to obtain information, take samples, enter premises, evacuate land or buildings and take control of any radioactive substance, nuclear device or irradiating apparatus [Section 29].

The European Communities (Ionising Radiation) Regulations, 1991 [S.I. No. 43 of 1991] were made to give effect to Council Directive 80/836/EC of 15 July 1980 (as amended) amending the Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionising radiation. The Regulations apply to persons ("persons responsible") involved in the production, processing, handling, use, transport, storage etc. of radioactive substances or any other activity involving a risk of ionising radiation [Regulation 3]. The Regulations specify dose limits for various categories of workers and members of the public. If these doses are to be exceeded, the person responsible must follow certain procedures designed to protect employees, and must seek the authorisation of the Radiological Protection Institute of Ireland [Regulation 8]. However, even where dose limits are not exceeded, persons responsible are obliged to keep all exposures as low as reasonably achievable (the ALARA principle, established by the International Commission on Radiological Protection) [Regulation 5].

The European Communities (Medical Ionising Radiation) Regulations 1988, [S.I. No. 189 of 1988] and the European Communities (Radiological and Nuclear Medicine Installations) Regulations, 1998 [S.I. 250 of 1998] give effect to Council Directive 84/466/Euratom of 3 September 1984, laying down basic measures for the radiation protection of persons undergoing medical examination or treatment. The 1998 Regulations establish criteria of acceptability for radiological and nuclear medicine installations. It gives effect to the provisions of the Council Directive 84/466/Euratom relating to efficiency of such installations and their equipment. The two basic principles expressed by the 1998 Regulations are that the exposure of a patient to ionising radiation must be medically justified [Regulation 3] and that the dose to the patient must be as low as is reasonably achievable [Regulation 4]. The Regulations make it an offence for a person to expose a patient to ionising radiation in the course of medical or dental treatment, unless that person has completed a course of training in radiation protection techniques [Regulations 5, 7 and 10]. Medical and dental practices must meet the requirements under the 1998 Regulations and the 1991 Regulations (referred to above). The 1991 Regulations require the authorisation of the Radiological Protection Institute of Ireland before a medical or dental practice may begin to expose patients to radiation [Regulation 4(4)], and give the Institute a continuing supervisory role [Regulation 4]. On the other hand, the Medical Council and the Dental Council are given the function, under the 1988 Regulations, of ensuring that practitioners have been adequately trained in radiation protection and techniques [Regulations 5, 6 and 7].

The European Communities (Protection of outside workers from ionising radiation) Regulations, 1994 [S.I. No. 144 of 1994] implements Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising

radiation during their activities in controlled areas. The Regulations provide for the radiation protection of workers liable to be exposed to high doses of radiation while working away from their employers' premises. The Regulations also apply to workers who come from, or who go to work in, another Member State of the European Union.

General occupational health and safety provisions are to be found in the Safety, Health and Welfare at Work Act, 1989. The Act covers all aspects of health and safety at work, including nuclear hazards. It establishes the Health and Safety Authority (HSA). Employers are required to identify and assess risks in the workplace and to establish consultation mechanisms between employers and employees.

b) Emergency response

At the international level, Ireland ratified both the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency and the 1986 Convention on Early Notification of a Nuclear Accident on 13 September 1991. One of the purposes of the Radiological Protection Act, 1991, as amended, is to give effect to the provisions of these two Conventions. The Radiological Protection Institute of Ireland is statutorily responsible under Section 7 of the 1991 Act for assisting in radiological emergency planning and for the implementation of measures to deal with such emergencies. The Institute is also responsible for giving assistance to and co-operating with other states in the event of a radiological emergency. The 1991 Act, as amended, also gives specific powers to inspectors in the event of any suspected radiological hazard [Section 29(2)], and extensive powers to ministers to order the slaughter of animals, destruction of crops, etc., or other food and disposal of the remains, when specified levels of radioactivity have been exceeded [Section 33, as amended by Section 65 of the Food Safety Authority of Ireland Act 1998].

A person who is licensed by the Institute under the 1991 Act, as amended, to deal with radioactive material is obliged under Section 34 of the Act to notify the Institute of any accident, loss or theft of any such material.

7. Radioactive Waste Management

One of the general functions of the Radiological Protection Institute of Ireland is to advise the government on radiological safety matters, including the disposal of radioactive substances [Radiological Protection Act, 1991 Section 7(1)(d)]. More specifically, the Minister for Public Enterprise has the power, after consultation with the various ministers concerned to make an order regulating the disposal of radioactive substances [Section 30(1)]. The order may prohibit disposal, save under licence issued by the Institute.

The Radiological Protection Act, 1991 (General Control of Fissile Fuels, Radioactive Substances and Irradiating Apparatus) Order, 1993 [S.I. No. 151 of 1993], which repealed and replaced the Nuclear Energy (General Control of Fissile Fuels, Radioactive Substances and Irradiating Apparatus) Order 1977, provides that activities involving radioactive waste products, including transport, may not be carried out without a licence from the Institute. The licence, which may be subject to conditions, is issued for a limited period and may be revoked by the Institute when the conditions of the licence are not being met.

The European Communities (Supervision and Control of Certain Shipments of Radioactive Waste) Regulations, 1994 [S.I. No. 276 of 1994] provide for the implementation of Council

Directive 92/3/Euratom of 3 February 1992 on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community, whenever quantities and concentrations of such waste exceed certain levels. The provisions of these Regulations governing such shipments supplement the existing Council Directives on basic safety standards for the health protection of workers and the general public against the dangers of ionising radiation.

The Dumping at Sea Act 1996 enforces strict new limitations on the types of substances that can be dumped at sea, with an express prohibition against the disposal of radioactive substances or materials irrespective of their activity level. The Act also extends the limit of Ireland's control from 12 miles up to 200 miles off the Irish coast and in some areas up to 350 miles off the Irish coast.

In this respect, it is relevant to note that Ireland ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter on 17 February 1982.

8. Non-Proliferation and Physical Protection

Ireland ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 1 July 1968 and the Comprehensive Nuclear Test Ban Treaty on 15 July 1999. It also ratified the1979 Convention on the Physical Protection of Nuclear Material on 6 September 1991.

9. Transport

The transport of radioactive materials in Ireland is prohibited save under licence of the Radiological Protection Institute of Ireland [Radiological Protection Act, 1991, Section 30]. The instrument setting out the current system of regulation is the Radiological Protection Act 1991 (General Control of Fissile Fuels, Radioactive Substances and Irradiating Apparatus) Order, 1993 [S.I. No. 151 of 1993]. The Order provides that the transport of fissile fuel and other radioactive materials, including their import and export, can only be undertaken with a licence issued by the Radiological Protection Institute of Ireland. The licence may be made subject to whatever conditions the Institute considers necessary. These licence conditions specify general safety measures that must be observed by the licensee and require in particular that the radioactive material be shielded, packaged and transported in accordance with the International Atomic Energy Agency's Regulations for the Safe Transport of Radioactive Material.

Ireland has ratified the International Convention concerning the Carriage of Goods by Rail (CIM) and the licence granted by the Radiological Protection Institute of Ireland will, where appropriate, specify that the provisions of the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID) which form Annex I of the Convention, be respected.

The maritime carriage of radioactive materials is undertaken in accordance with the Merchant Shipping (Dangerous Goods) Rules, 1992 [S.I. No. 391 of 1992] which was made under the Merchant Shipping (Safety Convention) Act, 1952 [No. 29 of 1952] and the European Communities (Minimum Requirements for Vessels Carrying Dangerous or Polluting Goods) Regulations, 1995 [S.I. No. 229 of 1995], as amended by the European Communities (Minimum Requirements for Vessels Carrying Dangerous or Polluting Goods) Regulations, 1995 (Amendment) Regulations 1998 [S.I. No. 3 of 1998] and by the European Communities (Minimum Requirements for Vessels Carrying Dangerous or Polluting Goods) Regulations, 1995 (Amendment) Regulations 1998 [S.I. No. 394 of 1998] and by the European Communities (Minimum Requirements for Vessels Carrying Dangerous or Polluting Goods) (Amendment) Regulations, 1999 [S.I. No. 96 of 1999] made under the European Communities Act,

1972 [No. 27 of 1972]. Observance of the International Maritime Dangerous Goods Code of the International Maritime Organisation (IMO) is normally required in compliance with the obligations imposed by the Irish rules.

In Ireland, the domestic and international transport of radioactive materials by air is regulated by the Air Navigation (Carriage of Munitions of War, Weapons and Dangerous Goods) Orders, 1973 and 1989 [S.I. Nos. 224 of 1973 and 130 of 1989] and which, combined with subsequent rules passed in furtherance of the Order, broadly speaking requires observance of the International Civil Aviation Organisation (ICAO) Standards and Recommended Practices.

10. Nuclear Third Party Liability

There are no specific provisions in Irish legislation governing nuclear third party liability. Furthermore, Ireland is not a party to any of the international conventions relating to nuclear liability.

II. INSTITUTIONAL FRAMEWORK

In Ireland, responsibility for nuclear and radiological protection matters is shared among several ministers but rests mainly with the Minister for Public Enterprise. Under the supervisory authority of the Minister, the Radiological Protection Institute of Ireland advises the government on radiological safety; administers a licensing system in respect of radioactive substances, irradiating apparatus and other sources of ionising radiation; monitors levels of radiation; carries out research; develops emergency plans and provides information to the public.

1. Regulatory and Supervisory Authorities

a) Minister for Public Enterprise

The Minister for Public Enterprise exercises general responsibility for nuclear and radiological protection matters, while other ministers have specific responsibilities over certain aspects of these. The Radiological Protection Institute of Ireland is accountable to the above Minister. It is obliged to make an annual report to the Minister, who in turn is required to lay it before Parliament [Radiological Protection Act, 1991, Section 17].

The Minister's power to regulate, restrict or prohibit (save under licence issued by the Institute) any activity relating to radioactive substances is also exercised by means of orders made under the 1991 Act after consultation with the ministers concerned and the Institute [Section 30(1)]. The Order [S.I. No. 151 of 1993], referred to earlier, which sets up a system regulating the use, transport, storage, disposal etc. of fissile fuels and other radioactive substances or devices, is an example of the exercise of this ministerial power.

The Minister is also empowered under Section 30(2) of the 1991 Act to give effect to European Union decisions relating to the protection of workers and the general public from ionising radiation; again, the mechanism is a ministerial order made after consultation with other ministers. It is also the Minister for Public Enterprise's responsibility to specify the permitted levels of activity in respect of animals, crops, water supplies, etc. intended for human consumption [Section 31, as amended by Section 65 of the Food Safety Authority of Ireland Act, 1998]. These levels are prescribed by regulations made by the Minister after consultation with the Ministers for Agriculture, Food and Rural Development, Finance, the Environment and Local Government, Health and Children, Marine and Natural Resources, the Institute and the Food Safety Authority of Ireland.

b) Minister for Agriculture, Food and Rural Development

If there is a risk that prescribed levels of radioactivity, have been exceeded, the Minister for Agriculture, Food and Rural Development may make regulations to control agricultural activities in a particular area [Radiological Protection Act, 1991, Section 32(1)(a) and (b), as amended]. The Minister can regulate the movement of animals, crops, food etc. into or out of the area, the harvesting of crops, the slaughter of animals and the sale, importation or exportation of animals, crops, food etc. The purpose of these powers is to protect the general public from levels of activity in food that exceed those specified. The Minister must, before making the regulations, consult with the Ministers for Public Enterprise, for Health and Children, for Finance, the Institute and the Food Safety Authority of Ireland. Where animals have been affected by excessive levels of activity, the Minister may order the slaughter and disposal of these animals [Section 33(1), as amended]. Similarly, where crops or food have been affected, the Minister may order their destruction and disposal [Section 33(2), as amended].

The Minister also has the power, in the event of a radiological emergency, to compulsorily acquire animals, crops, food and water resources etc. [Section 32(2)]. This can only be done after consultation with the Minister for Public Enterprise, the Institute and the Food Safety Authority of Ireland.

c) Minister for the Marine and Natural Resources

The Minister for the Marine and Natural Resources has the power to regulate fishing and aquaculture activities in an area where levels of activity, prescribed by regulations made under Section 31(1) of the Radiological Protection Act, 1991, as amended may have been exceeded [Radiological Protection Act, 1991, Section 32(1)(c) and (d), as amended]. The Minister must, before making the regulations, consult with the Ministers for Public Enterprise; Health and Children the Institute and the Food Safety Authority of Ireland. Where fish, fishery products or seaweed have been affected by excessive levels of activity, the Minister for the Marine and Natural Resources may order their destruction and disposal [Section 33(3), as amended by Section 65 of the Food Safety Authority of Ireland Act, 1998].

The Minister also has the power, in the event of a radiological emergency, to compulsorily acquire fish, seaweed or fishery products [Section 32(2), as amended by Section 65 of the Food Safety Authority of Ireland Act, 1998]. This can only be done after consultation with the Minister for Public Enterprise, the Institute and the Food Safety Authority of Ireland.

The Harbours Act, 1996 prescribes detailed provisions in relation to safety of navigation and security in harbours and provides broad statutory powers for harbour masters to give directions to ships masters including the prevention of ships navigating for safety reasons. Section 52(2) of the Act

specifically enjoins harbour masters from permitting entry of radioactive material (within the meaning of the IMO's International Maritime Dangerous Goods Code) without the consent of the Radiological Protection Institute of Ireland. In addition, Section 52(3) of the Act specifically prohibits ships, vehicles or conveyances which are nuclear powered or carrying nuclear weapons or nuclear material from entering a harbour unless a statutory exemption is granted or a ship is in distress.

d) Minister for Finance

Where prescribed levels of radioactivity may have been exceeded, the Minister for Finance can make regulations in relation to wildlife fauna, in order to protect the general public. Before doing so, the Minister must consult with the Ministers for Public Enterprise, Health and Children and Agriculture, Food and Rural Development, the Institute and the Food Safety Authority of Ireland [Radiological Protection Act, 1991, Section 32(1)(e), as amended]. The Minister for Finance can also order the destruction and disposal of any wildlife fauna affected by excessive levels of activity [Section 33(4), as amended].

e) Minister for Health and Children

Where prescribed levels of radioactivity as amended, may have been exceeded, the Minister for Health and Children may make regulations controlling the importation or exportation of any food into or out of Ireland. Before making such regulations, the Minister must consult with the Ministers for Public Enterprise, Agriculture, Food and Rural Development, the Institute and the Food Safety Authority of Ireland [Radiological Protection Act, 1991, Section 32(1)(f), as amended].

The Minister for Health and Children also has certain powers in relation to the medical use of radioactive substances and irradiating apparatus. The Minister is empowered to make regulations to prevent hazards to the health of persons using such substances or apparatus, and may also prohibit dealings with them except in accordance with specified conditions or the granting of a licence [Act No. 26 of 1953, Section 59].

2. Public and Semi-Public Agencies

a) Radiological Protection Institute of Ireland

i) Legal Status

This Institute was established under the Radiological Protection Act, 1991, and replaced the Nuclear Energy Board which was dissolved by the Act [Section 21]. All assets and liabilities of the Nuclear Energy Board were transferred to the new Institute [Section 22]. References to the Board in legislation predating the establishment of the Institute are to be read as references to the Institute [Section 21]. The Institute, like the Board, is a body corporate capable of suing and being sued in its corporate name, and able to acquire, hold and dispose of land and other property [1991 Act, Schedule 1, Item 1].

ii) Responsibilities

The Institute's functions are set out in the Radiological Protection Act, 1991, as amended. The Minister for Public Enterprise may, by order, confer additional functions on the Institute following consultation with other ministers specified in Section 9 of the 1991 Act.

The Institute's responsibilities fall into the following categories:

- monitoring activity and ionising radiation [Section 7(1)(a) and (b)];
- advising the government on radiological safety matters and on the relevant international standards [Section 7(1)(d) and (f)];
- monitoring any scientific, technological, economic or other development relating to nuclear activity and keeping the government informed of such developments [Section 7(1)(h)];
- carrying out or co-ordinating research [Section 7(1)(j)]; and
- assisting in planning and implementation of measures to deal with radiological emergencies [Section 7(1)(e) and (i)], and giving information to the public on radiological safety [Section 7(i)(k)].

The Act also specifies various specific functions for the Institute which make the Institute the main point of contact for Ireland in the international context. The Institute is responsible for exchanging information and co-operating with its counterparts in other states, and for giving assistance to other states in the event of a radiological emergency [Section 8(a)-(e)]. It is also charged with collecting and disseminating information relevant to nuclear activities [Section 8(e)] and with advising the government on representation of the state on international bodies dealing in nuclear energy [Section 8(m)].

The Institute is the national competent authority for the purposes of the Convention on Early Notification and the Convention on Assistance in the Case of a Nuclear Accident, and is the central national authority responsible for the physical protection of nuclear material [Section 27].

The Institute is the licensing authority in relation to fissile fuel and other radioactive substances [S.I. No. 151 of 1993]. It is also responsible for the appointment of inspectors under the Act [Section 28(1)].

iii) Structure

The members of the Institute are appointed by the Minister for Public Enterprise with the consent of the Minister for Finance. The Minister may appoint up to twelve members, including the chairperson, and must appoint at least seven [1991 Act, Schedule 1, Item 2]. Each member's term of office is determined by the Minister upon appointment, but is not to exceed five years [Schedule 1, Item 9].

In addition to the members, the Institute has a full-time Chief Executive Officer and staff [1991 Act, Sections 11 and 12]. It also has the power to establish committees, consisting of members of the

Institute and others, to assist and advise it in relation to its functions; however, any action of a committee is subject to confirmation by the Institute [1991 Act, Section 18].

iv) Financing

The Minister for Public Enterprise may advance amounts of money, from sums provided by Parliament (the Oireachtas), to the Institute for the purposes of its expenditure in performing its functions [1991 Act, Section 15]. In addition, the Institute may accept remuneration in return for services and facilities provided by it [Section 19(1)]. It may also accept donations, but only with the consent of the Minister for Public Enterprise and the Minister for Finance [Section 19(2)].

The Institute is required to keep accounts, have them audited, and submit them to the Minister for Public Enterprise. The Minister is required to lay copies of the Institute's Annual Report and Accounts before each House of Parliament [Section 16].

b) Food Safety Authority of Ireland

This Authority was established under the Food Safety Authority of Ireland Act, 1998 [S.I. No. 29 of 1998].

The principal function of the Authority is to ensure that food produced in Ireland and food distributed or marketed in Ireland meets the highest standards of food safety and hygiene reasonably achievable and complies with food legislation in respect of food safety and hygiene standards.

With regard to radioactivity in food, it is a function of the Authority to ensure that such food complies with the Radiological Protection Act, 1991 (General Control of Radioactive Substances, Nuclear Devices and Irradiating Apparatus), Order, 1993 [S.I. No. 151 of 1993]. Furthermore, Section 65 of the Food Safety Authority of Ireland Act, 1998 which amends certain sections of the Radiological Protection Act, 1991, specifies the role of the Authority in regard to the protection of individuals from levels of radioactivity in animals, fauna, poultry, eggs, crops, animal carcasses, feeding stuffs, fish, seaweed, bottled water or water supplied intended for human consumption or any food, where specified levels of radioactivity have been or are likely to be exceeded.

ITALY

[cont'd]

I. GENERAL REGULATORY REGIME

1. Introduction

In Italy, the regulatory regime for nuclear activities is based largely on two legislative instruments:

- The first, Framework Act No. 1860 of 31 December 1962 on the Peaceful Uses of Nuclear Energy, introduced a general regime based on a series of procedural requirements such as notifications and licences. Amendments were subsequently made under which small quantities of special fissile materials, raw materials and other radioactive materials laid down by Ministerial Decree (DM) were no longer subject to such formalities [Act No. 1008 of 9 December 1969 and DM of 15 December 1970];

- The second basic text is Legislative Decree No. 230 of 17 March 1995, amending the Decree of the President of the Republic (DPR) No. 185 of 1964. This Decree came into force on 1 January 1996. It enacts supplementary provisions mainly dealing with matters related to the safety of nuclear installations and the protection of workers and the general public against the hazards of ionising radiation arising from the peaceful uses of nuclear energy. Decree No. 230 provides, *inter alia,* for the transposition of existing Euratom Directives on radiation protection.

A series of decrees has been made in implementation of the Act of 1962 and other decrees are expected to implement Decree 230/95. In the meantime the decrees made in implementation of DPR No. 185/64 remain in force. These instruments, in addition to other acts, decrees and regulations which do not concern nuclear activities exclusively, constitute the framework for nuclear legislation in Italy.

At the end of the 1980s, important changes were made to the traditional legislative procedure. The key stage in this process was the adoption of Act No. 86 of 9 March 1989, pursuant to which Italy can incorporate European Union regulations, including Euratom regulations, into its internal legislation by means of a simplified and quasi-automatic procedure. More specifically, Parliament adopts a Community Act each year reporting on the situation and authorising the government to take the measures required to implement Community law. Such measures allow national rules, no longer in conformity with EU requirements, to be amended or repealed as necessary, and provide for the adoption of new provisions. The essential aim of this procedure to accelerate the incorporation of Community regulations is to bring legislation up to date as quickly as possible.

With regard to radiation protection, the first Act, adopted on 30 July 1990 [Act No. 212], provided, *inter alia,* for the implementation of Council Directives 80/836/Euratom, 84/467/Euratom and 84/466/Euratom. Since the Community Act for the year 1990 [No. 428 of 29 December 1991] did not refer to these Directives, in order to allow the government additional time for their

implementation, they were incorporated into the Community Act for the year 1991 [No. 142 of 19 February 1992]. The above-mentioned Directives have been supplemented from time to time by the most recent Directives on radiation protection, *i.e.* Council Directives 89/618/Euratom, 90/641/Euratom, 92/3/Euratom, 96/29/Euratom and 97/43/Euratom. Pursuant to the Community Acts, the government has to adopt legislative decrees with a view to implementing the requirements prescribed by these Directives into domestic law. Therefore, Decree No. 230, as cited above, is to be amended regularly pursuant to Community Act No. 25 of 5 February 1999 which refers to Council Directives 96/29/Euratom and 97/43/Euratom.

Furthermore, in respect of the institutional framework, mention should be made of Act No. 933 of 1 August 1960 establishing the National Nuclear Energy Commission *(Comitato Nazionale per l'Energia Nucleare* – CNEN*)*. Following its first re-structuring in 1971 [Act No. 1240 of 15 December 1971], the Commission was extensively re-organised again through an Act of 1982, which changed its name and extended its powers. The CNEN became the ENEA, namely the National Commission for Research and Development of Nuclear and Alternative Energy Sources *(Comitato Nazionale per la Ricerca e per lo Sviluppo dell'Energia Nuclear e delle Energie Alternative)*. Hence, the ENEA's activities were extended to other energy sources (except for hydrocarbons) [Act No. 84 of 5 March 1982]. However, this latter reform was also of short duration. Act No. 282 of 25 August 1991 redefined the ENEA's goals and responsibilities and renamed it as the National Agency for Nuclear Technologies, Energy and the Environment *(Ente per le Nuove Tecnologie, l'Energia e l'Ambiente)*. In addition to its previous responsibilities in relation to nuclear safety and radiation protection, it now also deals with environmental questions and new technologies. Recently, in January 1999, the ENEA was further re-structured (see *infra*, Part II "Institutional Framework").

Mention should also be made of the three referenda organised in 1987, when the anti-nuclear coalition won a resounding majority, obliging Parliament to announce a five-year moratorium on the construction of new power plants [Decision of 18 February 1987]. Although the moratorium came to an end in 1992, no official decision has yet been taken in this respect by the Italian authorities. At the present time, Italy's nuclear energy output is zero since its reactors in service have been closed down (*Caorso*) and are in the process of being decommissioned (*Trino, Latina and Garigliano*) since 1990. Lastly, the as yet unfinished power plant of *Montalto di Castro* has been reconverted into a multi-fuel plant equipped with gas turbines.

2. Mining Regime

Section 2 of Act No. 1860 of 1962 on the Peaceful Uses of Nuclear Energy provides that concessions for the mining of radioactive ores (listed in the fourth paragraph of Article 197 of the Euratom Treaty) are granted in accordance with the provisions of a Royal Decree of 1927 on mines [as amended by DPR No. 620 of 28 June 1955]. This Decree lays down rules for the granting of permits for prospecting and mining concessions for ores in general. Concessions are granted following consultations with the Higher Council for Mines.

Furthermore, the protection of workers in mines against ionising radiation is regulated by the above-mentioned Legislative Decree No. 230 and, in greater detail, by a Ministerial Decree of 13 May 1978 (made in implementation of the above-mentioned Presidential Decree No. 185 on the radiation protection of miners (see *infra*, Section 6 "Radiation Protection").

3. Radioactive Substances, Nuclear Fuel and Equipment

Regulations governing activities connected with radioactive substances, nuclear fuels and nuclear equipment are set out in Act No. 1860 of 31 December 1962 on the Peaceful Uses of Nuclear Energy, in the decrees implementing DPR No. 185 of 13 February 1964, as well as in Legislative Decree No. 230 of 1995.

The Minister for Industry, Commerce and Crafts (hereinafter referred to as the Minister for Industry) is the competent authority for such activities. Pursuant to Act No. 1008 of 19 December 1969 (amending the Framework Act of 1962), persons in possession of small quantities of special fissile materials, raw materials or other radioactive materials are exonerated, by Ministerial Decree of 15 December 1970 (in implementation of Act No. 1008) from the general declaration requirement. This gives more flexibility than the procedure established under the 1962 Act which required persons in possession of the above-mentioned materials to report them to the Minister within five days, irrespective of the quantity of materials held [Section 3]. However, in relation to radioactive materials, this same Section of the 1962 Act requires a declaration only from persons in possession of radioactive materials such that the total radioactivity or mass exceeds the levels laid down in one of the decrees implementing DPR No. 185 of 1964.

Under the terms of Decree No. 230, the declaration must also be made to the local authorities of the National Health Service and to other relevant authorities in each region. The declaration is also required for any ionising radiation-emitting equipment. An implementing decree will establish the technical details in relation to the obligation to declare materials and equipment.

Section 13 of Act No. 1860 of 1962 lays down the procedure regulating the use of radioisotopes. All such use requires a licence from the Minister for Industry. In addition, other ministers are involved depending on the use to which the substances are to be put. This provision has been supplemented by a Ministerial Decree of 1 March 1974 which contains detailed instructions on the information to be included in licensing applications: information relating to the applicant, the intended use of the radioisotopes (industrial, agricultural, medical or scientific), the location of the premises involved, the professional qualifications of personnel, etc.

Moreover, according to Decree No. 230, the use of radioactive materials and radiation-emitting devices is divided into two categories (A and B) requiring a licence from the Minister for Industry (category A) and clearance certificates from the Prefect of the region (category B) with the agreement of other competent authorities. The criteria and procedure applicable to this division into categories shall be laid down in a decree of the Prime Minister, made in agreement with the ministries concerned. However, authorities responsible for medical uses of such materials and devices shall be set up under regional legislation. Use includes trade in materials as well as activities related to their use, such as handling, treatment and the eventual disposal of waste into the environment [Sections 27 to 29].

4. Nuclear Installations

As already explained, the nuclear power programme has been terminated in Italy since 1987. In implementation of government decisions, Section 33 of Act No. 9 of 9 January 1991 provided that the National Electricity Company and building firms working in the nuclear sector had to be compensated for the costs and losses incurred following interruption of the Italian nuclear programme. This compensation has almost all been awarded at the time of writing (1999).

a) Licensing and inspection, including nuclear safety

The legislative and regulatory provisions applying to the construction and operation of nuclear installations in Italy are principally set out in Act No. 1860 of 1962 on the Peaceful Uses of Nuclear Energy and to a large extent reiterated in Legislative Decree No. 230/95 containing technical and administrative licensing procedures as regards nuclear safety and radiation protection.

While nuclear power plants are excluded from the scope of the 1962 Act, in accordance with Decree No. 230 of 1995, they remain subject to licensing by the Ministry of Industry, Commerce and Crafts, with the former National Electricity Company *(Ente Nazionale per l'Energia Elettrica* – ENEL*)* as liable operator. The prior opinion of the National Environmental Protection Agency (*Agenzia Nazionale per la Protezione dell'Ambiente* – ANPA) is also required (See *infra*, Part II "Institutional Framework", Section 3).

When filing a licensing application, the operator must submit detailed documentation concerning the siting of the installation, arrangements for release and disposal of radioactive waste, the cost and time required for construction and the financial security at his disposition. In short, the operator must show that he possesses the technical and financial resources required to ensure maximum safety.

A special administrative procedure for the prior selection of the site for nuclear electricity-generating plants was introduced by Act No. 393 of 2 August 1975. The 1975 Act establishes a special siting procedure involving the co-operation of the CIPE (Interministerial Committee for Economic Planning), the ENEA and the regional and local authorities. It also takes into consideration the administrative decentralisation policy giving the regions wider responsibilities in environmental protection and land-use planning.

The procedure introduced by Act No. 393 of 1975 was at the centre of the referendum debate on the siting of nuclear power plants. The outcome of the referendum led to the repeal of paragraph 13 of the only Section of Act No. 8 of 10 January 1983 (which amended the Act of 1975). This provision specified that if, in the context of the siting procedure for electricity-generating power plants, the local authorities could not agree within a period of 150 days on a suitable site, the siting decision was to be taken by the CIPE. Following the repeal of this provision, no new provisions governing this issue were adopted.

As far as the licence itself is concerned, the 1975 Act did not change the technical and administrative procedures for the licensing of nuclear installations as provided for by Decree No. 185 of 1964, nor those of Decree No. 230/95 which replaced it. Under Section 5, the operator submits the plans for the construction of the installation to the Minister for Industry, Commerce and Crafts who, after obtaining the opinion of the ANPA, decides for or against licensing by means of a Decree.

Following delivery of the clearance certificate (or the building permit), construction proceeds under the technical supervision of the ANPA. The operating licence is then granted on satisfactory completion of the non-nuclear and nuclear tests.

Specific provisions concerning the decommissioning of nuclear installations are an important new addition to Decree No. 230, since no such provision appears in DPR No. 185/64, and this omission had led the competent authorities to apply the legal instruments relative to construction and operation, which did not always represent an appropriate analogy. The operations involved in decommissioning are now licensed, as appropriate, in stages set forth in the provisions in question.

The Ministry for Industry determines the requirements concerning the status of the installation and of the site on the basis of a final report provided by the operator.

Section 10 of Decree No. 230 of 1995 governs the inspection of activities covered by this Decree. It is the responsibility of the ANPA to check that the installation is constructed in accordance with the initially-approved project and to supervise the carrying out of the nuclear tests. For this purpose, the ANPA inspectors, appointed by the ANPA Chairperson, are vested with wide powers, as regards both inspection of the installations and access to documents. They are also empowered to undertake regular inspections of installations during operation. The competent authorities are also given powers of inspection under Decree No. 230 (Inspectorate of Labour, National Health Service, etc.). Under Act No. 349 of 8 July 1986 establishing the Ministry of the Environment, this Ministry is responsible for carrying out technical controls on the state of air, water and land pollution [Section 8]. Although nothing specific is said about nuclear installations, the way in which this Section is drafted could enable experts appointed by this Ministry to become involved in inspection.

It is relevant to note that, at the international level, Italy ratified the 1994 Convention on Nuclear Safety on 15 April 1998.

b) Protection of the environment against radiation effects

Although the Act setting up the Ministry of the Environment [Act No. 349 of 8 July 1986] contains no express provisions on nuclear activities and radiation protection, the role of this Ministry in the nuclear field is defined implicitly in some of the general provisions in the 1986 Act.

Pending incorporation into national law of the provisions of Council Directive 85/337/EC on the assessment of the effects of certain public and private projects on the environment, Section 6 of the Act described, in a provisional manner, the impact assessment procedure to which installations capable of producing significant changes to the natural environment are subject. Pursuant to Section 6(2), an implementing Decree sets out the categories of installations subject to impact studies [Decree No. 377 of 10 August 1988]. The list includes nuclear power plants and other nuclear reactors (except for research reactors with a capacity less than 1 kw of constant thermal heat) as well as facilities for the long-term storage or final disposal of radioactive waste [Section 1].

A Decree of April 1999, which introduced technical standards concerning the impact assessment, fully implemented the 1985 Directive into national law.

A Decree of February 1998 of the President of the Republic supplementary to Decree No. 377/88 incorporated most of the provisions of Council Directive 97/11/EC which amended the 1985 Directive. In particular, this Decree extended the list of installations subject to the impact assessment procedure to, *inter alia*, installations for the storage of nuclear fuel or the treatment of nuclear materials.

Decree No. 377 also specifies that environmental impact studies should be carried out prior to applications for licences and clearance certificates and, in any event, before invitation to tender.

Environmental impact studies must include information relating to [Section 2 *et seq*. of the 1988 Decree]:

- the possible siting of the installation, having due regard to the effects on the surrounding environment;

- the disposal sites to be used for liquid waste, and to the characteristics and quantities of solid, liquid and gaseous waste generated by the installation;

- prevention and emergency plans in the event of damage to the environment caused during the construction or operation of the installation.

After receiving the backing of the Minister for the Environment, the project has to be published in two newspapers, one local and the other national.

c) Emergency response

In the context of the general protection of the public, a Presidential Decree of 1981 provides for measures to ensure assistance for the public in the event of a disaster. The provisions of this Decree are of general application and therefore cover nuclear accidents. The Decree aims to set up a framework for assistance at regional level, given the process of decentralisation which followed the creation, in 1972, of autonomous regional authorities.

In 1983, the Minister for Health sent a Circular on Emergency Situations to the regional health authorities on whose territory nuclear installations were located [Circular No. 53 of 2 June 1983]. The Circular specifies that the health authorities are responsible for organising plans to deal with emergency situations involving radiation. This task is performed in conjunction with the provincial committees set up under Presidential Decree No. 185 of 13 February 1964. The Circular describes different possible situations, the location of emergency centres and the health measures to be taken to treat victims and to protect the public.

A commission to study problems arising from emergency situations has been established [Decree of 2 July 1986]. Its primary role is to advise the Minister for Civil Protection in the event of an emergency situation. The risks covered by the Decree include nuclear risks as well as those arising from the transport of hazardous materials. The regime applicable to emergency situations has been substantially modified since specific new provisions concerning nuclear emergencies came into force.

Like Presidential Decree No. 185 of 13 February 1964, Chapter X of Decree No. 230 deals with nuclear emergencies [Sections 115 to 135]. These Sections describe the procedure to be followed in preparing “external emergency plans” to be put into action when an accident occurs in a nuclear installation and involves a risk for the local population. These provisions deal essentially with information required as to the content of the plan and its approval, and with the obligation to declare a state of emergency and to inform neighbouring regions of the danger. Chapter X differs from the previous regime, in that it incorporates the nuclear emergency plans into the national planning of protective measures in the event of a radiation emergency covering the entire country. This form of planning is the responsibility of the Department for Civil Protection assisted by the ANPA. A decree of the Prime Minister (on the proposal of the Minister for Health and in consultation with the other ministries and organisations concerned) lays down the reference dose levels for measures to be adopted in the event of an emergency. Provisions have also been introduced which incorporate Council Directive 618/89/Euratom concerning public information. Moreover, a standing committee of the Ministry of Health is charged with preparing, updating and disseminating this information. Finally, a centre for preparing and evaluating data concerning radiation emergencies has been set up within the ANPA.

In this context, it should be noted that, at the international level, Italy ratified the 1986 Vienna Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency on

25 October 1990 [Act No. 92 of 9 April 1990], and the 1986 Convention on Early Notification of a Nuclear Accident on 8 February 1990.

5. Trade in Nuclear Materials and Equipment

a) General provisions

Framework Act No. 1860 of 1962 on the Peaceful Uses of Nuclear Energy [Section 4] and the Ministerial Decree of 30 October 1990 listing goods subject to an import licence establish the regime governing the import of goods which require an import licence include radioisotopes and ionising radiation-emitting equipment. A Legislative Decree [Decree No. 89], adopted on 24 February 1997, sets out the list of dual-use goods subject to licensing, in accordance with Council Regulation (EC) No. 3381/94 of 19 December 1994 setting up a Community regime for the control of exports of dual-use goods.

Trade in radioactive ores, source materials and substances is subject to a licence from the Minister for Industry. Import and export licences, where required under the trade regulations applicable, are granted by the Minister for Foreign Trade after consultation with the Minister for Industry. The state has a right of pre-emption as regards source materials, a right which must be exercised within 30 days of the licence application [Section 4 of Act No. 1860]. According to Act No. 1008/69 modifying Act No. 1860, certain exemptions from the requirement to obtain a licence from the Ministry of Industry licensing are set out in a Decree of 15 December 1970 (implementing Act No. 1008).

Also, under the terms of Decree No. 230 of 1995, the import and production for commercial purposes of radioactive materials, products and equipment containing such materials, are subject to prior notification to the Ministries of the Environment and Industry and other ministries concerned, as well as to the ANPA, except for certain exemptions which are determined by the Minister for Industry on the advice of these ministries and of this Agency [Section 18].

All persons engaging in trade in ores, source materials or other radioactive materials must keep a special register containing records of their commercial operations [Section 20].

With regard to radiation protection, commercial operations are governed by the regime established in Decree No. 230. Also, decrees made by the Minister for Health, in agreement with the Minister for Industry, in implementation of Section 98 of Decree No. 230, specify those activities which are exempt from the prohibitions laid down in this Section, and those for which a licence can be granted. The main criterion used is that of the level of radioactivity of the products or equipment involved. The prohibitions apply to certain products and articles that contain radioactive materials (such as cosmetics, toys, lightning conductors, etc.), the manufacture, import, sale, use or possession of which are prohibited in principle.

Council Regulation (Euratom) No. 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States was incorporated into Italian law by a circular of the Minister for Industry [Circular No. 228 of 20 October 1993]. These Community provisions were adopted to allow the national authorities responsible for controlling radioactive substances to maintain a level of information identical to that existing before the abolition of border controls within the Community.

Following the adoption of Decree No. 230/95, which also provides for the implementation of Council Directive 92/3/Euratom of 3 February 1992 on the supervision and control of shipments of radioactive waste between Member States and into and out of the Community, Circular No. 228 remains in force only in respect of sealed sources, to which it applies subject to the amendments adopted to the regime established in Decree No. 230. In this context, the Circular sets out the procedures relating to the type of commercial operation to be undertaken and to the prior licences required(For radioactive wastes, see *infra,* Section 7 "Radioactive Waste Management".

b) Patents

Patents and industrial designs and models are subject to the rules laid down in Royal Decree No. 1127 of 29 June 1939, those contained in international conventions and incorporated into Italian legislation on the protection of industrial property rights and, since 1958, those in the Act ratifying and implementing the Euratom Treaty.

The Central Patents Office of the Ministry of Industry is responsible for carrying out the formalities required under Article 16 of the Euratom Treaty [Act No. 933 of 1 August 1960].

The Central Patents Office must forward to the ENEA all applications for patents for inventions or industrial models acknowledged as being specifically nuclear in nature or directly related and essential to the development of nuclear energy [Section 26 of Act No. 1860 of 1962].

6. Radiation Protection

Legislative Decree No. 230 of 1995 replaces DPR No. 185/64 as the basic text in Italy governing radiation protection. In furtherance of the general framework established by Act No. 1860 of 31 December 1962, this Decree also introduces a regime for supervising the safe conduct of nuclear activities and, in general, all activities involving the use of ionising radiation. This regime will be supplemented by the adoption of a number of implementing Decrees, in the same manner as those made in implementation of DPR No. 185.

Several examples may be mentioned. A Decree of the Prime Minister is to prescribe the numerical values and other conditions which determine the scope of application of Decree No. 230. This implementing Decree was made on the proposal of the Ministries for the Environment and Health, in conjunction with the other ministries, and following consultations with the ANPA and the other organisations concerned.

Another Prime Ministerial Decree (made under a similar procedure) is to establish the maximum dose limits for workers and the public. These dose limits are established, in the meantime, by Annexes III and IV to Decree No. 230.

a) Protection of workers

As provided by the 1995 Decree, responsibility for the radiation protection of workers lies with the Ministry of Labour and Social Security (acting through the Labour Inspectorate) [Section 59], the local authorities of the National Health Service and the ANPA (see *infra*, Part II "Institutional Framework").

Those persons, including the state, the regions, the provinces, the communes, public bodies, educational establishments and research laboratories, who, in the course of their work, expose workers to the hazards arising from ionising radiation, must comply with the provisions of the 1995 Decree.

The general rules for the radiation protection of workers, like DPR No. 185, are based upon the Euratom basic standards. This source is expressly cited in particular in the provisions for the adoption of dose limits [Section 96] mentioned above.

The 1995 Decree also regulates work in mines where radioactive substances are present and, in particular, defines the obligations of employers in relation to the radiation protection of workers in the mining industry. The conditions governing the application of these provisions are set out in a Decree of the Minister for Industry, who is also responsible for inspection activities to ensure protection against ionising radiation risks.

In particular, specific provisions have been introduced as regards the protection of outside workers covered by Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas. This involves, *inter alia*, the establishment for each worker of a personal radiation logbook with which he must be provided in compliance with the above Directive.

Finally, another very important innovation is the inclusion of provisions allowing the ALARA principle to be applied to the employer's activities.

b) Protection of the public

Decree No. 230 of 1995 also contains provisions on the protection of the public against ionising radiation. The Ministry of Health is responsible for such protection and must, in particular, control all sources of ionising radiation to avoid any contamination of the public and of the general environment [Section 97]. Regional and provincial commissions have been set up to give their advice on radiation protection and related problems.

Dose limits and maximum permissible concentrations for the public are established in accordance with Section 96 of Decree No. 230, in compliance with applicable Community Directives.

Other provisions concern the protection of patients undergoing radiology and in other branches of nuclear medicine, in compliance with Council Directive 466/84/Euratom of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment. These provisions concern the qualification of staff, the criteria for and methods of using radiation in medicine, the inventory of radiological equipment, quality control measures, etc. The Minister for Health has adopted seven decrees relating to equipment and documentation in nuclear medicine and on the training of medical staff in the field of radiodiagnosis.

c) Protection of the environment

The most important provisions relating expressly to the environment are contained in Decree No. 230, namely Sections 100 and 104.

Section 100 provides that in the event of an accident during an operation which involves radioactive substances, if the environment is affected, the operator must intervene to prevent the risk

of subsequent contamination or injury to persons. The Prefect of the Province and the local authorities of the National Health Service must be informed immediately.

Section 104 provides that the Ministry of the Environment is responsible for monitoring ambient radioactivity, while the monitoring of foodstuffs and drinks is entrusted to the Ministry of Health, with overall technical co-ordination being ensured by the ANPA (see *infra*, Part II "Institutional Framework"). All monitoring is carried out by national and regional networks, the latter acting under Directives issued by the above-mentioned Ministries.

The activities of the ANPA are also governed by relevant directives from these Ministries, and by Section 35 of the Euratom Treaty. Its functions include the co-ordination and standardisation of measurements, the introduction of new measuring stations, etc.

The situation described above is one result of the referendum held 18 April 1993 which abolished the powers of Local Health Units as regards the environment, entrusting these powers to the ANPA and to other relevant regional and provincial departments and organisations concerned.

7. Radioactive Waste Management

Decree No. 230 of 1995 regulates radioactive waste disposal in a more precise manner than DPR No. 185/64. In general, Section 102 provides that this waste must be managed in accordance with the rules of good practice and the instructions set out in the disposal licence; furthermore, any person producing, treating, handling, using, trading in or storing radioactive substances must conduct a whole series of assessments concerning the disposal of solid, liquid or gaseous radioactive waste in order to ensure that the limits and the other conditions governing disposal into the environment are observed [Section 103]. Except in cases covered by Chapter VII of the Decree (nuclear installations), radioactive waste disposal must be licensed by the authorities identified by regional legislation, while a decree of the Minister for the Environment, adopted in co-operation with the Ministers for Health & Industry and after consultations with the ANPA, determines the upper limits beyond which a licence is required. Section 33 also requires a prior licence to be obtained from the Ministry of Industry to build and operate installations for the storage or disposal of radioactive waste.

Decree No. 230 also implemented Council Directive 92/3/Euratom concerning transfers of waste. A Circular of the Ministry of Industry (No. 236 of 28 October 1994) adopted in order to implement this Directive into Italian legislation pending Decree No. 230, was basically transcribed into this Decree. Section 32 requires prior licensing for transfer, import, export and transit of radioactive waste, in compliance with the Directive. The procedure governing such licences is laid down in a Decree of the Minister for Industry.

Other technical and administrative obligations are prescribed in the event of any serious contamination of the environment in connection with the use and disposal of radioactive substances. In particular, the Prefect, other competent authorities in the region and the ANPA must be informed of the occurrence of a dangerous incident and there is an obligation to take all the measures required to restrict contamination in non-controlled areas and to prevent any risk to individuals and the public [Section 101]. A Decree adopted by the Ministers for the Environment and Health, following consultations with the ANPA, lays down the levels of serious contamination and other conditions governing the application of this Section.

At the international level, Italy ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter on 30 April 1984.

8. Non-Proliferation and Physical Protection

Act No. 1860 of 1962 provides that holders of special fissile materials must report them to the Ministry for Industry. Responsibility for controlling such materials, previously vested in the ENEA, was entrusted to the ANPA by Act No. 61/94 (see *infra*, Part II "Institutional Framework"), which requires the Agency to verify compliance with the physical protection measures applicable to nuclear installations and substances.

In addition, a Ministerial Decree of 19 April 1979 set up an Interministerial Committee for the Physical Protection of Nuclear Installations and Substances. This Committee is responsible for laying down standards in relation to protective measures designed to prevent criminal acts against nuclear installations or substances. The Committee is also required to provide its opinion on the security plan each operator prepares in respect of his installation and, if necessary, to suggest changes.

At the international level, Italy ratified the 1979 Convention on the Physical Protection of Nuclear Material on 6 September 1991. As regards non-proliferation, it may be noted that Italy is a Party to the Treaty on the Non-Proliferation of Nuclear Weapons, ratified on 2 May 1975 [Act No. 131 of 24 April 1975] and has agreed to act in accordance with the Guidelines for Nuclear Transfers issued in 1978 by the International Atomic Energy Agency (IAEA). It also ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 1 February 1999.

9. Transport

As regards safety and radiation protection, the transport of radioactive materials is governed by rules adopted by the competent authorities for the different types of transport, which take into account the Regulations for the Safe Transport of Radioactive Materials issued by the International Atomic Energy Agency (IAEA).

The transport of radioactive materials by rail is carried out in accordance with Legislative Decree No. 41 of 13 January 1999, which aims to implement Council Directive 96/49/EC and Commission Directive 96/87/EC on the transport of dangerous goods, including radioactive materials, by rail (Class VII). These provisions are based on the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID).

Transport by road is regulated by a Decree of 4 September 1996 adopted by the Minister of Transport and Navigation, amended by a Decree of 15 May 1997. These provisions were adopted with a view to implementing Council Directive 94/55/EC and Commission Directive 96/86/EC, and are based on the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR). Furthermore, Circular No. 162 of 16 December 1996, as amended on 4 April 1997, establishes the technical requirements which apply. Lastly, Circular No. 244/ of 26 May 1997 updates licence procedures or transport by road of radioactive and fissile materials.

The maritime transport of radioactive materials is regulated by a Decree of 6 April 1995 of the Ministry of Transport and Navigation which allowed for the adoption of some of the standards laid down by the International Maritime Organisation (IMO). This Decree was adopted pursuant to Regulation No. 1008 of 9 May 1968.

The air transport of radioactive materials, originally regulated by a Ministry of Transport Circular of 1982, is now subject to the provisions of Circular No. 334096/30 of 3 December 1992. These provisions are based on the requirements set out in the International Civil Aviation Organisation

Regulations. After defining its scope [Sections 1 to 5], the Circular describes the procedure to be followed for the transport of radioactive materials (consignor's and consignee's obligations) and designates the competent authorities (the Ministry of Industry, Commerce and Crafts, the Ministry of Transport and Navigation and the ANPA).

With regard to licences, the regulatory basis can be found in Act No. 1860 of 1962, as modified by DPR No. 1704 of 30 December 1965, which requires a licence from the Minister for Industry in conjunction with the minister concerned, depending on the mode of transport. There is provision for certain exemptions in the Decree of 15 December 1970 (adopted in implementation of Act No. 1008/69 modifying Act No. 1860).

DPR No. 1704/65 provides for the adoption of a regulation concerning safety and radiation protection in the transport of radioactive materials. According to Section 21 of Decree No. 230, this regulation is adopted by Decrees of the Minister for Transport and Navigation (following consultations with the ANPA) for the different modes of transport, in compliance with the Directives and Recommendations of the European Union and international agreements on the transport of dangerous goods.

10. Nuclear Third Party Liability

Act No. 1860 of 1962 on the Peaceful Uses of Nuclear Energy regulates nuclear third party liability in Italy, and implements the provisions of the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy, ratified by Italy on 17 September 1975, and of the 1963 Brussels Supplementary Convention, ratified on 3 February 1976.

Act No. 109 of 12 February 1974 authorised ratification of both Conventions and vested the government with the powers required to implement them by decree at national level. Consequently, a Presidential Decree of 1975 amended Section 1 (definitions) and Sections 15 to 24 (third party liability) of the 1962 Act to bring them into line with the above-mentioned Conventions [DPR No. 519 of 10 May 1975]. Furthermore, on 14 and 28 June 1985, Italy ratified the 1982 Protocols amending the two above-mentioned Conventions [Act No. 131 of 5 March 1985]. The most recent development was the ratification on 31 July 1991 and implementation by Italy of the Joint Protocol of 1988 relating to the application of the Vienna Convention and the Paris Convention [Act No. 147 of 23 April 1991]. It is also relevant to note that Italy ratified the 1971 Convention relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material on 21 July 1980.

The 1962 Act, as amended, provides for a system of absolute and exclusive liability for the operator of a nuclear installation in the event of any nuclear damage occurring in this installation or in connection with it [Sections 15 and 18]. When the operators of several installations are held liable for the same damage, they are jointly and severally liable for compensation [Section 17]. Nuclear operators are also liable in respect of damage caused by a combination of a nuclear incident and an incident other than a nuclear one, where the nuclear damage cannot be separated with certainty from the other damage.

Under Italian law, the maximum amount of liability of the operator of a nuclear installation for damage caused by a nuclear incident is fixed at Italian Lira (ITL) 7 500 million [Section 19]. If the amount of damage exceeds the limit of the operator's liability, thereby necessitating intervention by the state, the total amount of compensation may not exceed ITL 43 750 million.

A Ministerial Decree of 16 February 1976 approved a model certificate of financial security for the transport of nuclear materials, based on the model certificate recommended by the OECD Steering Committee for Nuclear Energy in accordance with the Paris Convention. Another Ministerial Decree of 1978 approved the general conditions of third party liability insurance policies for nuclear operators and for the transport of nuclear materials [DM of 3 March 1978]. Lastly, a later Decree [DM of 20 March 1979] implemented at national level the Steering Committee Decision of 27 October 1977 excluding certain categories of nuclear substances from the scope of the above Conventions. These three Decrees were adopted in implementation of the above-mentioned Presidential Decree of 1975.

II. INSTITUTIONAL FRAMEWORK

The radical changes which, since the late 1980s, have affected the Italian nuclear industry have inevitably been reflected at institutional level. The former competent authorities therefore have to be considered from a fresh angle and particular attention paid to the new bodies created. A study of the objectives and powers of these bodies highlights the issues to which today's legislators attach special importance.

Responsibility for the control of nuclear activities in Italy is shared amongst several ministries assisted by other bodies, such as the Interministerial Committee for Economic Planning (CIPE) and the National Environmental Protection Agency (ANPA). As regards the National Agency for New Technologies, Energy and the Environment (ENEA) and the National Electricity Company (ENEL), see the more recent developments under item 3(a) and (d) below.

1. Regulatory and Supervisory Authorities

a) Interministerial Committee for Economic Planning (CIPE)

Act No. 933 of 11 August 1960 which originally created the National Committee for Nuclear Energy (*Comitato Nazionale per l'Energia Nucleare* – CNEN), now the ENEA, set up an Interministerial Committee responsible for defining the general policy of the CNEN. A Presidential Decree of 1968 transferred its powers to the CIPE [DPR No. 626 of 30 March 1968]. The CIPE is responsible, in particular, for establishing the national nuclear power programme, though some of its duties are for the moment irrelevant due to the moratorium on the Italian nuclear programme. This applies in particular to the CIPE's approval of the programme concerning nuclear power plant construction over a number of years, and to its approval with regard to the suitability of sites for such plants.

Section 1 of Act No. 282 of 25 August 1991, which established the ENEA, expressly provides that the ENEA shall follow the guidelines laid down by the CIPE. In addition, after being submitted to the Ministry of Industry, Commerce and Crafts and examined by an Interministerial Committee, the ENEA's three-year programme of work has to be approved formally by the CIPE. Lastly, Section 16

of the Act provides that the ENEA Board of Governors may be asked to resign in the event of repeated non-compliance with CIPE directives.

The Committee also has decisive powers concerning the effective implementation of the National Energy Plan. Act No. 10 of 9 January 1991, which establishes the standards for the rational use of energy and for the development of renewable energy sources, provides that the CIPE shall adopt, at least once every three years, a series of guidelines on various subjects. The purpose is to co-ordinate the activities of the different public bodies involved, to promote the research and development of technology in the fields of production, recycling and use of renewable energy sources and to promote programmes to reduce energy consumption.

The CIPE meets under the chairmanship of the Prime Minister, and includes the Minister for the Budget and Economic Planning as Vice-Chairman, and the Ministers for Industry, Commerce and Crafts, Foreign Affairs, the Treasury, Finance, Public Works, Labour and Social Security, and Transport and Navigation. Other ministers may be called upon to take part in meetings of the Committee.

b) Prime Minister

Under Decree No. 230/95 on radiation protection, the Prime Minister is empowered to adopt basic decrees such as those laying down the application thresholds of Decree No. 230, dose limits for workers and the public and the reference dose levels for nuclear emergencies.

c) Minister for Industry, Commerce and Crafts

Act No. 1860 of 1962 on the Peaceful Uses of Nuclear Energy vests the Minister for Industry with the necessary powers to make regulations and issue the licences required in the nuclear field. The Minister is therefore the competent authority, in conjunction with the CIPE, for matters relating to nuclear power plants [Chapter II of Act No. 1860 of 1992]. In addition, he authorises by decree the operation of installations for the production and use of nuclear energy for industrial purposes, as well as of plants for the processing and use of ores, source materials, special fissile materials, enriched uranium and radioactive materials [Section 6 of the 1962 Act and Act No. 1240 of 1971, as amended by Act No. 84 of 1982 and Act No. 282 of 25 August 1991].

In implementation of the Legislative Decree of 1995 [Sections 15, 32, 34, 35, 36 and 55], the Minister for Industry, in agreement with the other Ministers concerned (Interior, Labour, Health and Environment) issues decrees laying down the levels of radioactivity and other conditions pursuant to which a license is required for different activities involving ionising radiation (including the mining industry, commercial operations and utilisation for industrial and research purposes), as well as the application procedures for licences. The same Minister authorises the above-mentioned activities, as well as the transfer of radioactive substances within the European Union, the operation of radioactive waste disposal sites, etc.

The Minister for Industry, Commerce and Crafts may also determine the amount and terms of the financial security covering the third party liability of the operator of a nuclear installation. He approves the general conditions of the insurance policy or other form of financial security by decree, in agreement with the Treasury Minister and after consultations with the Attorney General [Sections 19, 21 and 22 of the 1962 Act as amended by DPR No. 519 of 10 May 1975].

d) Minister for Labour and Social Security

The Minister for Labour and Social Security is generally responsible for the radiation protection of workers engaged in nuclear activities [Section 59 of Decree No. 230]. In agreement with the other ministers concerned, he establishes rules governing radiation protection and monitors their application through the controls of Health and Safety inspectors.

e) Minister for Health

Responsibility for protecting public health against the hazards of ionising radiation lies with the Ministry of Health and the National Health Service of the ANPA, whose aim is to prevent, by inspections or otherwise, the possibility of radiation contamination of the population or of any part of the natural environment, foodstuffs and beverages [Section 94 of Decree No. 230].

The Minister for Health, on his own or by decree jointly made with the other concerned ministers, has laid down a series of radiation protection standards [Sections 1, 11, 27, 30, 32, 55, 78, 82, 96, 98, 101, 110 and 114 of DPR No. 185]. These provisions concern, *inter alia*:

- the radioactivity and exposure levels below which certain activities are exempt from notification and licensing obligations;
- the details of training of personnel in radiology and nuclear medicine, the authorised criteria for radiological equipment, the specifications relating to patients' radiology records, etc.;
- the maximum permissible doses and concentrations for workers and the public;
- abnormal levels of contamination in the environment or in foodstuffs which require measures to reduce such contamination;
- the procedures for classifying transit areas and workers for the purposes of physical control;
- details of qualification requirements for experts;
- the methods and limits applicable to radioactive waste disposal in the environment.

The Higher Institute of Health and the Higher Institute for Labour Protection and Safety, as support organisations of the Ministry for Health, are consulted with regard to a number of decrees implementing Decree No. 230 (dose limits, reference dose levels for emergencies, official approval of certain sources, etc.)

A standing commission has been created in the Ministry for Health, the essential task of which is to prepare information for the public in the event of a nuclear emergency.

f) Minister for the Environment

Act No. 349 of 8 July 1986 set up the Ministry of the Environment which has since been involved in decision-making in collaboration with the other competent ministries. Although the

Minister is not expressly given any functions in the nuclear field in the Act of 1986, Section 2 provides, in a general manner, that the Minister for the Environment performs his functions with a view to ensuring protection of the soil, air and water. Moreover, paragraph 14 of Section 2 provides that the Minister, in agreement with the Minister for Health, proposes to the President of the Council the maximum concentration limits and maximum exposure doses with respect to chemical, physical or biological contamination. With regard to the establishment of ceilings governing the exposure of workers, the Minister for Labour and Social Security must be consulted before the proposal is submitted to the Prime Minister. In addition, whenever construction of an installation capable of having an impact on the surrounding environment is being planned, the Minister for the Environment reports on the compatibility of the project with environmental protection requirements.

Lastly, it should be noted that this Ministry has taken over some of the powers of the Minister for Health, in particular, the monitoring of environmental radioactivity, as provided for in Section 104 of Decree No. 230/95. Although this task continues to be performed at local level, the Minister for the Environment has an overall power of surveillance and may take over these tasks should the regional bodies fail to carry them out properly. Section 9 of the 1986 Act extends this power of surveillance to all the other functions delegated to local authorities in the field of environment, and authorises the Ministry to intervene directly should the regional authorities persist in failing to take action. Section 115 of Decree No. 230 also provides that the Minister for the Environment participate in the establishment of reference dose levels for the planning of radiation emergencies. The Minister is also involved in the preparation of numerous implementation decrees of Decree No. 230.

g) Minister for the Interior

In accordance with Decree No. 230 of 1995, the Minister for the Interior, who is generally responsible for public safety, assists with the drafting of regulations by other ministers in connection with the classification and licensing of commercial activities using nuclear and radioactive materials.

The same Decree provides that each nuclear installation must have an off-site emergency plan to ensure protection of the public against the harmful effects of a nuclear accident. Such plans consist of a series of co-ordinated measures to be taken by those responsible in the event of an incident at a nuclear installation which might put public safety at risk. The Minister for the Interior contributes to the establishment of the national radiological emergency plan [Section 125 of Decree No. 230], in conjunction with the Department of Civil Protection.

In addition, in accordance with Act No. 996 of 8 December 1970, the Ministry of the Interior and its services are responsible for taking the measures required to protect the public in the event of catastrophes.

As the authority associated with the Minister for the Interior in each region, the Prefect is competent to grant a clearance certificate for category B use of radioactive substances and appliances containing them, in industry and research. The Prefect is also responsible for preparing the emergency plan in the region (except the medical aspects) and for its application as part of the national emergency plan.

h) Minister for Transport and Navigation

This Ministry, established by Act No. 537 of 24 December 1993, is the result of a merger of two previous Ministries: the Ministry of Transport and the Ministry of the Merchant Navy. The duties

carried out by these two Ministries have been transferred to the Ministry of Transport and Navigation. Thus, the latter Minister is, at present, the competent authority, in conjunction with the Minister for Industry, Commerce and Crafts, for granting licences for the transport of nuclear and radioactive materials by road, rail, air and sea [Section 5 of Act No. 1860 of 31 December 1962, as amended by DPR No. 1704 of 30 December 1965].

i) Minister for Foreign Trade

The import of ores, source materials and radioactive materials is subject to authorisation by the Minister for Foreign Trade when such authorisations are required by financial and currency regulations. Together with the Finance Minister, the Minister for Foreign Trade has laid down the rules for importing goods, establishing in particular which goods require an import licence, including radioisotopes and ionising radiation-emitting equipment [Section 4 of Act No. 1860 of 1962 and DM of 30 October 1990 promulgating the list of goods requiring an import licence].

j) Minister for Education

Public institutions possessing radioactive materials for teaching or scientific research are required to report them to the Minister where the quantity of materials involved exceeds the prescribed levels [Section 3 of Act No. 1860 of 1962, as amended by Section 1 of DPR No. 1704].

The Minister is also involved in licensing the use of radioisotopes above certain quantities [Section 13, as amended by Section 3 of DPR No. 1704].

k) Treasury Minister

The Treasury Minister has to approve the general conditions of the financial security for the liability of nuclear operators when such security is not in the form of an insurance policy. Furthermore, notice of summons in respect of actions for compensation of nuclear damage are submitted to the Minister who may, in all cases, intervene in the proceedings [Sections 22 and 25 of Act No. 1860 of 1962, as amended by Section 2 of the DPR of 10 May 1975].

The Minister is also consulted by the Minister for Industry, Commerce and Crafts on the estimates of ENEA expenditure [Section 5 of Act No. 282 of 25 August 1991].

l) Minister for Universities and for Scientific and Technical Research

The above Minister is responsible for co-ordinating at national and international level all measures to promote the development of scientific and technical research. He is consulted by the Minister for Industry, Commerce and Crafts in connection with ENEA research and development programmes and its scientific, technical and industrial co-operation with international or foreign organisations [Section 1 of Legislative Decree No. 36 of 30 January 1999]. The Minister for Universities is also involved in determining the radiation protection qualifications of personnel in radiology and nuclear medicine [Section 110 of Decree No. 230 of 1995].

m) Minister for Foreign Affairs

The above Minister is also consulted by the Minister for Industry, Commerce and Crafts in connection with the activities of the ENEA in the field of international co-operation [Section 1 of Legislative Decree No. 36 of 30 January 1999].

n) Department of Civil Protection

This Department, which comes under the authority of the Prime Minister is entrusted, pursuant to Decree No. 230/95, with a number of regulatory and administrative tasks in the fields of public protection and radiation emergencies, in conjunction with other competent ministries.

o) State Advocate General

Presidential Decree No. 519 of 10 May 1975 provides that the opinion of the State Advocate General must be obtained before final approval may be given to the general conditions for insurance or other form of financial security decided on by the Minister for Industry, Commerce and Crafts in agreement with the Treasury Minister.

2. Advisory Bodies

a) Interministerial Council for Consultation and Co-ordination

This Interministerial Council was set up under the Ministry of Industry, Commerce and Crafts pursuant to Presidential Decree No. 185 of 1964 on radiation protection and was confirmed by Decree No. 230, Section 8. It meets under the chairmanship of the Director-General for Energy and Mining Resources and is composed of nine representatives of the ministries concerned and one representative of the ANPA. All members are appointed for four years by Decree of the Prime Minister, on the proposal of the Minister for Industry. The Council is responsible for co-ordinating, from the administrative point of view, the activities of the different government departments responsible for the application of Decree No. 230 of 1995, by reviewing all the provisions concerning the peaceful uses of nuclear energy.

b) Co-ordinating Committee for Radiation Protection of Workers and the Public

This Committee was set up by Act No. 619 of 1980, and includes representatives of the organisations mentioned in Section 1(e) above, as well as the National Research Council and the ANPA. The Committee is consulted by the Ministers for Health and the Environment on topics that fall within their competence.

c) Regional and Provincial Commissions for Public Health Protection Against the Hazards of Ionising Radiation

By Decree No. 185 of 1964, a commission was set up in each region under the chairmanship of the Regional Director of Public Health to give its advice on questions relating to public health protection against the hazards of ionising radiation. The commissions are involved in the licensing

procedures for the possession and use of radioactive sources and for radioactive waste disposal in connection with scientific, industrial and medical activities.

Decree No. 230 of 1995 now provides for such technical advisory bodies to be established at regional and provincial levels under legislation adopted at those levels.

d) Technical Commission for Nuclear Safety and Health Protection

This Commission was also set up by Decree No. 185 of 1964 and was confirmed by Decree No. 230 of 1995 [Section 9]. It consists of sixteen experts appointed by the ministries concerned, by the ENEA and by the ANPA, within which it is situated. The chairperson is appointed from amongst these experts by decree of the Prime Minister. The Commission gives its advice on questions relating to the licensing of nuclear installations and radiation emergencies as provided for in Decree No. 230, as well as at the request of the government.

3. Public and Semi-Public Agencies

a) National Agency for New Technologies, Energy and the Environment (ENEA)

Four important changes have been made within this body between 1960, the year in which the National Committee for Nuclear Energy (*Comitato Nazionale per l'Energia Nucleare* – CNEN) was set up [Act No. 933 of 1 August 1960], and 1999, the year of the latest re-structuring.

The first change, in 1971, gave the CNEN new powers, and in particular the task of undertaking, in collaboration with specialised companies, the construction of experimental facilities and the development of prototype reactors [Act No. 1240 of 15 December 1971].

The second change dates from 1982 when Act No. 84 of 5 March 1982 renamed and re-structured the CNEN. The acronym ENEA, which stands for National Committee for Research and Development of Nuclear and Alternative Energies (*Comitato Nazionale per la Ricerca e per lo Sviluppo dell'Energia Nucleare e delle Energie Alternative*), replaced the CNEN whose former duties were extended to include research into, and development of alternative energies. The ENEA, however, continues to perform the CNEN's statutory tasks, in particular, ensuring that nuclear energy and ionising radiation are used without causing any hazard.

Under the third reorganisation, dating from 1991, significant changes were made to the ENEA's duties [Act No. 282 of 25 August 1991]. While retaining its acronym, the ENEA is now called the National Agency for New Technologies, Energy and the Environment (*Ente per le nuove tecnologie, l'energia e l'ambiente*). The ENEA retains its technical and scientific responsibilities (special studies, research, experimental work, etc.) regarding nuclear activities, notably in the field of nuclear safety and radiation protection, while broadening its jurisdiction to include questions relating to the environment and to new technologies.

Lastly, Parliamentary Decree No. 36 of 30 January 1999, which repeals and replaces Act No. 282 of 25 August 1991, further widens the scope of the Agency's activities. The new tasks assigned to the ENEA essentially involve research in the field of sustainable development, innovation in terms of the production of small and medium-sized businesses and in relation to transfer of technology to such businesses, in particular in the energy field. As a civil service body, the ENEA

provides advanced technical support in the fields of energy, the environment and technological innovation.

i) Legal status

The ENEA is a body governed by public law which carries on its activities in accordance with the directives of the Interministerial Committee for Economic Planning (CIPE). It is placed under the authority of the Minister for Industry, Commerce and Crafts, and consults the Minister for Universities and for Scientific and Technological Research as regards R&D programmes, the Minister for the Environment in relation to projects which could affect the natural environment and the Minister for Foreign Affairs with regard to international activities [Decree No. 36/99, Section 1].

ii) Responsibilities

As regards new technologies, energy and the environment, the ENEA's duties are [Section 2]:

- to carry out and promote studies, research and development with respect to technological aspects;
- to carry out, promote and co-ordinate studies, research and experiments on the effects, including the economic and social consequences, of the development and use of technologies, and on the safety of nuclear installations and protection against ionising radiation;
- to co-operate in the scientific, technical and industrial fields, with the international bodies involved in the same sectors;
- to formulate and implement plans for the dissemination of know-how and research results to government departments;
- to train staff in technological subjects and disseminate the knowledge acquired;
- to give opinions to, and carry out technical controls on behalf of government, regional and local authorities.

To this end, the ENEA may conclude agreements with the competent ministries, the regions, the autonomous provinces of Trento and Bolzano, local authorities and certain local firms, as provided for by Act No. 142 of 8 June 1990. In addition, the ENEA was responsible, within three months of the entry into force of the Act, for setting up a consortium for the promotion of the rational use of energy and of renewable sources, and of businesses engaged in developing such technologies.

The control of nuclear safety, radiation protection, physical protection, etc. are the responsibility of the ANPA according to the Act [No. 61 of 1994] establishing that Agency.

b) National Institute of Nuclear Physics (INFN)

This Institute was set up under Act No. 1240 of 15 December 1971 as a public body with an autonomous budget, and is run in accordance with a Ministerial Decree of 1967. The CIPE supervises

the programmes of the INFN which are communicated to it by the Minister for Education [Act No. 1240, Sections 25 and 26; DM of 26 July 1967].

c) National Health Service

Act No. 833 of 23 December 1978 set up a National Health Service with responsibilities in the field of radiation protection. The Act determines and allocates between the state, the regions and local authorities, the various duties, structures and services aimed at promoting, maintaining and restoring the health of workers and the population.

The state maintains its powers concerning the health control of the production and use of nuclear energy and radioactive materials, while certain administrative functions are delegated to the regions concerning control, trade in and storage of radioactive materials, as well as environmental monitoring [Section 6(K) of the 1978 Act].

Under the 1978 Act, the Provincial Director of Public Health is no longer answerable to the Ministry of Health but to the regional authorities.

Decree No. 230 of 1995, entrusted various functions to the National Health Service, as well as to its regional structures.

d) Electricity Company, s.p.a. (ENEL, s.p.a.)

Act No. 1643 of 6 December 1962 nationalising the electricity industry in Italy set up a body governed by public law and possessing legal personality: the National Electricity Company (*Ente Nazionale per l'Energia Elettrica* – ENEL), responsible for all activities relating to the production, import, export, conversion, distribution and sale of electrical power. The ENEL accordingly managed and operated nuclear power plants in Italy and was also responsible for the power plant building programme. The ENEL therefore held a monopoly of national electricity [Act No. 1643 of 6 December 1962].

Important changes occurred in Italy in the energy field during the 1990s. In the first place, Acts Nos. 9 and 10 of 9 January 1991 significantly reduced the ENEL's monopoly to leave more room for independent producers and local businesses. Then, the ENEL was transformed into a limited company (ENEL s.p.a.) which made it possible for private individuals to take out shares in the company [Act No. 359 of 8 August 1992].

A legislative decree of March 1999, adopted in implementation of Directive 96/92/EC of the Parliament and of the Council concerning common rules for the internal market in electricity, provided that ENEL be re-structured, through the establishment of several companies, one of which would monitor the decommissioning of nuclear power plants.

e) National Environmental Protection Agency (ANPA)

In January 1994, the Italian Parliament implemented Decree No. 496 of 4 December 1993 providing for the creation of the National Environmental Protection Agency (*Agenzia Nazionale per la Protezione dell'Ambiente* – ANPA). This Decree became Act No. 61 of 21 January 1994.

The decision to create this Agency was a result of the referendum of 18 April 1993 which repealed the provisions giving Local Health Units responsibility for monitoring the environment. Since this issue was particularly sensitive, it was important to make a distinction as soon as possible between health questions and those relating to the environment as well as the corresponding roles of the different bodies in respect of these two questions.

The ANPA comes directly under the Minister for the Environment and is subject to controls by the Board of Auditors. Its powers, listed in Section 10(1) of Act No. 61, relate to a series of technical and scientific activities of national interest. Its main role is to carry out public duties, such as providing technical and scientific back-up to the Ministry of the Environment and associated bodies with a view to protecting the environment, the collection and periodic dissemination of data on the state of the environment, the formulation of proposals and opinions for both central government and local authorities concerning quality standards for air, water, soil, etc. Nuclear activities are expressly referred to under the letter "I" of the same Section which requires the Agency to exercise control over activities relating to the peaceful uses of nuclear energy and over the effects of ionising radiation on the environment. The Agency's functions are essentially radiation protection inspection, as well as formulating advice as to the legal, regulatory and administrative provisions affecting radiation protection of workers and the public.

Under Section 1(5) of the Act, the ANPA replaces the Nuclear Safety and Health Protection Directorate of the ENEA (ENEA-DISP), whose functions, staff, technical structures and equipment and financial resources are transferred to the new Agency.

JAPAN

I. GENERAL REGULATORY REGIME

1. Introduction

The starting point for discussion of Japan's nuclear legislation is the Atomic Energy Basic Law (the Basic Law) [No. 186, 1955]. The Basic Law states that its objectives are to secure energy resources for the future and to promote the research, development and use of nuclear energy for peaceful purposes [Chapter 1]. It goes on to establish a framework for the regulation of nuclear activities, specific aspects of which are to be dealt with in subsequent, separate Acts. The Basic Law created the Atomic Energy Commission (AEC) and the Nuclear Safety Commission (NSC) [Chapter 2]. Its provisions also deal in very broad terms with the mining of nuclear source materials [Chapter 4], control over nuclear fuel materials [Chapter 5], control over nuclear reactors [Chapter 6], protection from radiation hazards [Chapter 8] and compensation for damage caused by nuclear activities [Chapter 9]. These provisions, in effect, do no more than signal the state's intention to exercise regulatory powers in these areas by means of subsequent legislation. The most important of these later Acts are:

- the Law for the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (Regulation Law) [No. 166, 1957], as amended;
- the Law concerning Prevention from Radiation Hazards due to Radioisotopes etc. (Prevention Law) [No. 167, 1957]; and
- the Law on Compensation for Nuclear Damage [No. 147, 1961].

These laws will be discussed in more detail below.

2. Mining Regime

The Basic Law states that special provisions dealing with the mining of nuclear source material may be made by subsequent laws [Section 8]. It also states that the government may legislate to acquire all nuclear source material, to control all dealings with nuclear source material and to encourage the development of nuclear source material by means of subsidies and other financial incentives [Sections 9, 10 and 11]. The Power Reactor and Nuclear Fuel Development Corporation (PNC) withdrew from activities related to prospecting for nuclear source material in 1998 when it was reorganised as the Japan Nuclear Cycle Development Institute (JNC). Japanese mining law does not differentiate between uranium and other minerals.

3. Radioactive Substances, Nuclear Fuel and Equipment

Activities involving radioactive substances are governed by the Prevention Law while activities connected with the nuclear fuel cycle come within the scope of the Regulation Law.

The principal purpose of the Prevention Law is radiation protection and to this end it regulates the use, sale, lease, disposal etc. of radioisotopes and ionising radiation-generating equipment. In general, any person wishing to use radioisotopes or ionising radiation-generating equipment must obtain a licence to do so from the Minister of State for Science and Technology [Section 3]. The application must contain information about intended use, location, radiation safety measures to be observed, etc. The Minister of State for Science and Technology may attach conditions to the licence [Section 8] and may suspend or cancel it if there is non-compliance with the law or any condition thereof. The sale of radioisotopes is subject to licensing conditions similar to those regarding their use [Section 4]. The use of sealed sources containing radioisotopes below a prescribed quantity is exempt from licensing requirements, but advance notification to the Science and Technology Agency (STA) is necessary [Section 3]. The Prevention Law also contains criminal sanctions (fines and imprisonment) for non-compliance with its provisions [Chapter VII].

The purpose of the Regulation Law is to ensure the peaceful use of nuclear source material, nuclear fuel and nuclear reactors. It provides for a comprehensive licensing regime covering the following nuclear activities: refining nuclear source material, manufacture and use of nuclear fuel, construction and operation of reactors, storage and reprocessing of spent nuclear fuel, disposal of radioactive waste, and any other use of internationally-controlled material (that is, material subject to internationally agreed safeguards).

The Regulation Law requires that a person (other than a government-controlled entity) wishing to carry on a refining business must obtain the authorisation of both the Prime Minister and the Minister for International Trade and Industry (MITI) [Section 3]. Applications for a licence must contain information on the planned design, proposed safety measures and the intended construction and refining methods for the facility. The advice of the Atomic Energy Commission and the Nuclear Safety Commission must be obtained by the Prime Minister and MITI before the licence is granted [Section 4]. Licensees are required to keep records of their operations as prescribed by Order of the Prime Minister's Office.

Licensing requirements similar to those for refining activities apply to the manufacture and use of nuclear fuel and other internationally-controlled material.

Until 1980, reprocessing of spent fuel could be carried on only by the PNC (now the JNC) and the Japan Atomic Energy Research Institute (JAERI). However, an amendment to the Regulation Law, adopted in 1980, enabled the Prime Minister to authorise private companies to also carry out such activities. The Regulation Law specifies certain conditions which must be met by such companies, and provides for government supervision and inspection of the construction of the reprocessing facility and during its operation [Sections 44-46].

The Regulation Law was amended by Law No. 75 of 1999 to include the storage of spent nuclear fuel within its scope. Persons who undertake the storage of spent nuclear fuel outside nuclear power plants, reprocessing plants or other nuclear installations specified in the Law are required to obtain a licence from MITI and are subject to its supervision during the operation of the spent fuel storage facility [Section 43(4)-(26)].

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

The Regulation Law governs the siting, construction and operation of nuclear facilities. Two Cabinet Orders establish the details of a comprehensive licensing system: the Ordinance implementing the Regulation Law [Cabinet Order No. 324, 1957] and the Ordinance for the Definition of Nuclear Fuel Material, Nuclear Source Material, Reactors and Radiation [Cabinet Order No. 325, 1957]. The Prevention Law is also relevant in relation to the safety aspects of nuclear facilities.

Responsibility for the establishment and operation of a nuclear facility depends on the type of facility involved [Regulation Law, Section 23]. MITI is responsible for all commercial nuclear power facilities as part of the broader responsibility for all types of electricity generation under the Electricity Utility Industries Law [No. 170, 1964, as amended], as well as for spent fuel storage facilities. The Minister of State for Science and Technology, on behalf of the Prime Minister, is responsible for giving approval for the construction and operation of research reactors, experimental reactors, fuel manufacture and reprocessing facilities, and waste management and disposal facilities. The Minister for Transport is responsible for nuclear-powered ships. At all stages of the licensing process, both the AEC and the NSC are involved in advising the appropriate licensing authority.

On 9 June 1997, Environmental Impact Law No. 81, 1997 was adopted, establishing a general procedure for the environmental impact assessment of large scale projects which could have a significant impact on the environment. The construction of a power plant is among the types of projects for which a mandatory environmental impact assessment is required.

The licensing procedure is divided into three main stages: approval of a particular site, the granting of a construction licence, and finally, approval to operate the installation. A construction licence for a reactor can only be granted if the minister responsible is satisfied that the reactor will be used only for peaceful purposes, the construction is consistent with the national atomic energy development plan, the applicant has the necessary technical and financial resources, and the location, structure and equipment of the reactor all comply with safety requirements [Section 24]. Before granting a licence, the relevant minister must seek the views of both the AEC and the NSC on the proposal [Section 24(2)]. Once the construction licence has been granted, no change in the design or construction method is allowed unless approval has been sought and obtained for the change from the minister [Sections 26 and 27]. Before the reactor can begin to operate, an inspection must be carried out which satisfies the minister that the construction conforms to the approved design and methods and to all the relevant technical standards [Section 28]. The operator must also have an approved set of safety regulations and procedures in place before operations may commence [Section 37]. The operator must submit to an annual inspection of the facility by the relevant Ministry [Section 29] and must also provide an operating plan which conforms to the requirements set out for such plans in orders issued by the Ministry [Section 30].

Section 33 provides that a licence may be revoked if the operator has failed to comply with any of the obligations pursuant to the Act, any applicable orders made under the Act or any licence condition.

Several regulations made under the Regulation Law deal in detail with the various types of reactor. The Regulations concerning the Installation and Operation of Reactors for Power Generation [Order No. 77, 1978 adopted by MITI] cover application procedures for commercial reactor design and construction and for alteration of facilities, limits on access to controlled areas, storage of nuclear

materials and waste and security measures. The construction and operation of research reactors are dealt with under the Regulations concerning Installation, Operation etc. of Nuclear Reactors in use for Testing and Research Purposes [Order No. 83, 1957 adopted by the Prime Minister].

The Regulation Law also contains penalties for various activities related to the operation of nuclear reactors, for example, using nuclear fuel without a permit [Section 77], non-compliance with restrictions on the transfer of nuclear fuel, failure to lay down approved safety rules [Section 79] and failure to maintain records of internationally controlled material or to provide information on such material as required [Section 80]. Such penalties are applied to other nuclear activities, such as refining nuclear source material, the manufacture of nuclear fuel and storage and reprocessing of spent nuclear fuel, disposal of nuclear waste, etc.

In relation to nuclear safety, Law No. 157 of 13 December 1999, which will enter into force on 1 July 2000, amends the Regulation Law in order to strengthen the nuclear safety requirements within nuclear facilities. In this respect, the Law provides for appointment of "energy safety inspectors" under STA and MITI in order to carry out periodic inspections of facilities. It further provides that it is compulsory for nuclear operators to organise safety training for radiation workers.

Moreover, Japan accepted the 1994 Convention on Nuclear Safety on 12 May 1995.

Finally, it should be noted that the Law on Compensation for Nuclear Damage [No. 147, 1961] prohibits the operation of a nuclear installation if the financial security for damage required by the law is not in place in respect of that installation.

b) Emergency response

Special Law No. 156 on Emergency Preparedness for Nuclear Disaster (hereinafter referred to as the "Special Law"), adopted on 17 December 1999 aims to enforce countermeasures in the event of a nuclear disaster. In this respect it modifies and complements the countermeasures against natural disasters described in the Basic Law for Disaster Countermeasures.

Under the Special Law, the nuclear operator must take measures to prevent nuclear disasters, prepare an Emergency Plan and establish a Nuclear Disaster Prevention Organisation. This Organisation is responsible for taking necessary measures to prevent or mitigate nuclear damage, should an emergency situation arises.

Moreover, the nuclear operator shall appoint a Nuclear Disaster Prevention Manager. The Manager shall inform the competent ministers, mayors and governors of municipalities and prefectures, promptly after such an event takes place and, upon the request of governors or mayors, the competent ministers shall promptly dispatch their appropriate personnel.

The nuclear operator is also required to install and maintain equipment for measuring radiation doses and to provide special radiation protection clothes and communication equipment.

Relevant ministers are to establish Off-Site Centres, which shall take necessary measures in the event of an emergency situation, in each prefecture where a nuclear installation is located.

In the event of an emergency situation, the Prime Minister issues a Declaration of Nuclear Emergency Situation and notifies the public located in the area where urgent countermeasures must be adopted.

The Law further provides that, in the event of an emergency situation, several structures will be established:

- Within the Prime Minister's Office, a Government Countermeasures Headquarters shall be created, and in emergency situations the Prime Minister, as a director of the Headquarters, can request the Director General of the Defence Agency to dispatch the Self-Defence Force. He can also request technical advice regarding the implementation of urgent countermeasures from the Nuclear Safety Commission.

- A Joint Council for Countermeasures in the event of Nuclear Disaster shall be created within the Off-Site Centre in order to facilitate exchange of information and co-operation among the various organisations concerned.

The Government, local authorities, relevant organisations and operators shall take urgent measures such as notifying information, evacuation, collecting information including radiation dose rate, rescuing victims, regulating emergency transportation, measuring exposure dose rate of residents, etc.

Lastly, in order to inform nuclear operators on disaster prevention measures and to collect information in the event of an emergency, STA and MITI appoint Experts for Nuclear Disaster Prevention at the nuclear installations.

At the international level, Japan accepted the 1986 Conventions on Early Notification of a Nuclear Accident and on Assistance in the Case of a Nuclear Accident or Radiological Emergency respectively on 9 June 1987.

5. Trade in Nuclear Materials and Equipment

While Japan imports nuclear fuels, materials and technology, it also has a highly developed nuclear industry and the corresponding potential to supply numerous nuclear and nuclear-related services and equipment.

Japan has a clearly-defined nuclear export policy based on assurance of peaceful uses and non-proliferation, including compliance with the London Club Guidelines, elaborated by the Nuclear Suppliers Group (London Club).

In 1962, the Atomic Energy Commission issued a policy statement to the effect that nuclear materials, reactor cores and units for the reprocessing of special nuclear materials, exported from Japan, be used solely for peaceful purposes, thus setting a basic principle for nuclear exports control, consistent with the principles of the Basic Law [Section 2].

The Regulation Law provides for control of nuclear material and equipment while the Prevention Law regulates the sale of radioactive materials and equipment.

The Regulation Law restricts the transfer, import and export of nuclear fuel to those who are engaged in refining, manufacturing or reprocessing such material, and to operators of nuclear facilities [Section 61]. These restrictions do not apply where the government receives or transfers nuclear fuel at the national level or in accordance with international arrangements.

The sale and import of radioisotopes for medical purposes are governed by the Medical Supplies Act [No. 145, 1960] and are subject to licensing requirements. Trade in medical X-ray apparatus is regulated by an Ordinance of the Ministry of Health and Welfare and is subject to notification, but not licensing, requirements.

The import and export of nuclear materials and equipment are also subject to the provisions of general trade law, namely the Foreign Exchange and Foreign Trade Control Law [No. 228, 1949] and its implementing orders and regulations which describe the procedures for obtaining import and export licences and approvals. MITI is responsible for this Act and its implementing legislation. Nuclear material and equipment are classified as "exceptional items" which means that prior approval must be obtained for their export and importation. The Import Trade Control Order [Cabinet Order No. 414, 1949] and the Export Trade Control Order [Cabinet Order No. 378, 1949] contain the basic rules for import and export activities, while the procedures to be followed to obtain the necessary licence are set out in the Import Trade Control Regulations [MITI Ordinance No. 77, 1979] and the Export Trade Control Regulations [MITI Ordinance No. 64, 1949].

6. Radiation Protection

Both the Prevention Law and the Regulation Law govern radiation protection issues.

The aim of the Prevention Law is to regulate the use, sale, lease, disposal or any other handling of radioisotopes and ionising radiation-generating equipment in order to prevent ionising radiation hazards and to secure public safety [Section 1]. Pursuant to this Law, applications must be made to the Minister of State for Science and Technology for any activity connected with radioisotopes or ionising radiation-generating equipment. Granting of the licence depends on whether the site, structure and equipment proposed conform to the standards laid down by the Order of the Prime Minister [No. 56, 1960], and whether potential hazards from ionising radiation have been dealt with satisfactorily [Sections 6, 7 and 7(2)]. The Prevention Law also sets out dose limits for exposure to ionising radiation. The limit is 50 mSv per year for workers whose work involves radiation activities, and 1 mSv per year for members of the public. In 1980, the Prevention Law was amended to introduce a system of inspection and approval of radioisotopic equipment and to prescribe compulsory training courses for radiation protection supervisors. The amendments also established a training institution to conduct these courses. In 1995, further amendments established a system for leasing radioisotopes and simplified the licensing system for the use of radioisotopes with a lower risk of radiation hazard.

The Regulation Law deals with safety questions in relation to nuclear reactors and nuclear fuel. The licensing procedure involves scrutiny of safety measures and accident prevention at every stage. Detailed rules on these matters are contained in the Ordinance for the Enforcement of the Law Concerning Nuclear Source Materials, Nuclear Fuel Materials and Nuclear Reactors [Ordinance No. 324, 1957], in ordinances issued by the Prime Minister's Office and MITI, and in notifications issued by STA and MITI.

In addition to these laws, there are also the Regulations on the Prevention of Ionising Radiation Hazards [Ordinance of the Ministry of Labour, No. 41, 1972].

The Nuclear Safety Commission, which has a significant advisory role in the licensing process for nuclear reactors, was established in 1978 to take over responsibility for safety issues formerly dealt with by the Atomic Energy Commission. This was accomplished by an amendment to the Law for the Establishment of the Atomic Energy Commission [No. 188, 1955]. It has the following areas of responsibility:

- regulatory policy for the safe utilisation of nuclear energy;
- safety aspects of the regulation of nuclear fuel, source material and nuclear reactors;
- protection against hazards resulting from the use of nuclear energy;
- protection against hazards resulting from radioactive fallout;
- any other matters of importance in the regulation of the safe use of nuclear energy.

7. Radioactive Waste Management

The legislation applicable to the management of waste resulting from nuclear reactor operations is the Regulation Law. In relation to waste resulting from the use of radioisotopes and ionising radiation-emitting equipment, the Prevention Law is applicable.

Waste management policy is determined by the AEC (basic policy) and the NSC (safety aspects), but that policy is implemented through the licensing system for nuclear activities. Pursuant to Chapter V(II) of the Regulation Law, application may be made to the Prime Minister for a licence to engage in nuclear waste disposal activities [Section 51(2)]. The licence may authorise either the storage of waste or (in the case of low-level waste) its final disposal by underground burial. The licence application must include information about the type of waste and its properties, the location of the proposed storage or disposal facilities, a safety plan, an engineering plan and a management plan. The application must also establish that the project has adequate technical and financial resources. The site must conform to standards specified in the relevant Prime Ministerial Orders [No. 1, 1988 and No. 47, 1988]. Once the licence has been granted, the operator of the waste management facility must submit to supervision and inspection by the Science and Technology Agency at regular intervals [Sections 51(8)-(10)].

The Prevention Law has a series of provisions dealing with obligations in relation to those responsible for the disposal of radioisotopes and material contaminated by radioisotopes [Sections 19-26]. Measures to prevent ionising radiation hazards, in accordance with the technical standards laid down by order of the Prime Minister's Office must be taken. Failure to comply with these standards will result in the Minister of State for Science and Technology ordering the suspension of the disposal activities. Records must be kept of disposal activities and of the results of monitoring radiation levels at waste storage and disposal facilities. Further provisions require that all waste disposal operators develop their own internal rules for the prevention of radiation hazards, that these rules be approved by STA, and that training and medical examinations be made available to all employees entering waste storage and disposal facilities.

As far as the dumping of radioactive waste at sea is concerned, Japan has been a Party to the 1972 London Convention on Prevention of Marine Pollution by the Dumping of Waste and Other Matters since 15 October 1980. Up until early 1994, the Convention permitted the dumping at sea of certain low-level radioactive waste. However, in 1993, Japan's Atomic Energy Commission decided

to discontinue dumping at sea as a means of disposal and, since 20 February 1994, all Parties to the Convention have become bound by a 25-year ban on the dumping at sea of any radioactive waste.

8. Non-Proliferation and Physical Protection

Japan has been a Party to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons since 8 June 1976 and to the 1979 Convention on the Physical Protection of Nuclear Material since 28 October 1988. It also ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 8 July 1997.

Provisions regarding the peaceful use of nuclear materials are established in the Basic Law and the Regulation Law. Article 2 of the Basic Law states that research into, development and use of nuclear energy shall be limited to peaceful purposes and provides, *inter alia*, that import, export, possession etc. of nuclear fuel shall be subject to regulations for control purposes. The Regulation Law lays down detailed regulations for the different types of nuclear activities, including provisions for control of the use of internationally-controlled material [Chapter VI(II)]. The Regulation Law specifies that such material means nuclear source material, nuclear fuel, reactors and other material or equipment to which safeguards and other regulations are applied pursuant to the Safeguard Agreement concluded with the International Atomic Energy Agency (IAEA) and other agreements concluded with foreign governments or international organisations, subject to the Additional Protocol to the Safeguard Agreement, in relation to research, development and use of nuclear energy [Section 2].

Under the authority of the Prime Minister, STA exercises responsibility for nuclear activities. The International Affairs and Safeguards Division in the Atomic Energy Bureau of STA is in charge of safeguards, and Chapter VII of the Regulation Law provides that inspectors appointed by the Prime Minister are to have access to the offices, facilities or places where nuclear fuel is present in order to carry out controls as required by this Law. If premises contain internationally-controlled material, persons appointed by the supplier state or IAEA inspectors also have inspection powers. Japan applies IAEA safeguards to nuclear material in conformity with its obligations under the Nuclear Non-Proliferation Treaty. On 16 June 1999, new provisions were added to the Regulation Law to incorporate the requirements of the Additional Protocol to the Safeguard Agreement, which Japan signed within the framework of the IAEA in 1998. The new provisions establish the duty of persons who undertake specified activities, defined as the activities listed in Annex I of the Additional Protocol, to report to the Prime Minister [Section 61(9)(2)]. They furthermore provide that users of internationally controlled material are subject to regular inspection by the Prime Minister to the extent necessary for the implementation of the Safeguard Agreement [Section 61(8)(2)]. The Prime Minister may designate one or more organisation(s) to conduct inspections under his control [Section 61(23)(1)]. The new provisions of the Law allow the IAEA inspectors to enter the offices, facilities or premises of the users of internationally-controlled material and persons carrying out internationally specified activities to conduct complementary inspections in the presence of officials appointed by the Prime Minister, within the limits established by the Additional Protocol [Section 68].

Chapter VI(II) of the Regulation Law contains accounting provisions: users of nuclear fuel must keep records and must report any loss or theft. Failure to maintain records of internationally-controlled material or provide information on such material as required is punishable by a fine of up to Japanese yen (JPY) 200 000 [Section 80]. Criminal sanctions, carrying prison sentences, also apply to the unauthorised use of specified nuclear fuels [Chapter VIII].

The Regulation Law provides that people engaged in any of the nuclear activities to which it applies it (refining, manufacture, reactor operation, reprocessing, waste disposal and use of nuclear fuel material) are responsible for establishing rules for the physical protection of specified nuclear

materials in their establishments [see, for example, Section 12(2)-(5)]. These rules must conform to requirements specified in various ministerial orders. The orders are issued by different ministers, depending on the type of nuclear activity addressed. The Prime Minister issues orders laying down a framework for physical protection in relation to reactor development, reprocessing and waste management, while MITI has a similar responsibility in relation to commercial power reactors, and the Minister for Transport is responsible for nuclear ships.

The physical protection rules established by a nuclear operator can only be modified with the approval of the minister responsible (who also has the power to order that certain modifications be made). The operator must appoint a physical protection supervisor to ensure compliance with the rules [Sections 12(3), 22(7), 44(3), 51, 51(24) and 57(3)].

9. Transport

The administrative requirements and safety standards applicable to the transport of radioactive materials in Japan are set out in ordinances of the Prime Minister's Office and the Ministry of Transport, which incorporate the 1985 edition of the IAEA's Regulation for the Safe Transport of Radioactive Material into domestic law.

In order to prevent exposure to radiation and, in the case of fissile materials, to prevent criticality, during the transport of radioactive materials, different governmental agencies are responsible for the application of laws and ordinances for the different modes of transport, with classification of packages into different categories according to the specific radioactivity, form, characteristics and total radioactivity of the contained radioactive materials and the dose equivalent rate from the packages.

Overland transport (transport by rail and road) is governed by various regulations adopted by STA and the Ministry of Transport pursuant to the Regulation Law (for nuclear materials) and the Prevention Law (for radioisotopes). Such transport operations are supervised by both STA and the Ministry of Transport to ensure that technical standards are met. The procedure is as follows:

(a) STA issues a certificate of package design approval after examination of the package's safety in terms of structure, material, manufacture, handling, maintenance control etc.

(b) STA, if it is satisfied that it has been manufactured in accordance with the approved design, and in light of inspections and tests in relation to material, dimensions, welding, pressure, heat conditions, shielding, etc., assigns registration numbers to the individual packages and issues the applicant a packaging approval certificate.

(c) Prior to each transport operation, the applicant also applies to STA to have the packages approved. Having confirmed that they are in conformity with (a) and (b) above, and that they meet standards regarding the appearance of the packages, surface dose equivalent rate and leakage, the certificate of confirmation is issued by STA.

(d) Prior to each transport operation, the applicant furthermore applies to the Ministry of Transport for approval of the method of transport. Upon confirmation that the mode of transport (method of loading of the packages on the vehicles, marking and labelling, loading limits, etc.) are in conformity with the technical standards, the Ministry of Transport issues a certificate of approval.

(e) Prior to each shipment, the applicant must formally notify the prefectural Public Safety Committee (PSC) concerning the specific transport plans. The PSC then gives guidance and instruction in relation to safety issues, if necessary, and issues a permit for the transport operation.

Concerning *maritime transport*, basically the same procedure as applies to overland transport is followed, except that the competent bodies are the Ministry of Transport and the Maritime Safety Agency (MSA). The applicable legislation is the Ship Safety Law [No. 11, 1933], which has incorporated the provisions of the IAEA Regulations for the Safe Transport of Radioactive Materials concerning packages and the provisions of the International Maritime Organisation's (IMO) 1960 International Convention for the Safety of Life at Sea (SOLAS) concerning the structure and facilities of the ship. In the case of combined overland and maritime transport, packages are approved by STA on the basis of the Regulation Law (or the Prevention Law for radioisotopes). This approval procedure is sufficient to satisfy the conditions of the Ship Safety Law. Prior notification in the case of maritime transport is provided to the Head of the Regional Maritime Safety Headquarters of the MSA with jurisdiction over the port of departure of the ship.

In relation to *air transport*, the procedure outlined above with regard to overland transport is also followed; in this particular field the competent body is the Ministry of Transport. The applicable legislation is the Civil Aeronautic Law [No. 231, 1953]. In the case of combined overland and air transport, packages are approved by STA on the basis of the Regulation Law (or the Prevention Law for radioisotopes), which is sufficient to satisfy the conditions of the Civil Aeronautic Law.

10. Nuclear Third Party Liability

Japan is not a Party to either the 1960 Paris Convention or the 1963 Vienna Convention on civil liability for nuclear damage. However, it has established a national regime dealing with compensation for nuclear damage. The three major legislative instruments to be considered in this context are the Law on Compensation for Nuclear Damage, the Ordinance implementing the Law on Compensation for Nuclear Damage [Cabinet Order No. 44, 1962], and the Law on Indemnity Agreements for Compensation for Nuclear Damage [No. 148, 1961].

The Compensation Law provides that the operator of a nuclear installation is exclusively and strictly liable for nuclear damage resulting from the operation of his installation [Section 3(1)]. The operator's liability is unlimited. The Compensation Law requires each installation to be insured for a prescribed amount (pursuant to the amendment of 28 April 1999 to the Compensation Law, JPY 60 billion for the operation of nuclear reactors) [Section 7] and prohibits the operation of the installation if the required financial security is not in place [Section 6].

In addition to the funds available from the operator's insurance, the Law on Indemnity Agreements provides that the government may conclude an agreement with the operator according to which it will indemnify the operator for any amount payable as compensation which is not covered by the operator's financial security. This indemnity is of particular importance in the event of nuclear damage resulting from earthquakes or volcanic eruptions as this type of damage is not covered by private liability insurance. The amount provided under the indemnity agreement is equal to the amount of the operator's private insurance. The operator is required to pay an annual fee to the government in order to benefit from this indemnity arrangement [Sections 2, 4 and 6].

Finally, the Compensation Law also provides for the possibility of state aid where the cost of nuclear damage exceeds the amount of the operator's financial security [Section 16(1)].

The legislative provisions dealing with indemnity agreements and, with state aid will remain in force until 2009.

Jurisdiction to hear a claim for compensation for nuclear damage is determined by the ordinary rules of civil litigation. However, the Compensation Law provides for the possibility of referring a claim to a Dispute Reconciliation Committee for Nuclear Damage Compensation, whose function would be to mediate in respect of disputes concerning compensation [Section 18].

The Compensation Law was amended by Law No. 85, 1994, which came into force on 1 July 1995. The amendment prescribes that nuclear damage which occurs due to the operation of a nuclear reactor (including fuel manufacture, spent fuel reprocessing, etc.) are outside the scope of the Product Liability Law. This distinction was required since both laws provide for strict liability and a nuclear operator could be considered a "producer" within the meaning of the Product Liability Law.

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities

While responsibility for the regulation of certain nuclear activities is vested in the Minister for International Trade and Industry and the Minister for Transport according to the type of activity involved, the ultimate authority in the nuclear field remains the Prime Minister and his Office. This is illustrated by the fact that, frequently, regulations are brought into force and supplemented by Cabinet Order. Also, as explained below, the Science and Technology Agency reports directly to the Prime Minister's Office, and is responsible for general co-ordination with regard to nuclear policies.

a) Prime Minister

The Basic Law initially provided for the establishment of the Atomic Energy Commission, within the Prime Minister's Office, for the purpose of developing national policies on the research, development and use of nuclear energy [Section 4]. In 1978, the Atomic Energy Commission's responsibilities were divided and the Nuclear Safety Commission was created, also within the Prime Minister's Office, to take over responsibility for the safety aspects of nuclear activities. One of the main regulatory agencies, the Science and Technology Agency (STA), also functions directly under the authority of the Prime Minister's Office.

b) Minister for International Trade and Industry (MITI)

The Regulation Law provides that an application for a licence for a commercial power reactor or a spent fuel storage facility is to be determined by MITI with the approval of the Prime Minister. In considering an application, the Minister is advised by the AEC and the NSC on the regulatory and administrative aspects of design, construction and operation.

The Agency of Natural Resources and Energy (ANRE) is established within MITI. It is headed by a director-general and is divided into the Nuclear Energy Industry Division, the Nuclear Power Division, the Nuclear Power Safety Policy Division, the Nuclear Power Safety Administration Division, and the Nuclear Power Operating Administration Office.

The Agency's tasks include the promotion of the nuclear energy industry, the study of nuclear power generation, inspection of nuclear power plants, the study of technical improvements in reactor design, approval of design modifications submitted by reactor operators and the study of reactor decommissioning technology.

The ANRE is assisted in its work by the Nuclear Sub-Committee of the Advisory Committee for Energy and the Electricity Utility Industry Council.

c) Minister for Transport

The Minister for Transport is responsible for all forms of transport of radioactive materials. In relation to transport by rail or road, the Regulation Law and the Prevention Law provide that this responsibility is shared with STA. Both the Ship Safety Law regulating the transport of radioactive materials by sea and the Civil Aeronautics Law regulating the transport of radioactive materials by air are administered by the Minister for Transport.

d) Science and Technology Agency (STA)

The Law for the Establishment of Science and Technology Act [No 49, 1956] established STA as the central planning, co-ordinating and administrative body in relation to nuclear research, development, use and safety. The Agency also provides administrative support for the AEC, the NSC and the Radiation Council and is the parent body for the Atomic Energy Bureau and the Nuclear Safety Bureau (see below).

The Agency is headed by a Minister of State, who is also the Chairperson of the Atomic Energy Commission. Pursuant to the Prevention Law, STA administers the licensing system for the use, sale, lease and disposal of radioisotopes [Chapter II]. Under the Regulation Law, STA also administers the licensing and regulatory regime governing research reactors and activities involving the treatment and manufacture of nuclear source material and nuclear fuel reprocessing, radioactive waste management and disposal [Chapters II-VI].

The *Atomic Energy Bureau*, which is part of STA, is headed by a director-general and is divided into six divisions. The Policy Division plans programmes and develops policy, co-ordinates the work of related government agencies, plans the budget, liaises with local authorities and implements third party liability provisions. The International Affairs and Safeguards Division is responsible for international co-operation, safeguards and other means of regulating internationally-controlled materials, and for supervising the Nuclear Material Control Centre. It is also responsible for information collection and analysis. This Division was established in July 1997 by combining the Research and International Affairs Division of the Atomic Energy Bureau with the Safeguards Division of the Nuclear Safety Bureau. The Power Reactor Development Division is in charge of the development of reactor technology and supervises the Japan Nuclear Cycle Development Institute (JNC). The Technology Promotion Division plans and promotes research and development and supervises the National Institute of Radiological Sciences (NIRS). The Nuclear Fuel Division plans and promotes research and development and is involved with nuclear fuel cycle activities such as

enrichment and reprocessing. The Radioactive Waste Policy Division develops basic policy for radioactive waste management, co-ordinates the work of related government agencies, and plans and promotes research and development programmes relating to radioactive waste and decommissioning of nuclear facilities. The Atomic Energy Development Agencies Administration oversees the work of the Japan Atomic Energy Research Institute (JAERI).

The *Nuclear Safety Bureau*, which is also part of STA, is headed by a director-general and is divided into four divisions. The Nuclear Safety Policy Division is responsible for overall radiation monitoring, emergency measures and safety reviews of reactors and nuclear fuel facilities and for regulating radioactive waste management and disposal. The Reactor Regulation Division is responsible for regulating the safety aspects of research reactors and reactors under development. The Nuclear Materials Regulation Division regulates fuel cycle activities such as manufacturing and reprocessing. The Radiation Protection Division is responsible for regulating activities concerning radioisotopes and ionising radiation-generating devices.

New legislation which is to reorganise the whole government was adopted on 8 July 1999. It is expected to come into effect on 1 January 2001. This legislation redefines the function of each ministry or agency within the government in order to facilitate efficiency of administrative procedures.

2. Advisory Bodies

a) Atomic Energy Commission (AEC)

The AEC was established by the Basic Law, with a view to developing policies on all matters related to the research, development and utilisation of atomic energy [Section 5]. The AEC operates under the terms of its own legislation, the Law for the Establishment of the Atomic Energy Commission (the Establishment Law) [No. 188, 1955].

Although its functions are advisory, it is a powerful body, which can make recommendations on its own initiative, through the Prime Minister, to other ministries and agencies involved in regulating the use of nuclear energy. These ministries and agencies are also obliged to consult with the AEC in the course of carrying out their own licensing and other regulatory activities.

The main task of the AEC is to consider and make recommendations on the following matters:

- policies on the utilisation of atomic energy;
- co-ordination between different government agencies involved in regulating nuclear activities;
- the content of regulations dealing with nuclear fuel and nuclear reactors (apart from safety issues);
- promotion of nuclear energy research;
- policies on training of professional and technical staff working in the field of nuclear energy;
- collection of data, preparation of statistics and research on the use of nuclear energy.

The AEC consists of the Minister of State for Science and Technology (who is the Commission's chairperson) and four commissioners, who are appointed by the Prime Minister for a period of three years. A commissioner's appointment may be renewed following approval by the Diet "Diet (Japanese Parliament)".

The commissioners are supported in their work by a number of advisory committees attached to the AEC. The Committees advise the Commission on issues such as nuclear fuel recycling, international nuclear issues, etc.

b) Nuclear Safety Commission (NSC)

The NSC came into existence in 1978 as a result of a decision that nuclear safety issues should no longer be dealt with by the AEC (which was also responsible for the promotion of nuclear energy), but by an independent body, so as to institute a clear separation of responsibility between the development and use of nuclear energy and nuclear safety and health protection. Like the AEC, the NSC is a powerful advisory body. Its functions are:

- to make policies on the regulation of the safety of nuclear installations;
- to issue guidelines for the safety of nuclear material and reactors;
- to issue guidelines on the prevention of ionising radiation hazards;
- to make recommendations on any other aspects of radiation safety as it considers appropriate.

Licensing authorities are obliged to consult the NSC on safety and radiation protection issues in the course of their licensing procedures.

The NSC consists of a chairperson and four commissioners, appointed by the Prime Minister for a period of three years. A commissioner's term of office may be renewed following approval by the Diet.

A number of advisory committees are attached to the NSC to provide expert assistance to the commissioners, the most important of these being the Committee on Examination of Reactor Safety and the Committee on Examination of Nuclear Fuel Safety. Other committees advise on questions such as safe transport of radioactive materials, environmental radiation monitoring and safety research, safety regulations for radioisotopes, emergency planning.

c) Radiation Council

The Radiation Council is a specialised body, directly answering to the Minister for Government Agencies. It is governed by the Law concerning Technical Standards of Radiation Protection [No. 162, 1958].

The principal function of the Council is to establish technical standards for radiation protection and measurement of radioactivity levels [Section 5].

The Council has a maximum of thirty members, appointed by the Prime Minister. Members are appointed on the basis of relevant specialist knowledge, and may be either from within or outside government agencies or outside. They hold office (on a part-time basis) for a period of two years (unless they belong to government agencies) [Section 7].

d) Special Committee on Energy Policy

This Committee of the House of Counsellors was set up by the Diet in 1979 to study Japan's long-term energy policy and to submit proposals and draft legislation giving effect to these proposals to the government. The Committee is assisted in this task by specialists in the field.

The Committee is made up of 21 members of the Diet, appointed for a period of 6 years.

e) Other Advisory Bodies

MITI consults several committees for advice in the course of its procedures for the licensing of commercial nuclear power reactors. In particular, it seeks the advice of the Advisory Committee on Environmental Matters and the Technical Advisory Committee on Nuclear Power. MITI also consults the Electric Power Resources Development Co-ordination Council, whose approval must be obtained before any application to build and operate a commercial reactor is granted.

3. Public and Semi-Public Agencies

The Science and Technology Agency (STA) is the umbrella organisation for the research and development bodies described below.

a) Japan Atomic Energy Research Institute (JAERI)

The Japan Atomic Energy Research Institute (JAERI) was established pursuant to the terms of the Basic Law. The Japan Atomic Energy Research Institute Law [No. 92, 1956] sets out the functions of the Institute and its structure.

i) Legal Status

Law No. 92, 1956 established the JAERI. The Institute is obliged to report on its activities to the Prime Minister [Section 36].

ii) Responsibilities

The main responsibilities of the Institute are [Section 22]:

- to conduct both basic and applied research on nuclear energy;
- to design, construct and operate research reactors;
- to train research specialists and engineers in nuclear energy;

- to import, produce and distribute radioisotopes; and

- to collect data on nuclear energy and to disseminate the results of its own research work.

In 1985 the Japan Nuclear Ship Research and Development Agency was merged with the Institute.

iii) Structure

The JAERI is managed by a board of directors consisting of the president, two executive vice-presidents, eight executive directors and up to two auditors. The president and the auditors are appointed by the Prime Minister with the consent of the AEC. The president appoints the other members of the board with the consent of the Prime Minister. The president, vice-presidents and members are appointed for a term of four years and the auditors for two years [Sections 10, 12 and 13].

iv) Financing

The major part of the Institute's funds is provided by the government. The Institute is required to prepare financial statements for the previous year for submission to the Prime Minister, as well as budgetary estimates and a programme of work for the following year for submission to the Finance Minister and the Prime Minister [Sections 4, 11 and 26].

b) Japan Nuclear Cycle Development Institute (JNC)

i) Legal status

The Power Reactor and Nuclear Fuel Development Corporation was reorganised as the Japan Nuclear Cycle Development Institute (JNC) by the Law introducing Partial Amendments to the Atomic Energy Basic Law and the Power Reactor and Nuclear Fuel Development Corporation Law (Law No. 62, 1998). The JNC undertakes research and development necessary for establishing the nuclear fuel cycle.

The JNC is endowed with the status of a separate legal entity [Section 3] and is placed under the authority of the Prime Minister's Office through the Atomic Energy Bureau of STA.

ii) Responsibilities

The main responsibilities of the Institute are [Section 24]:

- to develop the fast breeder reactor and conduct related research;

- to develop nuclear fuel for the fast breeder reactor and conduct related research;

- to develop technology for the reprocessing of nuclear fuel materials and conduct related research; and

- to develop technology for treatment and disposal of high-level radioactive waste.

iii) Structure

The JNC is managed by a board of directors, consisting of the president, two executive vice-presidents, up to seven directors and up to two auditors. The president is appointed by the Prime Minister with the consent of the Atomic Energy Commission. The president appoints the other members of the board, with the consent of the Prime Minister. The president and the executive vice-presidents are appointed for a term of four years, and the directors and auditors for two years [Sections 11, 13 and 14].

Law No. 62, 1998 created a management review board which consists of up to 15 members [Section 22]. This board provides an external evaluation of the management of JNC.

iv) Financing

The JNC's funding is made up of contributions from the government and from private industry. The annual budget and programme of JNC are submitted through the Atomic Energy Bureau of STA for approval by the Prime Minister and Finance Minister.

KOREA

I. GENERAL REGULATORY REGIME

1. Introduction

Korea's principal nuclear energy legislation [Framework Act No. 483 of 11 March 1958 on Atomic Energy] dates back to 1958 but has been amended many times. In 1982, a significant revision of the original Act, with a view to consolidating all existing legislation in the nuclear field, was adopted by the Korean Parliament [Act No. 3549 of 1 April 1982]. In 1986, another amendment was made [Act No. 3850 of 12 May 1986], whose main aim was to provide the legal basis for the establishment of a Nuclear Waste Management Fund. In 1995, Act No. 483 was again amended [Act No. 4940 of 5 January 1995], in particular to promote the establishment of an Integrated Nuclear Promotion Plan.* This Plan, to be adopted every five years, defines the future orientations of the utilisation of nuclear energy, including measures in the field of safety [Section 8(2) bis].

A further amendment [Act No. 5233] was made on 30 December 1996. The main provisions of the amendment are as follows:

- the establishment of the Atomic Energy Safety Commission [Section 5];
- the establishment of the Atomic Energy Fund for Research & Development [Section 3(2)];
- the opening of the Public Hearing Procedures [Section 104(5)].

Another amendment [Act No. 5820] introduced on 8 February 1999 provides that the Prime Minister is to assume the role of Chairperson of the Atomic Energy Commission. It also states that technical standards are to be prescribed by ministerial ordinance, and provides for the simplification of certain licensing procedures.

The 1982 amendment laid the foundation for all of Korea's subsequent nuclear legislation, and particularly:

- Presidential Decree No. 10927 of 30 September 1982, as amended in 1989 [Decree No. 12729 of 16 June 1989], which consolidated eleven previous decrees covering all aspects of the peaceful use of nuclear energy; and

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* The 16 nuclear power plants currently installed in the Republic of Korea ("Korea") provide 27.7% of the country's total electricity production, or about 12 016 MWe. In addition, Korea has scheduled a major nuclear infrastructure programme to be implemented over the next 15 years: 16 new nuclear units will be built by 2015.

- Ordinance No. 275 of 13 April 1983 of the Prime Minister, also revised [Ordinance No. 356 of 4 January 1990], which implemented the basic 1982 Act and the afore-mentioned Presidential Decree.

There are also instructions issued by the Minister of Science and Technology, which concern technical standards and operational procedures to be followed by nuclear operators.

The purpose of the 1982 Act, as stated in Section 1, is to help improve the people's welfare and standard of living and to ensure the protection and safety of the public against radiation hazards, by encouraging scientific progress and industrial development of activities related to the production and use of nuclear energy.

From an institutional standpoint, the Minister of Science and Technology is responsible for nuclear safety and regulation. The Minister of Trade, Industry and Energy is in charge of construction and operation of nuclear power plants and nuclear waste disposal facilities.

Also of significance is the Atomic Energy Commission, which was created by the 1958 Act. Its powers and structure have been substantially changed over the years, reflecting the many amendments to the 1958 Framework Act since its adoption. On a general basis, the Commission advises the government on nuclear issues and sets broad guidelines for the peaceful use of nuclear energy in Korea. However, through the amendment introduced by the Act of 30 December 1996, the Commission was divided into two sub-commissions: the Atomic Energy Commission and the Atomic Energy Safety Commission.

Lastly, a large number of specialised bodies contribute actively to the smooth operation of nuclear activities. In this context, the roles of the Korean Atomic Energy Research Institute (KAERI), the Korean Institute of Nuclear Safety (KINS) and the Korean Electric Power Company (KEPCO) are particularly important.

2. Mining Regime

Originally, the 1958 Atomic Energy Act contained a specific provision [Section 17] regarding the mining regime. It stipulated that the regime for mining radioactive ores had to be defined by a separate Act. In 1982, a general Mining Act covering all ores was adopted; in particular Section 3 deals with mining activities related to uranium and thorium. As a consequence, the 1958 Atomic Energy Act as revised contains no provisions dealing with prospecting and mining activities.

3. Radioactive Substances, Nuclear Fuel and Equipment

Procedures for the possession and use of nuclear materials and radioisotopes are set out within the framework of Act No. 3549 of 1 April 1982, as amended in 1995, 1996 and 1999. Additional provisions are contained in Presidential Decree No. 10927 of 30 September 1982 (as amended in 1989 and 1995) and in Ordinance No. 275 of 13 April 1983 (as amended in 1990).

Chapter VI [Section 2] of the amended 1982 Act deals with the use of nuclear materials. According to Section 2 of the Act, the term "nuclear materials" encompasses both nuclear fuel materials and source materials. Two parallel, but separate, procedures are established, depending on the nature of the nuclear materials in question. Thus, the use or possession of nuclear fuel materials

requires a licence [1982 Act, Section 57], whereas source materials need only be reported [Section 64].

Any person intending to possess or use nuclear fuel materials must therefore obtain a licence from the Minister of Science and Technology [Section 57] in accordance with the provisions of the Presidential Decree. Before issuing such a licence, however, the Minister is required to ensure that [Section 58]:

- there shall be no impediments to implementation of the utilisation of nuclear energy;
- the applicant has the technical capability to use and to possess nuclear fuel materials;
- nothing about the site, infrastructure or equipment of the installation concerned or the storage and disposal facilities for nuclear fuels shall preclude preventive measures being taken in the event of a risk of radioactive contamination; and
- the proposed activities do not constitute a danger to human health, property and the environment.

The Minister of Science and Technology may, at any time, revoke a licence or take similar action (such as suspension of the licence, or repair of the installation) if he considers that the requirements of the permit as provided for in Section 58 have not been met, these activities are likely to jeopardise public safety or that they are not in line with the existing technical standards [1982 Act, as amended, Section 62].

Any person planning to use source materials must submit the notification thereof to the Minister of Science and Technology. Plans for their use must satisfy the technical standards set by Presidential Decree No. 10927 of 1982, as amended in 1989 [Act of 1982, as revised, Section 64(1)], and must be approved. If the proposed methods are deemed inappropriate, the above-mentioned Minister may order that they be corrected or that additional measures be taken [Act of 1982, Section 64(3)].

In addition, Decree No. 10927 exempts certain cases:

- Section 172 lists the fuels which, because of their type or quantity, do not require a licence;
- Section 179 exempts from the notification procedure source materials whose radioactivity is less than 0.002 μCi/g and uranium or thorium used in quantities below 900 grams.

Licensing applications and official notifications must contain detailed information on the applicant's identity and address, the nature and quantity of the substances used or possessed, the purpose and methods for their use, and technical details regarding the location, structure and equipment of the facilities where the substances are to be used. In the case of nuclear fuels, additional information is required on methods of storing or reprocessing spent fuels [Ordinance of the Prime Minister No. 275 of 13 April 1983, as amended in 1990, Section 68 and 75].

The use or sale of radioactive isotopes or radiation-generating devices generally requires a licence from the Minister of Science and Technology [1982 Act, Section 65], which is granted on three conditions [Section 66]:

- that the location and structure of the installation complies with the technical standards established by the 1982 Presidential Decree, as amended in 1989;

- that neither the radioisotopes, the contaminated materials nor the ionising radiation-generating devices pose a threat of radioactive contamination;

- that non-destructive testing by radioisotopes or radiation-generating devices conform not only to the above-mentioned two conditions, but also to the technical standards established by the Presidential Decree.

In addition, the 1982 Act stipulates the grounds for the revocation or suspension of licences [Section 68], its safety conditions [Section 70], the mandatory technical standards [Article 71], etc. The details of these procedures are set out in the 1982 Presidential Decree and the Prime Minister's 1983 Ordinance, both as amended.

With regard to sealed radioisotopic sources or ionising radiation-generating devices, the 1982 Act stipulates that if the quantities or capacities involved are below the limits set by the Prime Minister's Ordinance, their use need only be reported [Section 65].

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

i) Construction and operation

Chapter IV of Act No. 4940 of 1995, as amended, deals with the regime for the construction and operation of nuclear reactors and related facilities. According to Section 9 of Presidential Decree No. 14797, "related facilities" means:

- nuclear reactor coolant system facilities;

- instrumentation and control system facilities;

- processing and storage facilities for nuclear fuel materials;

- radioactive waste disposal facilities;

- radiation control facilities;

- nuclear reactor containment facilities;

- nuclear reactor safety system facilities;

- other facilities which are concerned with the safety of nuclear reactors as specified by the Minister of Science and Technology.

The construction of a reactor and related facilities requires prior licensing by the Minister of Science and Technology [Section 11]. Applications for construction permits must supply information on the applicant's identity, the chosen site and the intended purposes of the reactor or the installation, as well as technical construction specifications, etc. [Ordinance No. 567 of 1996, Section 2].

Technical files are examined by the Korean Institute for Nuclear Safety (KINS), which in turn submits an evaluation of the construction project to the Minister of Science and Technology. The KINS report must be approved by the Atomic Energy Commission before the Minister of Science and Technology may issue a construction permit [Decree No. 14797 of 1995, Section 22].

Accordingly, construction on any given site may commence only with the Minister's written approval [1995 Act, Section 12]. Furthermore, the Minister is required to ensure that:

- the applicant possesses the technical and professional capability needed to complete the job without danger;

- the chosen site and the installation's structure and equipment comply with the technical standards laid down in Presidential Decree No. 14797 of 1995 so as not to impair the protection of persons and property against ionising radiation;

- the proposed construction involves no danger of environmental pollution; applicants are also required to provide ministerial authorities with an environmental impact study [see Section 4, (b) "Protection of the environment against radiation effects", *infra*].

Lastly, before construction may get underway, the prospective builder must also notify the Minister of Science and Technology of the intended plans and construction methods [1995 Act, Section 14]. Section 8 of the 1996 Ordinance stipulates the minimum requirements.

Grounds for the revocation of a building permit are set out in Section 17 of the 1995 Act. Among them are the discovery of illegalities in the preliminary stages of the application process, unjustified failure to carry out construction work during a period exceeding that established by Presidential Decree No. 14797 of 1995 and, more generally, the violation of standards prescribed by the Framework Act.

The procedure for obtaining an operating licence for a nuclear reactor and related facilities is quite similar to the above-mentioned procedure for the pre-construction phase. While certain conditions – including those relating to the operator's technical and professional capability and to environmental protection – are the same, the prospective operator must supply additional information on the reactor's operating capacity and its compliance with the technical standards specified by Presidential Decree [1995 Act, Section 22].

Any nuclear power plant owner must appoint a person who holds an operator's licence to supervise the reactor's operation [Section 26]. Persons eligible to perform this function must possess an operator's licence attesting to their past experience in another installation and/or a technical training degree. Operators' licences are issued directly by the Ministry of Science and Technology.

The choice of operator is left to the owner's discretion. Notwithstanding, the Minister of Science and Technology may order an operator's removal if it turns out that the person has not fulfilled his duties in an appropriate manner [Section 28(1)]. In such cases, the owner must dismiss the said person and appoint another within 30 days [Section 28(2)].

Inspections must be carried out, both during the pre-operational phase [1995 Decree, Section 27] and after operations have begun [Section 42]. The purpose of such inspections, which are performed by specialised officers of the Ministry of Science and Technology, is to make sure that the operation of a reactor, as well as the safety measures, comply with the technical standards set by current regulations.

The grounds for revoking an operating licence are very similar to the ones for revoking a construction permit [1995 Act, Section 24]. Once an operating licence has been revoked, the reactor owner must surrender any nuclear fuel, ensure that the radioactive contamination caused by the materials used is as low as possible, and dispose of the spent fuel generated during operations [Decree No. 14797 of 1995, Section 40].

Lastly, Ordinance No. 567 of 1996 also deals with situations that require the competent authorities to be notified. These include notification of replacement of the licensee [Section 15], notification of discontinuance of operations [Section 22], notification of decommissioning of reactor [Section 23], etc.

ii) Decommissioning

The 1995 amendment to the Atomic Energy Act contains provisions concerning the safety of decommissioning operations for power reactors and other fuel cycle facilities. Their owners must, in particular, submit in advance a decommissioning plan for approval by the competent authorities.

b) Protection of the environment against radiation effects

The concept of an environmental impact study appears for the first time in the 1982 amendment of the Atomic Energy Framework Act. While Section 11 considers the impact study an essential component of the material to be submitted by applicants for construction permits, full details of such studies are defined by Ordinance No. 567 of 1996.

In the pre-operational phase, detailed information on the installation and the state of its surrounding environment (natural, social and economic) is required [1983 Ordinance, Section 3]. This information includes:

- an evaluation of the environmental impact of the construction and operation of the proposed installation;
- the type of measures to be taken in order to minimise environmental impact, and ecological monitoring systems;
- an estimate of the consequences of an accident on the surrounding area.

Thereafter, operators are required to protect the environment from any dangers that their installations may represent. Accordingly, studies on the state of the environment must be carried out periodically and the results are submitted to the Minister of Science and Technology if there is a real risk of radioactive contamination of the environment. In such a situation, the Minister orders the operator to take all necessary steps to preserve the environment [Decree No. 10927 of 1982, Section 111].

c) Emergency response

Section 98 of the 1995 Act provides the basis for emergency procedures. Accordingly, the operator is required to take the appropriate safety measures without delay in the case of:

- a major risk of a nuclear accident due to an earthquake, fire or any other type of catastrophe;
- failure of nuclear related facilities; or
- a danger of radioactive contamination.

Section 301 of the 1995 Decree suggests the most appropriate emergency measures, depending on the nature of the danger.

Furthermore, in an emergency, the exposure of workers to ionising radiation must be kept to a minimum by reducing the duration of such exposure; exposure thresholds are set by the Minister of Science and Technology. In addition, operators must promptly notify the Minister of Science and Technology of the nature of the accident as well as the safety measures that have been taken. In turn, the Minister may order a suspension of use of certain nuclear equipment, the disposal of radioactive materials, adoption of measures to reduce the effects of contamination or any other preventive measures he considers necessary [1995 Act, Section 98].

Each reactor must be equipped with a series of alarms and monitoring mechanisms, including, *inter alia*, a warning system for operating problems [Decree No. 10927 of 1982, Section 80], an emergency cut-off system and various systems to monitor the chain reaction [Sections 81 and 82].

Emergency measures are also contained in Notice No. 92(18) of 1 December 1992 of the Minister of Science and Technology.

Furthermore, at the international level, Korea acceded to the 1986 Conventions on Early Notification of a Nuclear Accident and on Assistance in the Case of a Nuclear Accident or Radiological Emergency respectively on 8 June 1990.

5. Trade in Nuclear Materials and Equipment

Import and export procedures for nuclear reactors and related facilities, nuclear fuel materials and radioisotopes must be determined by the Minister of Science and Technology, in agreement with the Minister of Trade, Industry and Energy [1982 Act, Section 106]. In accordance with Section 106 of the 1982 Act, detailed procedures for custom clearance of nuclear materials and radioisotopes are provided for in the "Unified Public Notice" issued by the Ministry of Trade, Industry and Energy.

The legal basis of export and import control of nuclear materials and equipment for the prevention of nuclear proliferation is the Foreign Trade Act [Act. No. 3895 of 1986]. The Ministry of Trade, Industry and Energy is responsible for the implementation of this Act. Chapter IV, Section 21 of the Act sets forth the regulations related to export control of strategic goods, including nuclear materials and equipment. The "Public Notice for the export and import of strategic goods", under the Foreign Trade Act, provides the control list, control area, licensing procedures and government agencies which are responsible for the licensing of specific items.

The Technology Development and Promotion Act [Act No. 2399 of 1972] is also used to control the export of nuclear-related technology. The Act is implemented by the Ministry of Science and Technology.

The Korean Government revised the Public Notice under the Foreign Trade Act to adhere to the guidelines of the Nuclear Suppliers Group (NSG) (London Club). The new Public Notice came into force on 1 October 1995, before Korea joined the NSG and the Zangger Committee.

The export and re-export of nuclear items are subject to the approval of the relevant governmental agency. Nuclear items on the control list of NSG Part I and related technology are subject to the approval for the Ministry of Science and Technology before their export or import. In the case of dual use items, the Ministry of Trade, Industry and Energy gives the approval of export and import. In approving the export and import of nuclear-related technology, the Ministry of Science and Technology must consult with the Ministry of Trade, Industry and Energy.

Any person who has obtained export approval in a false or unlawful manner and any person who has exported nuclear materials and equipment without permission is liable to punishment by imprisonment for not more than five years or to a fine ranging up to three times the price of the goods concerned [Foreign Trade Act, Section 54]. This Section also applies in the case of export which has taken place without prior licensing.

6. Radiation Protection

The Atomic Energy Act of 1982, as amended in 1986, lays the foundations for the radiation protection regime [Section 97]. It requires nuclear operators to take the necessary action to prevent and control the effects of radioactivity on human health. New provisions were incorporated in the Framework Act in 1995 concerning in particular a radiation dosimetry system, intended to ensure greater reliability in the management of radiation exposure of workers [Section 90(4)]. Also, the ALARA (As Low As Reasonably Achievable) principle was incorporated in the Act in 1995. This principle has been used in implementing radiation safety programmes.

The radiation protection regime is described in greater detail in Presidential Decree No. 10927 of 1982 [Chapter VI], as amended, and Ordinance No. 275 of 1983 [Chapter V], as amended.

a) Protection of workers

The 1982 Decree stipulates that, following the use of radioactive materials, a nuclear operator must assess exposure to radiation and the level of contamination within the installation and the area under surveillance [Section 298]. Since the purpose of this monitoring is to avoid jeopardising the health of workers and of other people with access to the areas at risk, regular monitoring is necessary, especially in the radiation areas; these areas are listed in a table inserted into Section 107 of the 1983 Ordinance.

The same Decree also provides that workers and all other persons having access to areas at risk shall undergo periodic compulsory medical examinations [Section 299]. These examinations shall consist of consultations with specialists (to describe working conditions and the symptoms experienced) as well as a series of strictly medical examinations [1983 Ordinance, Section 109]. The results of these examinations must be noted and kept permanently in each worker's file. On the other hand, the medical files of former employees must be submitted to the Minister of Science and

Technology or handed over to specialised institutions designated by the aforementioned Minister [Section 122].

b) Protection of the public

General information on the protection of the public can be found in Section 96 of the 1982 Act. This provision calls for the establishment of an exclusion area around a reactor, related facilities or a nuclear fuel cycle facility. The purpose is to protect human health, property and the general public from the hazards of ionising radiation. A presidential decree may order and determine restrictions of access or residence of the public in the exclusion area [Section 96(2) and (3)].

More specific provisions on radiation safety control for the public are dealt with in Notice No. 94(7) of the Minister of Science and Technology [Notice of 29 February 1984, revised on 9 September 1996]. This Notice establishes the maximum permissible concentration of radiation in air and water and radiation exposure dose limits for the human body.

7. Radioactive Waste Management

In 1996, the Korean Government decided to change the administrative system for radioactive waste management. The Korean Electric Power Corporation (KEPCO) is now in charge of radioactive waste management, which was previously under the competence of the Korean Atomic Energy Research Institute (KAERI).

Radioactive waste management operations consist of the following:

- treatment and disposal of radioactive waste;
- transport and disposal of radioactive waste resulting from the shutdown or decommissioning of nuclear installations;
- packaging, transport and interim storage of spent fuel;
- site selection, purchase, construction and operation of permanent disposal facilities or interim storage facilities for radioactive waste and spent fuel; and
- research, development and analysis related to radioactive waste management.

Korea is a Party to the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter.

8. Non-Proliferation and Physical Protection

Korea ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (NPT) on 23 April 1975, the 1979 Convention on the Physical Protection of Nuclear Materials on 7 April 1982, and the 1996 Comprehensive Nuclear Test Ban Treaty on 24 September 1999. In connection with the NPT, the Safeguards Agreement between Korea and the IAEA has been in force since 14 November 1975, and the government established a state system for the accounting and control of

nuclear materials (SSAC) at the Ministry of Science and Technology, immediately after the Safeguards Agreement entered into force.

In Korea, safeguards and physical protection of nuclear materials are provided for in the Atomic Energy Act together with subsidiary legislation. The latest amendment to the Atomic Energy Act concerning safeguards and physical protection matters was adopted in December 1994 and entered into force on 5 January 1995. The amendment provides the legal basis for state inspections by the Minister of Science and Technology. The state inspection system has unique features. Under the Atomic Energy Act, each nuclear facility must prepare an "Accounting and Control and Physical Protection Procedure" and submit it to the government for approval. The purpose of the state inspection is to determine whether or not the nuclear facility is being operated according to the approved Procedures. On safeguards and physical protection matters, all detailed regulations are to be provided for in Notices of the Minister of Science and Technology. Four Notices related to safeguards and physical protection entered into force on 23 July 1996.

In addition to the international framework referred to in the opening paragraph of this section, the Republic of Korea and the Democratic People's Republic of Korea concluded an agreement in which both countries pledge to refrain from producing, possessing or using nuclear weapons (31 December 1991). This bilateral agreement and the resulting sectoral non-proliferation pact call for the creation of a Commission to participate in the inspection of both countries' nuclear installations in order to verify the absence of weapons of any sort. To date, this Commission has not yet been established and the implementation of mutual inspections under the bilateral agreement has not taken place.

9. Transport

Regulations relating to the transport of radioactive materials are set forth in Sections 86 *et seq.* of the 1982 Atomic Energy Act, as amended.

Any nuclear operator planning to transport radioactive materials, etc. outside the workplace must notify the Minister of Science and Technology accordingly [Section 86]. The notification must include a series of documents listed in Section 99(2) of the 1983 Ordinance. The Minister, after examining an application, may request that any information he deems unclear or inadequate be corrected or supplemented [1982 Decree, Section 235(2)]. In addition, operators must submit the radioactive materials to be transported for inspection by officers of the Ministry of Science and Technology, in order to verify whether a transport licence may in fact be issued [1982 Decree, Section 237].

Under the 1994 amendment of the 1982 Act, packages for the transport of radioactive materials are to be inspected and certified by officers of the Ministry of Science and Technology, in order to ensure a higher level of safety in the transport of radioactive materials [Sections 90(2) and (3)].

Transport by rail, road, sea or air, as well as the packaging of transported materials, must comply with the technical standards established by ministerial decree [Act of 1982, Section 87]. The packaging conditions are laid down in the 1982 Decree, as amended in 1989 [Sections 239 and 240]:

- radioactive materials must be sealed within a container labelled to indicate the nature and quantity of the contents;

- handling must be simple and safe;

- steps must be taken to ensure that changes in temperature or pressure do not cause a container to break;

- preventive measures must be taken against any leakage or chemical or electrical reaction arising from contact between packaging and the radioactive materials contained therein, etc.

These requirements do not apply to the transport of low-level materials listed in Section 101 of the 1983 Ordinance.

The 1982 Decree supplemented these procedural rules with a separate regime for each possible mode of transport [Sections 241 *et seq.*: Vehicles; Sections 256 *et seq.*: Ships; Sections 267 *et seq.*: Aircraft].

The regime described above applies to the transport of radioactive materials only; there is a separate transport procedure for source materials, and yet another for radioisotopes. Nevertheless, an analysis of these provisions reveals a clear similarity among the various modes of transport.

Source materials must be placed in appropriate containers that provide total insulation. Each container must be labelled to indicate the nature and quantity of its contents. In addition, source materials must be packaged in such a way as to absorb and neutralise the radiation they emit. The radiation given off at the surface of the container must not exceed 200 millirems per hour [1982 Decree, Section 189].

The procedure for transporting radioisotopes and materials contaminated by radioisotopes is established in Section 218 of the 1982 Decree. As above, transport must be carried out in special containers, except for cases in which:

- measures to prevent the leakage and dispersion of radiation are taken prior to transport; or

- preventive action to reduce the danger of radiation has been formally approved by the Minister of Science and Technology.

Ionising radiation levels at the surface of containers must not exceed the thresholds imposed by the Minister of Science and Technology, and the weight of substances transported must not compromise minimal safety measures. Further information on precautions to be taken prior to and during transport is also set out in Section 218.

10. Nuclear Third Party Liability

Korean legislation on nuclear third party liability is to be found in Act No. 2094 of 24 January 1969 on compensation for nuclear damage, as amended by Act No. 2765 of 7 April 1975, Act No. 3549 of 1 April 1982 and Act No. 3849 of 12 May 1986. Additional, more detailed provisions regarding this legislation were introduced by Presidential Decree No. 5396 of 3 December 1970, which was in turn amended by Presidential Decrees No. 6701 of 25 May 1973, No. 7756 of 22 August 1975 and No. 12092 of 19 March 1987. This legislation is supplemented by Act No. 2764 of 7 April 1975 on indemnification agreements for the compensation of nuclear damage. Presidential Decree No. 7755 of 22 August 1975, as amended by Presidential Decree No. 12093 of 19 March 1987, further specifies the conditions of the regime.

Act No. 2094 on Compensation for Nuclear Damage covers the nuclear damage caused by the operation of reactors, processing and reprocessing activities, and the use of nuclear fuels, as well as the transport, storage and disposal of nuclear fuels or of items contaminated therefrom [Section 2].

This Act holds operators liable for nuclear damage caused by the carrying out of an activity listed in Section 2. This liability is strict and exclusive. In the event nuclear materials are transported between operators, the consignor is liable for any damage, unless the operators involved have agreed otherwise [Section 3]. The Act nevertheless provides for exemptions from liability under special circumstances such as earthquakes, war, natural disasters or other similar events.

The Act contains no express provision limiting an operator's liability. The operator is required to take out insurance or some other form of financial security of an amount that varies according to the category and power of the installation involved [Section 5]. Unless an operator has constituted a deposit to cover his obligation to provide compensation for nuclear damage, he must, in addition to his insurance policy, have concluded an indemnification agreement with the government to provide for such compensation. Under such agreements, the government agrees to bear the cost of all compensation due under the Act, up to the maximum financial security an operator is required to maintain, in so far as this security is not covered by the operator's insurance [Section 9(1)].

In addition, the indemnification agreement also makes the government responsible for compensating nuclear damage caused by tidal waves, floods, storms or lightning, or if unavoidable circumstances prevent a claim from being filed within the dates between which the relevant insurance contract is valid [Act No. 2764 of 7 April 1975, Section 4(2); and Decree No. 7755 of 22 August 1975, Section 2(2)].

As regards international aspects, it should be pointed out that Korea is not currently a party to any of the conventions on nuclear third party liability.

II. INSTITUTIONAL FRAMEWORK

Korean legislation has been extensively revised since the Framework Act was adopted in 1958, bringing about a gradual but significant administrative re-structuring. As a result, most nuclear-related bodies have been substantially transformed, in both their form and their powers. One example is the former Atomic Energy Office, which was established on 21 January 1959 under the Framework Act, dissolved in 1973 and re-convened as the "Nuclear Energy Bureau", under the auspices of the Ministry of Science and Technology, with significantly reduced responsibilities.

In Korea, nuclear-related activities are organised and supervised by the Atomic Energy Commission, the Ministry of Science and Technology or the Ministry of Trade, Industry and Energy, as the case may be. Sometimes joint action is required.

The two Ministries are made up of specialised departments and technical bodies of a public or semi-public nature, which deal with topical issues. In the area of research, the Korean Atomic Energy Research Institute (KAERI) plays a predominant role.

1. Regulatory and Supervisory Authorities

a) Minister of Science and Technology, including the Nuclear Energy Bureau

Generally speaking, the Minister of Science and Technology ensures the enforcement of nuclear legislation, as embodied in the Framework Act of 1982, save where jurisdiction is expressly conferred on the Minister of Trade, Industry and Energy or the Atomic Energy Commission. However, some functions require joint action.

The Minister of Science and Technology is invested with extensive powers. The Minister is in charge of:

- establishing basic policies for the promotion of science and technology programmes;
- co-ordinating the ministers responsible for establishing policies related to nuclear technology;
- establishing training programmes for highly qualified scientists and engineers;
- financially supporting national research centres and subsidiary scientific institutes within the government; and
- promoting international technical co-operation and securing a desirable environment for scientific and technical progress.

In performing his tasks, the Minister receives technical support from several bodies, including the Korean Atomic Energy Research Institute (KAERI) and the Korean Institute for Nuclear Safety (KINS) (see below Section 2 “Advisory Bodies”).

Nuclear Energy Bureau

i) Legal status

The origins of the Nuclear Energy Bureau date back to Korea’s first law relating to atomic energy, in the late 1950s. Until 1973, the Bureau was continuously involved in the nuclear decision-making process, but its role was re-defined by Act No. 2437 of 15 January 1973. Today, the Nuclear Energy Bureau is part of the Minister of Science and Technology.

ii) Responsibilities

The Nuclear Energy Bureau consists of four divisions and their functions are described below. Also, the Nuclear Safety Officer assists and advises the Director-General of the Nuclear Energy Bureau on nuclear safety and radiation activities.

The *Nuclear Policy Division* is responsible for:

- definition of basic policy for the use and development of nuclear energy as well as its short and long-term objectives;
- collection and dissemination of information on nuclear energy;
- provision of staff support for the Atomic Energy Commission;
- drafting and amendment of the Atomic Energy Act and its related decrees;
- establishment of a system for promotion of nuclear activities;
- operating the national and international safeguards system;
- performing export and import control of nuclear items on the trigger list; and
- checking and inspecting the physical protection of nuclear materials.

The *Atomic Energy International Co-operation Division* is responsible for:

- establishment and management of the international co-operation policy;
- operation of bilateral nuclear joint committees;
- implementation of bilateral and international nuclear energy co-operation agreements;
- co-operation with the International Atomic Energy Agency and the OECD Nuclear Energy Agency; and
- preparing mutual inspections between North Korea and South Korea in the framework of the Joint Declaration on the Denuclearisation of the Korean Peninsula.

The *Nuclear Safety Division* is responsible for:

- licensing the production, construction, ownership, control, management and operation of nuclear reactors and installations;
- licensing the acquisition, production, import and export, possession, control and management of nuclear material and nuclear fuel cycle facilities;
- management of nuclear safety regulatory affairs;
- regulatory review of design and construction methods;
- verification and inspection of nuclear installations, nuclear reactor performance tests, including pre-operational tests, start-up tests and nuclear reactor operation; and
- analysis and assessment of operational safety-related events.

The *Radiation Safety Division* is responsible for:

- licensing and supervision of the use of radioisotopes and industrial X-ray apparatus;
- control of the transport and disposal of radioactive materials;
- assessment of the effects of nuclear activities on the natural habitat near the installations;
- licensing of holders of radioactive materials; and
- establishment and co-ordination of radiological emergency measures and of physical protection of nuclear facilities.

b) Minister of Trade, Industry and Energy

The task of the Minister of Trade, Industry and Energy is to propose general policy with regard to energy production and the utilisation of resources, in accordance with the recommendations of the Atomic Energy Commission. This action takes the form of a series of activities intended chiefly to conserve resources and ensure that energy is used rationally. More specifically, he defines basic policy with respect to programmes for the development of nuclear energy and supervises the electricity generation of nuclear power plants.

Special attention must be given to the Electric Power Office, which includes a Nuclear Power Division. The functions of this Division include the following:

- establishment of basic policies for nuclear power plant development;
- supervisory control of nuclear power plant construction and operation;
- control of supply and demand of nuclear fuel; and
- co-ordination of matters related to radioactive waste and spent fuel treatment.

In addition, the Ministry exercises control over a large number of energy-related bodies, including the Korean Gas Company, the Korean Electric Power Corporation and the Korean Oil Company, as well as the Institute of Energy Economics and the Institute of Energy and Resources.

2. Advisory Bodies

a) Atomic Energy Commission

Created by Act No. 483 of 11 March 1958 [Section 4(2)], the Atomic Energy Commission was initially responsible directly to the President of the Republic of Korea. When the Ministry of Science and Technology was created in 1967, the Commission's chairpersonship was awarded to the new minister, then to the vice-prime minister. From 1994 until 1999, this function was assured by the Deputy Prime Minister of Finance and Economic Planning [Section 5]. Since 1999, this function has been assured by the Prime Minister.

Over the years, there has been some shifting of responsibilities and a number of changes. An important change into the structure of the Commission was introduced by Act No. 5233 of 30 December 1996. The Commission was divided into two separate commissions. One is the Atomic Energy Commission whose functions were reduced; the other is the Atomic Energy Safety Commission which took responsibility for those functions which are no longer to be performed by the Atomic Energy Commission. The Atomic Energy Commission is required to deliberate and decide upon a series of important issues concerning government policies pertaining to the peaceful use of nuclear energy. Its main activities include the following:

- planning general policy on the peaceful uses of atomic energy;
- co-ordination of the competent administrative bodies;
- estimation and allocation of expenditures of bodies competent in the field of nuclear energy;
- promotion of research activities in the use of nuclear energy;
- training of researchers and engineers;
- measures concerning radioactive waste management;
- planning of protective measures against the dangers of radioactive fallout; and
- other matters that are deemed important and suggested to the Commission by its chairperson.

The Atomic Energy Commission is responsible to the Prime Minister and has seven to nine members including its chairperson, who is the prime minister. The remaining members of the Commission are the Minister of Science and Technology, the Minister of Trade, Industry and Energy, and other members recommended by the chairperson, in particular from industry, universities, and research institutes.

In addition, the Atomic Energy Commission established a special committee, the Atomic Energy Utilisation and Development Committee.

b) Atomic Energy Safety Commission

The Atomic Energy Safety Commission is established under the Minister of Science and Technology in order to make important decisions on the safety of nuclear energy. Its main activities include the following:

- co-ordination of nuclear energy safety management;
- regulation of nuclear materials and reactors;
- training of researchers and engineers in the field of nuclear energy safety management;
- management of radioactive waste; and preventive measures against radioactive risks.

The Atomic Energy Safety Commission is composed of five to seven members including its chairperson, who is the deputy prime minister.

3. Public and Semi-Public Agencies

a) Korean Atomic Energy Research Institute (KAERI)

i) Legal status

The Korean Atomic Energy Research Institute (KAERI) is a government-funded corporate body responsible for research and development of the peaceful applications of nuclear energy.

This Institute was originally established in 1959, as an affiliated organisation of the Office of Atomic Energy (OAE). OAE was established in 1959 by the Atomic Energy Act of 1958. Under OAE, there were three affiliated research institutes, namely the Atomic Energy Research Institute, the Radiological Research Institute (RRI) and Radiation Research Institute in Agriculture (RRIA).

In 1967, the administrative functions of OAE were transferred to the Atomic Energy Bureau which was newly established within the Ministry of Science of Technology (MOST).

In 1973, AERI, RRI and RRIA were merged into one and became the present KAERI, a corporate body, according to the KAERI Establishment Act [Act No. 2443 of 15 January 1973].

ii) Responsibilities

KAERI is the national nuclear research, development and training institute established to promote the peaceful uses of nuclear energy, to advise the Minister of Science and Technology with the aim of contributing to national economic development and the enhancement of public welfare, and to carry out integrated research and development activities in the nuclear field. It is also involved in developing nuclear technology and improving systems for safety and protection against ionising radiation.

In 1994, the Technology Center for Nuclear Control (TCNC) was established within KAERI in order to deal with national inspections for accounting and control of nuclear materials in all facilities covered by IAEA safeguards. This Centre plays a key role in demonstrating Korea's nuclear transparency in the world nuclear community.

iii) Structure

KAERI is operated by the Board of Trustees whose members are from, *inter alia*, the government, nuclear-related industries and academic circles.

The president is responsible for the management of the Institute. Amongst those who report to the president are the vice-presidents for basic research, advanced reactor development, nuclear fuel cycle research and development, and the Directors for the HANARO Centre (a research reactor used for training, research and isotope production), the Technology Centre for Nuclear Control (TCNC) and the Nuclear Training Centre.

In addition, KAERI operates the Korean Cancer Centre Hospital (KCCH) in Seoul as an affiliated organisation.

b) Korean Institute for Nuclear Safety (KINS)

i) Legal status

Act No. 4195 of 14 February 1990 provides for the Korean Institute of Nuclear Safety's autonomy from KAERI, to which it was previously attached. At present, the Institute is directly responsible to the Minister of Science and Technology.

ii) Responsibilities

The Institute is responsible for assisting the government in its licensing and regulating activities with particular attention to protection of public health and the environment.

It is generally responsible for the following activities related to nuclear safety:

- safety review and evaluation of nuclear installations;
- inspection of nuclear installations;
- research and development of regulatory and technical standards;
- regulation of radioisotopes and ionising radiation sources; and
- technical support for development of regulatory policy.

iii) Structure

KINS is made up of seven technical divisions: the Planning Division, the Nuclear Licensing Division, the Nuclear Regulatory Inspection Division, the Radiation Safety Division, the Research and Safety Development Division, the Nuclear Safety Technology Division, and the Administration Division.

c) Korean Electric Power Company (KEPCO)

Korea's nuclear industry is built around the national power company, KEPCO, which is the country's exclusive generator, distributor and carrier of electricity. It is the owner and operator of all nuclear power plants in Korea (at present, 16 power reactors are in operation and four reactors under construction). KEPCO also possesses 98% interest in the Korean Power Engineering Co. Ltd. (KOPEC), 41% of Korean Heavy Industries Co. Ltd. (HANJUNG), 100% of Korean Power Plant Services Co. Ltd. (KPS) and 95% of Korean Nuclear Fuel Co. Ltd. (KNFC).

KEPCO is a state-owned company which is currently responsible to the Minister of Trade, Industry and Energy. In 1989, the government sold off 21% of its shares. At the end of 1999, the government was in possession of 52% of its shares.

KEPCO is responsible in particular for:

- development of electric power resources and research in related industries;
- power generation, transmission and distribution and research in related industries;
- investment in, and contribution to, the businesses mentioned above and other projects to which the government is committed;
- training of personnel by the KEPCO Training Centre and the technical schools operated by KEPCO; and
- testing services for electrical equipment.

LUXEMBOURG

I. GENERAL REGULATORY REGIME

1. Introduction

In Luxembourg, regulation of nuclear energy is based on the Framework Act of 25 March 1963 on the protection of the public against the hazards of ionising radiation, which established general principles governing nuclear activities. These principles were expanded in detail in the Grand Ducal Regulation of 8 February 1967, which was subsequently repealed and replaced by the Grand Ducal Regulation on the protection of the public against the hazards of ionising radiation [Regulation of 29 October 1990]. This Regulation was in turn partially amended by three Regulations of the same name of 17 August 1994, 22 February 1996 and 6 April 1999. It applies to the import, production, manufacture, possession, transit or use, for commercial, industrial, medical, scientific or other purposes, of equipment or substances capable of emitting ionising radiation. It also applies to the treatment, handling, storage, elimination and disposal of radioactive substances or waste and to any other activity involving a risk arising from ionising radiation [Section 1.1].

The Minister of Health and his services assume prime responsibility for nuclear energy matters; other government departments have general advisory functions within their respective spheres of competence.

In Luxembourg there are neither public or semi-public bodies responsible for research and development projects in the field of the peaceful uses of nuclear energy, nor installations for the production of nuclear energy.

2. Mining Regime

Luxembourg legislation has no special provisions relating to nuclear ores. Consequently, the ordinary law relating to mining applies; therefore operators of mineral deposits must obtain a prior concession from the government.

3. Radioactive Substances, Nuclear Fuel and Equipment

In accordance with Section 2 of the Act of 25 March 1963 on the protection of the public against the hazards of ionising radiation, which refers to the application of special provisions with regard to the production, possession, use and marketing of nuclear equipment and substances, irrespective of the type of use, the relevant rules were established in further detail by the Grand Ducal Regulation of 29 October 1990.

The production and marketing of nuclear materials require a licence – which may be general or specific in form – issued for a fixed or indeterminate period by the Minister of Health [1990 Regulation, Section 2.2]. A special licence is required for each product in the case of the possession and import of irradiated foodstuffs or radiopharmaceutical products [Section 8.2]. The import of nuclear substances for medical purposes must also be covered by a certificate from a pharmacist approved by the competent authority of the country of origin of the product; the use of such products is confined to members of the medical or veterinary professions approved for this purpose by the Minister responsible for Health.

In addition, the Grand Ducal Regulation of 17 August 1994 prohibits the manufacture, import, sale or installation of fire or smoke detectors including radioelements.

4. Nuclear Installations

The provisions governing nuclear installations are contained in the Grand Ducal Regulation of 29 October 1990.

Nuclear installations are divided into four categories from I to IV according to the risks they present [Section 2.1].

Chapter 2 of the Regulation lays down separate licensing conditions for each category of installation, notably with relation to the technical information to be supplied, public information and participation in the licensing procedure, etc. A prior license from the competent authorities is nevertheless required for each of these categories. The authority competent to issue licences is the Minister of Health, except for Category I installations, for which the operators are obliged to obtain a licence from the Government in Council. The administrative formalities are always dealt with by the Minister of Health and licence applications for all classified installations, irrespective of category, are sent to the Radiation Protection Division of the Health Department for opinion.

The Government in Council (Category I) or the Minister of Health, after consultation of the Radiation Protection Division, (Categories II, III and IV) lay down the conditions to which the granting of the licence is subject. Reasons are always given for any refusal to grant a licence.

The following information must be included with licensing applications [Section 2.6.1]:

- the applicant's name, occupation and address;
- the nature and purpose of the installation in question, the type and characteristics of the radiation emitted, the characteristics of the equipment used, etc.;
- the person responsible for physical control and the implementation of any measures required to ensure compliance with licensing conditions and any requirements laid down by the Regulation;
- the training in radiation protection of the staff responsible for receiving, producing, distributing, using, maintaining and supervising radioactive substances and equipment;
- a draft of the third party liability insurance contract covering nuclear activities;
- a plan of the installations and premises containing radioactive substances or equipment;

- a safety report describing the most serious incidents which could occur in the installation.

The licensing authority may suspend or withdraw a licence in the event of failure to comply with the provisions of this Regulation or the conditions attached to the licence [Section 2.1.3].

At the international level, Luxembourg ratified the 1994 Convention on Nuclear Safety on 7 April 1997.

5. Trade in Nuclear Materials and Equipment

Trade in nuclear materials and equipment is subject to the Act of 25 March 1963 [Section 2] which provides that rules governing the import, transport, sale, etc. of any equipment or substance capable of emitting ionising radiation shall be laid down by administrative regulation.

Thus, the Regulation of 29 October 1990 on the protection of the public against the hazards of ionising radiation provides that the import, transport, sale, etc. of radioactive substances are subject to prior licensing [Section 1.1].

The licensing procedure for the transit of radioactive substances is contained in two legislative instruments: the Grand Ducal Regulation of 31 July 1989 on the transfer of nuclear materials, equipment and technology and on physical protection conditions, and the above-mentioned Regulation of 29 October 1990.

The former of these two Regulations was revised by the Ministerial Regulation of 3 February 1993, which repealed and replaced its first Annex containing definitions of nuclear materials, equipment and technology.

The latter Regulation lists in Chapter 3 the conditions to be met for licensing. These provisions apply both to the transit and the transport of radioactive substances. Thus, transport and transit operations can only be carried out by persons or firms previously authorised to do so by the Minister of Health.

Licences may be limited to a single operation or considered valid for several operations. In the latter case, each operation must be notified in advance to the Radiation Protection Division of the Ministry of Health.

Applications must contain detailed information about the sender and the addressee, the origin of the substances in question, the qualifications of the staff involved, the nature and intensity of the radiation emitted, etc. Applicants must also produce a certificate from the insurer covering the nuclear risks involved in the operation to be carried out.

6. Radiation Protection

The Grand Ducal Regulation of 29 October 1990 constitutes the basic text governing radiation protection in Luxembourg. This Regulation was adopted to implement Council Directive 80/836/Euratom of 15 July 1980 laying down the revised basic standards for the health protection of the general public and workers against the dangers of ionising radiation, as amended by Council Directive 84/467/Euratom of 3 September 1984.

Chapters 5, 6 and 7 of the Regulation contain provisions relating to the dose limits for members of the public and workers, while Chapter 8 deals with the protection and safety of the public. Chapter 6 of the Regulation was partly amended by the Regulation of 17 August 1994. More specifically, Section 6, paragraphs 1, 3, 4 and 7, required amendment to comply with Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas. A second partial amendment of Section 6.3 resulted from the adoption of the Grand Ducal Regulation of 22 February 1996.

Generally speaking, the Minister of Health is the competent authority for the radiological protection of the public; he exercises his powers in collaboration with the Minister of Labour in regard to the health protection of workers.

The provisions relating to dose limits for the public and workers take into consideration the ALARA principle (As Low As Reasonably Achievable). Thus, the exposure of the public and workers to ionising radiation, where such exposure is controllable, must be kept as low as reasonably possible, as must the number of persons and workers exposed to such radiation [Section 5.1].

The overall dose limit for members of the public is set at 1 mSv (100 mrem) per year. That for occupationally-exposed workers must not exceed 10 mSv (1 rem) per year. The Regulation also lays down dose limits for certain categories of persons, notably adolescents and pregnant women.

After having laid down dose limits, the Regulation of 1990, as amended by the Regulations of 14 August 1994 and 22 February 1996, describes the operational rules to protect workers, apprentices and students exposed to radiation [Chapter 6]. Thus Section 6.1 defines “controlled area” and “supervised area” while other provisions [Section 6.2 *et seq.*] supply relevant practical information.

A new Chapter 12 of the Regulation of 14 August 1994, as amended by the Grand Ducal Regulation of 22 February 1996, governs the protection of “outside” (contract) workers. Thus, the Radiation Protection Division of the Health Department is responsible for ensuring that outside workers enjoy the same protection as that afforded to workers employed on a permanent basis [Section 12.2]. In addition, the head of the installation of a “controlled area” in which outside workers are employed is responsible, either directly or through contractual agreements, for the operational aspects of their radiation protection [Section 12.4].

The Radiation Protection Division of the Health Department is responsible for monitoring the protection and safety of the general public. Its tasks include in particular [1990 Regulation, Section 8.1]:

a) the regular monitoring of radioactivity in the air, water, soil and food chain, and the studying of measures to be taken and the co-ordination of emergency assistance in the event of an accident;

b) the evaluation and monitoring of radiation doses received by occupationally exposed persons, by members of the public living in the neighbourhood of radioactive sources, and by the public as a whole. The Radiation Protection Division is informed immediately of any accidental exposure or emergency situation;

c) the regular verification of the effectiveness of radiation protection measures and techniques at places of work where there is a risk of exposure to ionising radiation.

When a danger to health exists, the Minister of Health is empowered to issue orders, after consultation with the medical inspector of the district concerned and the radiation protection expert answerable to the chief health medical officer, recommending the emergency measures to be taken. To remain valid, however, any such orders must be confirmed within three months by a public administration Regulation [Act of 25 March 1963, Section 3].

Lastly, reference should be made to the provisions relating to the medical use of ionising radiation. In this respect, the Act of 10 August 1983 concerning the medical use of ionising radiation provides that the use of such radiation for diagnostic or therapeutic purposes shall be subject to conditions relating to the training of physicians and to standards for apparatus and equipment [Section 1].

In particular, the practice of general radiodiagnosis and radiotherapy is restricted to medical specialists having received appropriate training. The use of unsealed radioactive sources on humans is limited to physicians who have undergone specialised training in nuclear medicine and who have been approved by the Minister of Health. The conditions for such training are to be laid down in Grand Ducal regulations [Section 2].

The Act further requires prior licensing by the Minister of Health for any utilisation of apparatus and equipment used for radiodiagnosis, radiotherapy or nuclear medicine. The conditions for the possession and utilisation of such apparatus and equipment are laid down in specific regulations [Section 4].

More detailed provisions are contained in the Grand Ducal Regulation of 17 February 1987 concerning the medical use of ionising radiation, adopted in implementation of the Act of 10 August 1983. This Regulation is based directly on Council Directives 80/836/Euratom of 15 July 1980, 84/467/Euratom of 3 September 1984, and 84/466/Euratom of 3 September 1984.

The Regulation further specifies the provisions of the Act of 10 August 1983 concerning radiodiagnosis [Chapter 1], radiotherapy [Chapter 2] and nuclear medicine [Chapter 3], essentially with respect to the training of physicians, the useful life of appliances, the distribution of radiological tasks among the different fields of medicine and their classification according to the appliances, isotope selection and the conditions to be observed during examinations and treatment by radiation.

It also contains provisions common to radiodiagnosis, nuclear medicine and radiotherapy, in particular with regard to the possession and use of appliances and facilities and the establishment of an individual radiological book for patients, in which the physician must note each radiological or therapeutic intervention, he carries out and the number of exposures [Chapter 4].

Annex I of the Regulation was repealed an replaced by the Grand Ducal Regulation of 13 May 1989 which amends the list of radiological interventions associated with different medical specialities, aside from radiation used for diagnostic purposes or electroradiology.

7. Radioactive Waste Management

There is no special legislation in Luxembourg dealing with the management of radioactive waste. These activities are subject to the Regulation of 29 October 1990 on protection of the population against the hazards of ionising radiation, the scope of which extends to the reprocessing, handling, storage, elimination and disposal of radioactive waste [Section 1.1].

Facilities for the collection, processing, conditioning and storage of radioactive waste have been included in Category II [Section 2.1] and require prior licensing. Applications must be made to the competent authority, namely the Minister of Health. Licensing applications are sent to the mayor of the commune in which the facility is to be built, and to the mayors of communes within a radius of 100 metres from the outside boundaries of the facility. Licensing applications must be posted for a period of 15 days, following which an inquiry is carried out. At this stage, the opinions and comments of the commune concerned are taken into account. Within 40 days, the relevant information must be sent to the Minister of Health who, having consulted the Radiation Protection Division of the Health Department, the Labour and Mines Inspectorate and any other relevant bodies, lays down the licensing conditions. Reasons must always be given for any refusal to grant a licence [Section 2.4].

Licensing applications for facilities dealing with radioactive waste must contain additional information as compared to those for other types of classified installations. First of all, a description must be given of the management, purification and disposal measures proposed and secondly, more detailed information, depending on whether the waste in question is liquid, solid or gaseous, has to be provided [Section 2.6.1].

8. Non-Proliferation and Physical Protection

The physical protection rules in Luxembourg are contained in the Regulation of 31 July 1989 concerning transfers of nuclear materials, equipment and technology and the conditions of physical protection.

Section 1 provides that no one may transfer nuclear materials and equipment or nuclear technological data and derivatives to a non-nuclear weapon state, except for peaceful purposes. Annex 1 of the Regulation, which provides the definitions of nuclear materials, equipment and technological data, was repealed and replaced by the Ministerial Regulation of 3 February 1993 on transfers of nuclear materials, equipment and technology.

The Regulation makes a distinction between exports to a non-European Union country [Chapter I] and those to European Union countries [Chapter II]. In the first case, exports are subject to a prior licence from the Minister of Foreign Affairs and Foreign Trade. In the second case, exports can be made without restriction as long as a number of specified conditions applying to each of the substances concerned are fulfilled.

At international level, Luxembourg, as a Euratom Member State, ratified, on 6 September 1991, the 1979 Convention on the Physical Protection of Nuclear Material.

As regards non-proliferation, Luxembourg has, since 2 May 1975, been a Party to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons. Furthermore, the safeguards system set up under the IAEA and the security control provided for under the 1957 Euratom Treaty are applied in Luxembourg. It also ratified the 1996 Comprehensive Test Ban Treaty on 26 May 1999.

9. Transport

The International Regulations concerning the Carriage of Dangerous Goods by Rail (RID), the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), the IATA Restricted Articles Regulations, and the IMO International Maritime Dangerous Goods Code, are applied in Luxembourg.

The international rules governing the transport of nuclear substances were harmonised in Luxembourg's legislation by the Grand Ducal Regulation of 29 October 1990, whose provisions apply to all modes of transport. Transport operations are subject to a licence, which may be general or specific, issued by the Minister of Health [1990 Regulation, Section 3.1].

Transport licence applications must specify the identity of the applicant and of the consignee, the origin and physical and chemical characteristics of the substances concerned, etc. The licensing order lays down the conditions attaching to the licence and the preventive measures which must be taken to protect the public and workers.

Lastly, under the Regulation of 27 March 1964 establishing the conditions of appointment and powers of the radiation protection expert to assist the chief health medical officer, this expert must give his opinion on the level of protection and safety before and after each transport operation of radioactive substances [Section 2].

10. Nuclear Third Party Liability

There are no special rules in Luxembourg legislation governing nuclear third party liability. However, it is provided that cover against nuclear risk necessary for the operation of a nuclear installation in Categories I to III or for transport operations could be subject to specific conditions attached to the licence [1990 Regulation, Sections 2.6.1 and 3.1].

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities

a) Minister of Health

The Minister of Health is responsible for enforcing radiation protection legislation. For this purpose, he closely supervises nuclear activities through licensing procedures enabling him to intervene extensively in the production and use of nuclear energy. As regards the health protection of workers, he carries out his duties in liaison with the Minister of Labour [Regulation of 29 October 1990].

Within the Ministry of Health, the Radiation Protection Division, which is part of the Health Department, gives effect to measures to protect individuals and ensure the safety of nuclear installations [Sections 2.10 and 8.1]. More precisely, it is responsible for monitoring the exposure of the public and the environment to ionising radiation.

b) Minister of Labour

The Minister of Labour exercises certain powers regarding the health and safety of workers in collaboration with the Minister of Health. The Labour and Mines Inspectorate, a sub-division of this Ministry, plays a particularly important role in nuclear activities.

This department co-operates with the Radiation Protection Division throughout the licensing procedure laid down for nuclear installations. Thus, its opinion is required when an application is submitted [1990 Regulation, Section 2.3, 2.4, 2.5 and 2.7]. The Labour and Mines Inspectorate is kept informed of any decision of the Minister of Health to suspend or refuse a licence [Section 2.13] and of any accidental exposure of workers to ionising radiation [Section 5.6].

c) Minister of Energy

The Minister of Energy acts in an advisory capacity in connection with licensing applications for nuclear installations in Categories I and II (nuclear power stations, reprocessing plants, etc.).

d) Other ministerial powers

The Ministers responsible for Social Security, the Interior, Transport, Foreign Affairs, Justice, the National Economy, and Agriculture each participate in their respective fields of competence in certain decisions affecting nuclear energy.

2. Advisory Bodies

Higher Health Council

The Higher Health Council (*Conseil supérieur d'hygiène)* was set up in 1963 under the Minister of Health as an advisory body on all health questions [Ministerial Regulation of 18 April 1963, Section 1]. The Higher Council thus reports to the Minister on scientific and technical matters relating to health, and proposes measures which it deems appropriate [Section 2].

The Higher Health Council has a maximum of thirty members, most of whom sit as *ex officio* representatives of the Ministries of Health, Agriculture, Labour, Justice, and the Interior. The other members may be either nationals or foreigners. The Council may also ask national or foreign experts to attend its meetings in an advisory capacity [Section 3].

The chairperson, vice-chairperson and the secretary are appointed by the Minister of Health from among the members of the Council [Section 5].

The Executive Committee of the Higher Health Council consists of five members, namely the chairperson, the vice-chairperson and the secretary together with two other members nominated by the Council. The Executive Committee is responsible for day-to-day management and allocates work to the different sections of the Council. Meetings of the Council are called by the Executive Committee at the request of the Minister of Health except in emergencies when they may be called by the chairperson, or in his absence by the vice-chairperson [Section 6].

The Higher Health Council is divided into five sections, one of which deals with toxic and dangerous products. The Executive Committee can set up special sections where a particular question is not appropriate for any of the existing sections. Each section appoints its own chairperson and rapporteur [Section 7].

MEXICO

I. GENERAL REGULATORY REGIME

1. Introduction

Mexico (the United Mexican States) currently has one nuclear power plant, *Laguna Verde*, located on the Gulf of Mexico. It consists of two units, the first of which has been operating since 1990 and the second since 1995. Mexico also has uranium resources and is engaged in a programme of nuclear research and development. It has a comprehensive body of laws and regulations governing its nuclear activities, the most important of which are described in the following paragraphs.

The Political Constitution of the United Mexican States states, in relation to nuclear activities, that the development of strategic areas will be the exclusive responsibility of the public sector, and that the Federal Government will always maintain ownership and control over public bodies created for that purpose. The Constitution of Mexico provides that matters related to radioactive ores and nuclear power generation are within the scope of strategic areas [Articles 25 and 28].

With regard to the prospecting for, mining and use of radioactive ores, the Mexican Constitution contains provisions indicating that such ores will not be subject to any concession or contract, and that only the state may carry out such activities in accordance with the relevant law [Article 27-VI].

The 1984 Act on Nuclear Activities, adopted pursuant to Article 27 of the Constitution, was promulgated on 27 December 1984 and entered into force on 5 February 1985 [Official Gazette *(Diaria Oficial de la Federacion)*, 4 February 1985]. It regulates all nuclear activities in Mexico and repeals and replaces a similar Act of 1978, also adopted pursuant to Article 27 of the Constitution.

The 1984 Act specifies that nuclear energy will be used solely for peaceful purposes, in accordance with Article 27 of the Constitution, and that the Federal Government will establish regulations governing the use of radioactive materials [Section 2]. The Act regulates prospecting for and mining of radioactive ores, the use of nuclear fuels, research in nuclear science and technology, the nuclear industry and all related matters [Section 1]. These different aspects of nuclear activities will be dealt with under the appropriate headings below.

The General Radiological Safety Regulations of 22 November 1988, which entered into force on 23 November 1988, were made in implementation of the 1984 Act on Nuclear Activities. They repeal all other national regulations on the same subject and contain administrative and technical provisions relating to the radiological safety of radioactive installations, ionising radiation sources and ionising radiation-emitting devices. The Regulations of 14 June 1991 (in which entered into force on 15 September 1991) amending the General Health Act, also contain provisions dealing with the radiation protection aspects of nuclear activities, but they are restricted to medical purposes.

The Ministry of Health published the Official Guidelines No. NOM-002-SSA2-1993 on the organisation and provision of radiotherapy services, including the related technical aspects of radiation protection.

In addition, the Ministry of Labour and Social Development issued the Official Guidelines No. NOM-012-STPS-1993, on 15 June 1994 (which entered into force on 16 June 1994), relating to safety at workplaces involving ionising radiation sources.

A Decree of 27 December 1995 (which entered into force on 1 January 1996) provides for controls over the import and export, whether temporary or permanent, of certain materials or waste including, in particular, radioisotopes, nuclear fuels, radioactive waste and ionising radiation-emitting equipment.

As regards the transport of hazardous materials, including Class 7 "Nuclear Materials", the Ministry of Communications and Transport issued Regulations for Transport by Land of Dangerous Materials and Wastes, which entered into force on 8 April 1993.

Finally, an Act of 29 December 1974 (which entered into force on 1 January 1975) deals with third party liability for nuclear damage.

2. Mining Regime

In accordance with Article 27 of the Constitution, radioactive ores are the property of the state; no contracts or concessions may be granted for their prospecting, mining and use [1984 Act on Nuclear Activities, Section 1]. Any person who has knowledge of a radioactive ore deposit must immediately notify the Ministry of Energy [Section 6]. Any person with a mining concession who discovers radioactive ores on his land must inform the Ministry by written notification within ten days of this discovery in particular so that the property rights of the state are protected and assessment of the ores can be undertaken [Section 7].

The 1984 Act on Nuclear Activities provides that the Ministry of Energy is to assign exclusive responsibility for prospecting activities to a decentralised public body, the Mineral Resources Board (*Consejo de Recursos Minerales*). The Ministry determines its programme of activities and technical conditions governing such work [Section 9]. The 1984 Act specifies that the Ministry is to assign exploration rights for radioactive ores to another decentralised public body, the Commission for Mining Development (*Comision de Fomento Minero*) in accordance with the policies established for the achievement of the objectives or priorities of the national programme; only that Commission was permitted to set up and operate plants for the use of such ores [Section 10]. However, that public body was dissolved by the Mining Act of 26 June 1992, which assigned all its activities to the Mineral Resources Board [Section 5 Provisional].

3. Radioactive Substances, Nuclear Fuel and Equipment

The regulatory regime governing radioactive substances, nuclear fuel and equipment is laid down in Chapter III of the 1984 Act on Nuclear Activities under "Nuclear Industry". This definition includes, *inter alia*, the various stages of the fuel cycle, including uranium enrichment, fuel reprocessing, heavy water production, design and manufacture of nuclear equipment and components for steam supply systems in nuclear power plants, production and applications of radioisotopes; the nuclear industry is specified as being of public interest [Section 11].

The 1984 Act provides that the production, use and application of radioisotopes are priority activities for the development of the national economy [Section 16]. These activities must be carried out within the context of programmes approved by the Federal Government, acting through the Ministry of Energy, in accordance with the research and technical development policy established by the Federal Government [Sections 12 and 18].

Radioactive materials and equipment used for medical purposes require a prior licence from the Ministry of Health [Section 29].

The production, use and application of radioisotopes may be undertaken by the public sector, in particular by the social services, on its own or in conjunction with the private sector; both require prior licensing from the Ministry of Energy. Licences for the production of radioisotopes based on the use of nuclear fuel are issued after hearing the opinion of the National Nuclear Research Institute (*Instituto Nacional de Investigaciones Nucleares*) and other competent authorities, depending on whether they are to be used for medical, industrial or agricultural purposes [Section 16].

The production of radioisotopes from nuclear reactors, on the other hand, may only be undertaken by public bodies, universities, institutes and research centres, licensed in accordance with the Act; such licences are granted by the Ministry of Energy. Finally, licences for the production of radioisotopes from nuclear fuels are also granted by the Ministry and notification thereof will be published in the Official Gazette [Section 16].

The possession, import, export, use, transfer, transport, storage and disposal of radioactive materials or ionising radiation-emitting equipment is prohibited without a licence [General Radiological Safety Regulations, Sections 189 and 190].

Nuclear fuels are the property of the state; only the Federal Government may authorise their use, in accordance with the provisions of the Act and under the control of the National Nuclear Safety and Safeguards Commission (*Comisión Nacional de Seguridad Nuclear y Salvaguardias*) [1984 Act, Section 17].

4. Nuclear Installations

Mexican law makes a distinction between “nuclear” installations and “radioactive” installations [1984 Act, Section 3].

Nuclear installations are defined as those in which nuclear fuel is manufactured, processed, used, reprocessed or stored, while radioactive installations are those in which radioactive material or equipment containing such material is produced, manufactured, stored or used, or in which radioactive waste is treated, conditioned or stored [Section 3].

Nuclear electricity generation falls under the sole jurisdiction of the Federal Electricity Commission (*Comisión Federal de Electricidad*) which is responsible for the design and construction of nuclear power plants, having regard to the opinion of the National Nuclear Research Institute [Section 15].

The use of nuclear reactors for purposes other than electricity generation is restricted to public bodies, universities, institutes and research centres, licensed in accordance with this Act [Section 16].

a) Licensing and inspection, including nuclear safety

The siting, design, construction, operation, modification, shutdown, decommissioning and dismantling of nuclear and radioactive installations requires a licence granted by the Secretariat of Energy. Licences for the construction and operation of such installations are valid for a limited period, and their renewal, modification, suspension or cancellation are regulated by the provisions of the relevant regulations [Section 26]. Nuclear and radioactive installations must meet the siting, design and construction, etc. requirements established under the Act [Section 25].

Mexico ratified the 1994 Convention on Nuclear Safety on 26 July 1996.

i) Nuclear installations

Licences for the construction and operation of a nuclear installation are granted only following approval of the information submitted on the manner in which the safety objectives will be met and on the procedures and methods to be applied for the siting, design, construction, operation, modification, decommissioning and final shutdown of the installation. For each different stage, the information necessary to assess environmental impact must be provided to the National Nuclear Safety and Safeguards Commissions. The corresponding emergency plan must also be submitted. This information must be provided in accordance with the conditions laid down by the provisions of this Act [1984 Act, Section 28].

Under Mexican legislation, two environmental impact assessments are required for nuclear installations: the first considers the environmental impacts from their radiological, nuclear and physical safety points of view, and the second covers all other aspects. The latter assessment is carried out under authority of the Ministry of the Environment, Natural Resources and Fisheries [General Act on Ecological Equilibrium and Environmental Protection, Section 154].

ii) Radioactive installations

The conditions for the licensing of radioactive installations are laid down by the General Radiological Safety Regulations of 22 November 1988. The National Nuclear Safety and Safeguards Commission, under the Ministry of Energy, is the licensing authority for such installations [Section 219]. The Commission issues, renews, revokes and suspends permits or licences based on Section 50-V of the 1984 Act on Nuclear Activities.

Applications for licences for the construction, operation, modification, shutdown or decommissioning of radioactive installations require different procedures; all must provide information on the radiological safety of the installation concerned [Section 219].

Applicants for a licence to construct a radioactive installation must, in particular, provide the following information to the Commission [Section 220]:

- description of the radiological safety characteristics to be applied in the design of the installation, and the methods for controlling the processes and materials used;
- proposed activities;
- siting;

- quality assurance programme.

Applicants for a licence to operate a radioactive installation must in particular provide the following information with respect to radiological protection [Section 221]:

- general specifications of the installation;
- organisational measures implemented by the applicant;
- radiological safety policy and quality assurance programme;
- type of ionising radiation sources;
- environmental impact assessment;
- risk analysis and emergency plan; and
- procedures for decommissioning, dismantling and final shutdown.

Applications for a licence to modify a radioactive installation must include information on the reasons therefor and the radiological safety implications thereof [Section 222].

Finally, applications for a licence to decommission, dismantle or finally shut down an installation must include a detailed report on information on the decommissioning and dismantling programme in the context of radiological safety operations; if there is radioactive waste, a report on the procedures for its processing, conditioning and final disposal; and documentation ascertaining that the radiological safety conditions comply with those established in the operating licence [Sections 223 and 224].

iii) Inspections

The National Nuclear Safety and Safeguards Commission is responsible for inspecting and monitoring nuclear and radioactive installations to ensure compliance with radiological safety conditions, to account for radioactive materials and for safeguards purposes [1984 Act, Section 32].

Such inspections take place at the request of interested parties, or as frequently as the Commission deems necessary [1998 General Radiological Safety Regulations, Section 235].

b) Protection of the environment against radiation effects

As already mentioned, the 1984 Act on Nuclear Activities and the 1988 General Radiological Safety Regulations provide for an environmental impact assessment in the licensing procedure for nuclear and radioactive installations [Sections 28 and 22, respectively].

In addition, Section 154 of the General Act on Ecological Equilibrium and Environmental Protection of 1988 (which entered into force on 1 March 1988) applies to nuclear activities. The Act provides that the Ministry of Energy together with the National Nuclear Safety and Safeguards Commission, and where relevant, the Ministry of Health, must ensure that all such activities are carried out in accordance with the nuclear safety and radiological protection regulations in force for

nuclear and radioactive installations, so as to avoid any risk to human health and preserve the ecological equilibrium. The Ministry of the Environment, Natural Resources and Fisheries is the authority responsible for environmental impact assessments.

Nuclear activities referred to in the 1988 Ecological Equilibrium Act include prospecting for and mining of radioactive ores, nuclear fuel supply, all uses of nuclear energy and the nuclear industry in general. In addition, the Environmental Impact Regulations of 7 June 1988 were issued in implementation of the 1988 Ecological Equilibrium Act and entered into force on 8 June 1988. They contain detailed provisions on the subject and require, *inter alia,* risk studies, preventive and mitigating measures [Sections 3 and 5].

c) Emergency response

Both the 1984 Act and the 1988 General Radiological Safety Regulations specify that applications for licences for nuclear and radioactive installations must include emergency plans.

In the event of imminent danger or risk for the personnel of a nuclear or radioactive installation or for the population in general, the National Nuclear Safety and Safeguards Commission will order, or carry out, as the case may be, the removal, seizure and safe-keeping of ionising radiation sources or equipment containing such sources. The Commission may also order, as a preventive measure, the temporary or permanent shutdown of nuclear or radioactive installations and specify the relevant corrective measures. It may keep the installation permanently shut down in case the measures taken are inadequate [1984 Act, Section 34].

Any person who has knowledge of an incident involving nuclear or radioactive materials or equipment containing such materials must immediately inform the Commission. Natural or legal persons licensed to carry out the activities regulated by the 1984 Act must inform the Commission immediately of such an incident, and then confirm in writing within 24 hours [Section 23].

The 1988 General Radiological Safety Regulations provide that before start-up of a radioactive installation, the operator must have established an emergency plan in accordance with the conditions of the National Civil Protection System and based on a study of the radiological consequences of any accident that might occur in the installation [Section 124]. The purpose of the plan is to restrict exposure to ionising radiation to a level as low as reasonably achievable (the ALARA principle), control any accident that may occur and obtain all the information required to determine the causes and consequences of such an accident. It should as a minimum include [Section 125]:

- equipment processes for the radiological measures required to assess and determine the situation created by the accident;
- protection measures needed to reduce exposure to ionising radiation;
- intervention levels to serve as guidelines for the application of the above measures;
- protection measures for the neighbouring population, in accordance with the National Civil Protection System.

The head of the radiological protection group of an installation, the occupationally-exposed personnel or the licensee must also immediately report a radiological incident to the National Nuclear Safety and Safeguards Commission [Section 175].

All emergency plans should be carried out in accordance with the National Civil Protection System [Section 124]. As regards the *Laguna Verde* nuclear power plant, there is a specific plan named External Radiological Emergency Plan (*Plan de Emergencia Radiológica Externa* – PERE) which establishes the participation and responsibilities of the federal, local and municipal authorities. Like all emergency plans, it is co-ordinated by the Ministry of the Interior, which is the competent authority for the National Civil Protection System.

Furthermore, at the international level, Mexico has been a Party to the 1986 Convention on Early Notification of a Nuclear Accident and the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency since 10 May 1988.

5. Trade in Nuclear Materials and Equipment

The Federal Government, through the Ministry of Energy and in co-operation with other competent authorities, is the authority responsible for controlling the import and export of nuclear materials and fuels. Radioactive ores or material will be exported having regard to national needs, and will in no case exceed 5 percent of known resources, in accordance with the National Development Programme provided for in Article 26 of the Political Constitution of the United Mexican States [1984 Act, Section 18-V]. The National Nuclear Safety and Safeguards Commission gives its opinion, prior to the licensing of imports and exports of radioactive materials and equipment containing them, and also in connection with nuclear materials and fuels, for purposes of security, registration and control [Section 50-IX].

Applicants for a licence to import ionising radiation sources must, in particular, submit to the Commission, the following information: the number of their operating permit or licence, the activity level of the radioisotopes, their physical and chemical form, the specifications of the equipment containing the radioactive material, the type of packaging and a physical protection and radiological safety plan [1988 General Radiological Safety Regulations, Section 193]. The same procedure applies for exports of ionising radiation sources [Section 195].

A Decree of 27 December 1995, which entered into force on 1 January 1996, sets out the list of goods which require import and export licences. It provides for controls over the import and export of nuclear and radioactive materials including nuclear fuel, radioisotopes, radioactive waste and ionising radiation-emitting equipment, also for medical purposes. The Decree specifies that all export and imports into Mexican territory, on a temporary or permanent basis, require a licence issued in advance by the Ministry of Energy through the National Nuclear Safety and Safeguards Commission [Sections 1 and 2]. The licence is to be presented by the applicant before any import or export of the listed material [Section 3].

The health authority also requires a health permit prior to the import or export of ionising radiation sources for medical purposes [1988 General Health Act, as amended in 1991, Section 125].

6. Radiation Protection

The regulations governing radiation protection in Mexico were adopted in implementation of the 1984 Act on Nuclear Activities and the 1988 General Health Act. Official Guidelines on Radiological Safety were issued by the Ministry of Health in 1993, and Official Guidelines on Safety at Workplaces involving ionising radiation sources were issued by the Ministry of Labour and Social Development the same year.

The 1984 Act provides that natural or legal persons authorised to operate nuclear or radioactive installations in accordance with the Act and its regulations are directly responsible for radiation safety, and must arrange for the retention of the necessary personnel who will be responsible for providing advisory assistance, training, evaluating working procedures, monitoring, and preparing safety manuals, in all matters related to radiation protection in the workplace [Section 27]. A Decree of 15 April 1997 amended the provisions of the General Health Act [Official Gazette of 7 May 1997] in relation to the use of toxic and dangerous medicine. In particular, Section 125 of the Act now provides that the Ministry of Health, in co-operation with the National Nuclear Safety and Safeguards Commission, will grant the necessary licences.

The 1988 General Radiological Safety Regulations are the most important in this series of regulations covering all aspects of radiation protection, and the National Nuclear Safety and Safeguards Commission, under the control of the Ministry of Energy, is the competent authority in this respect [Section 4].

The Regulations set out the dose limitation regime, specifying that the authorised limits are those set by the Commission, on dose equivalent limits and exposure conditions, and on the measures to be taken for planned or emergency exposures [Part III].

The Regulations provide, *inter alia*, that ionising radiation sources, sealed or unsealed, as well as ionising radiation-emitting equipment, must be equipped with a safety system. Only the licensees may modify the design or operating conditions of these sources or equipment, with prior approval of the Commission [Sections 56 and 57], and they cannot be transferred without a licence or authorisation by the Commission [Section 58]. As regards the use of X-ray equipment for medical diagnosis, the technical standards to be complied with are laid down by the Ministry, through the Commission [Section 91]. Nevertheless, radiation protection regulations relating to the use of ionising radiation sources exclusively for medical purposes, are also within the competence of the Ministry of Health [General Health Act, 1991, Sections 124 and 125]. A Decree of 15 April 1997 amended the provisions of the General Health Law [Official Gazette of 7 May 1997] in relation to the use of toxic and dangerous medications. In particular, Section 125 of the General Health Law now provides that in the case of radioactive sources for medical or diagnostic use, the Ministry of Health will issue the necessary licences in co-ordination with the National Nuclear Safety and Safeguards Commission.

The 1988 Regulations lay down the obligations of licensees and radiation personnel. In particular, all licensees, as already specified in the 1984 Act, must establish a radiological protection group in their installations, responsible for implementation and surveillance of all radiation protection measures in the workplace [Section 145].

All occupationally-exposed personnel must have received appropriate training for their particular work and the relevant authorisation by the Commission. They must have knowledge of and apply the basic radiation protection principles and the instructions in the installation's radiological safety manual and emergency plan [Sections 144 and 159].

The Regulations also provide for preventive measures in the event of an ionising radiation hazard and specify in this respect that the Commission may order the temporary, partial or total closure of the radioactive installation involved; as regards hazards from ionising radiation sources or ionising radiation-emitting equipment, the Commission may remove them or dispose of them whenever it considers it necessary for safety purposes [Section 182].

During 1996, the Ministry of Energy, through the National Nuclear Safety and Safeguards Commission, issued several technical regulations to implement the 1988 General Health Act. These provisions are issued as Official Guidelines and deal with the following subjects:

- NOM-001-NUCL-1994, specifies the factors for dose determination and implements Section 10 of the General Health Act [Official Gazette of 6 February 1996];

- NOM-002-NUCL-1994, establishes the required technical conditions for testing methods applicable to sealed sources of nuclear material [Official Gazette of 23 February 1996];

- NOM-003-NUCL-1994, classifies radioactive facilities using unsealed sources of nuclear material as required by the 1988 General Health Act [Official Gazette of 7 February 1996];

- NOM-005-NUCL-1994, sets up the annual limit of intake and derived air concentration of radionuclides for the establishment of dosimetric controls over internal exposures of occupationally exposed personnel [Official Gazette of 16 February 1996];

- NOM-006-NUCL-1994, establishes the criteria for the annual limit of critical groups of the public [Official Gazette of 20 February 1996];

- NOM-007-NUCL-1994, details the safety requirements for permanent implants containing radioactive material in humans for medical purposes [Official Gazette of 4 March 1996];

- NOM-008-NUCL-1994, sets out the maximum limit for superficial contamination and nuclear material in the workplace, as a preventive measure [Official Gazette of 5 March 1996].

The General Health Act, in force since 1 July 1988, and the General Radiological Safety Regulations made in implementation of the 1984 Act on Nuclear Activities [Official Gazette of 22 November 1988] originally applied to all radioactive installations, transport of radioactive materials and waste and radiation sources. Both were modified by a Decree published on 14 June 1992, in force since September 1991. The modification restricts the authority of the Ministry of Health to activities involving radiation sources for medical purposes [Section 198]. The Ministry of Health is the authority responsible for implementing the Regulation [Section 4]. The Regulation prohibits the operation of an installation where radiation sources or radioactive materials are used or disposed of without a health licence issued by the Ministry of Health. Persons responsible for radiological safety must ensure that patients undergoing treatment are adequately protected, in accordance with the Ministry of Health's Guidelines for such establishments [Section 103].

A licence from the health authorities is still required for the possession, import and export of, trade in, transport and use of ionising radiation sources for medical uses [Section 125].

On 11 October 1994, the Ministry of Health issued the Official Guidelines No. NOM-002-SSA-2-1993, which repeal the Guidelines issued on 2 February 1988, for the organisation, operation and health engineering of radiotherapy services. They set out revised general rules which apply to personnel using ionising radiation for diagnosis and are mandatory in public and private establishments.

The Ministry of Health, as the competent authority, has also issued the Official Rule NOM-088-SSA1-1994, which is concerned with protecting the health of the public against the hazards which might arise from imported foodstuffs. This Rule sets up the maximum radionuclide level and is

mandatory for any person or legal entity importing foodstuffs for retail within the national territory [Official Gazette of 28 June 1995].

Furthermore, the Ministry of Labour and Social Development revised the Guidelines issued on 15 February 1991, and on 15 June 1994 published new Official Guidelines No. NOM-012-STPS-1993 on health and safety at workplaces where ionising radiation sources are handled, stored or transported, and which are capable of contaminating the working environment. These Guidelines entered into force on 16 June 1994. They define the duties of employers in such workplaces and provide that they must implement preventive measures and controls to ensure that employees do not receive radiation doses in excess of the dose limits established by such Official Guidelines, and by the 1988 Regulations on Radiological Protection, which also establish employees' obligations in relation to medical examinations, restrictions due to radiological safety, etc. The tables set out the maximum permissible intake limits of radionuclides. A Federal Regulation relating to safety, health and the environment in the workplace of 20 January 1997 further extends the powers of the Ministry of Labour and Social Development to make rules governing the prevention of accidents in the workplace and ensuring that health and safety conditions for workers conform to those established by the federal labour legislation.

7. Radioactive Waste Management

The 1984 Act specifies that the Federal Government, through the Ministry of Energy, is responsible for the storage and disposal of nuclear fuels and radioactive waste irrespective of their origin [Section 18-VII].

The conditions governing applications for a licence for the establishment of a final repository and for the processing, conditioning and final disposal of low and intermediate level radioactive waste are the same as those for radioactive installations, as laid down in Sections 219, 220, 221 and 223 of the 1988 General Radiological Safety Regulations (see *supra*, Section 4 "Nuclear Installations") [Sections 202 and 206].

The National Nuclear Safety and Safeguards Commission classifies radioactive waste according to its specific activity, radiotoxicity, chemical and physical form, etc. [Section 207].

The final disposal of flammable, explosive, liquid or compressed gaseous radioactive waste is prohibited [Section 204]. Final disposal of radioactive waste at sea is also prohibited [Section 205]. It is also forbidden to mix radioactive waste with other materials, except as part of a conditioning process approved by the Commission [Section 208].

Licensees of radioactive installations which produce low or medium level liquid radioactive waste from unsealed sources may by authorised by the Commission to dump the waste in the installation's drainage system under specific conditions laid down by the Regulations [Section 211].

The National Nuclear Safety and Safeguards Commission has also issued Guidelines No. NOM-004-NUCL-1994, which sets out the criteria governing the identification and classification of radioactive waste produced by the nuclear industry, as defined by Section 11 of the 1984 Act on Nuclear Activities. These Guidelines apply to the management, processing, storage, disposal and transportation of nuclear material [Official Gazette of 4 March 1996].

The processing, conditioning and final disposal of radioactive waste from high-level sealed and unsealed radioactive sources may only be undertaken in accordance with the Safety Regulations for Nuclear Installations [Section 214 of the General Radiological Safety Regulations].

In August 1996 the Ministry of Energy adopted three Regulations in the field of radioactive waste management. These Regulations, published in the Official Gazette on 12, 14 and 15 August 1996 respectively, entered into force on the day following their publication. The first of the Regulations [NOM-018-NUCL-1995] defines the methods to be used to determine the concentration of radioactivity in radioactive waste containers so as to ensure proper treatment, conditioning and permanent storage of the waste. The second Regulation [NOM-019-NUCL-1995] deals with the requirements for operating a permanent surface storage facility (up to 30 meters underground) for containers of low-level radioactive waste in gaseous, liquid or solid form. The third Regulation [NOM-020-NUCL-1995] relates to the requirements for radioactive waste incineration facilities, and provides, *inter alia*, that such a facility must be constructed and operated so as not to permit a dose to the public in excess of 0.10 mSv per year.

The conditioning and final disposal of radioactive waste from ionising radiation sources arising from medical uses are also subject to a licence from the Ministry of Health, in co-operation with the National Nuclear Safety and Safeguards Commission [General Health Act, 1988, Sections 125 and 375-III, and 1988 Regulations, Sections 146-III and 149-V, as amended in 1991].

On 7 April 1975 Mexico ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter.

8. Non-Proliferation and Physical Protection

The 1984 Act on Nuclear Activities sets out definitions for non-proliferation and physical protection as follows:

- the purpose of safeguards is to organise and maintain a national system of control and registration of all nuclear materials to ensure that none of the said materials are diverted from peaceful applications to manufacture nuclear weapons or other non-authorised uses [Section 24];

- the purpose of physical protection in nuclear and radioactive installations is to avoid international acts which harm or may harm public health and safety, such as theft or unauthorised use of nuclear or radioactive materials [Section 22].

The National Nuclear Safety and Safeguards Commission inspects nuclear and radioactive installations to account for materials, control and check the physical protection measures and the application of safeguards in the installations [Section 32].

Following such inspections, the Commission will give its opinion on the deficiencies or anomalies noted, and propose the corrective measures required. It will then check that the measures have been implemented [Section 33].

Mexico ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 21 January 1969 and the 1996 Comprehensive Nuclear Test Ban Treaty on 5 October 1999. It is also party to the 1979 Convention on the Physical Protection of Nuclear Material, ratified on 4 April 1988.

Furthermore, Mexico is the depository of the 1967 Treaty for the Prohibition of Nuclear Weapons in Latin America (Tlatelolco Treaty) and has been party to the Treaty since 20 September 1967.

9. Transport

The transport of radioactive materials and ionising radiation-emitting equipment require a licence from the Ministry of Energy, acting through the National Nuclear Safety and Safeguards Commission [1984 Act, Section 29]. Such licences are delivered in accordance with the provisions of the 1984 Act [Section 30].

Applicants for a licence to transport radioactive materials must in particular [1988 Radiological Safety Regulation, Section 198]:

- propose the person to be responsible for radiation protection;
- describe the radioactive material to be carried, including the containers and packaging;
- describe in detail the physical protection and radiological safety plan;
- describe the safety equipment and devices;
- submit a risk analysis and emergency plan in the event of an accident involving radioactive materials during transport or during storage in transit;
- specify the route to be followed throughout the transport operation; and
- give the name of the entity legally authorised to provide the security for any damage caused by ionising radiation.

The radiological safety rules applicable to the transport of radioactive materials are established in the transport regulations for each mode of transport [Section 199]. Regulations in that respect are to be issued by the National Nuclear Safety and Safeguards Commission. The transport of nuclear and radioactive materials is also subject to the Regulations for the Transport by Land of Dangerous Materials and Wastes, published in the Official Gazette on 7 April 1993, and in force since 8 April of the same year. The competent authority is the Ministry of Communications and Transport. These provisions apply to the transport of materials classified as No. 7 "Radioactive Materials" [Section 18], irrespective of the provisions to be issued by the National Nuclear Safety and Safeguards Commission.

The Ministry of Communications and Transport has issued Official Rules NOM-003-SCT2/1994 to implement the 1993 Regulations for the Land Transport of Dangerous Materials and Wastes. These Rules set out the labelling requirements for packages of dangerous materials conveyed by land transport, including radioactive materials which are categorised as Class 7 dangerous materials.

The obligation to have insurance cover for damage arising during the transportation of dangerous materials [as provided by Sections 109 and 122 of the 1993 Regulations], has been deferred by the Ministry of Communications and Transport in order to give the Mexican insurance industry time to respond to this requirement.

10. Nuclear Third Party Liability

The Act on Third Party Liability for Nuclear Damage was adopted on 20 December 1974 and entered into force on 1 January 1975. The Act regulates third party liability for any nuclear damage caused by the use of nuclear reactors, nuclear fuels or the resulting radioactive waste [Section 1].

"Nuclear damage" is defined as loss of life, personal injury, or any damage or material loss resulting directly or indirectly from the radioactive properties or a combination of such properties with toxic, explosive or other properties of nuclear fuel or radioactive products or waste or hazardous radioactive substances produced in, coming from or sent to a nuclear installation [Section 3(c)].

The "operator of a nuclear installation" is defined as the person designated or authorised as such by the competent authority of the state (of the United Mexican States), within whose jurisdiction the installation is situated [Section 3(e)].

The liability of the operator is strict [Section 4]. He is liable for all damage caused by a nuclear incident occurring in a nuclear installation for which he is responsible, or by an incident involving hazardous nuclear substances produced in his installation [Sections 3(a) and 5].

Where nuclear damage involves the liability of more than one operator, the operators concerned are jointly and severally liable [Section 8]. The cumulative liability of those operators may not, however, exceed the maximum limits laid down by the Act [Section 9].

The operator of a nuclear installation is liable for damage caused by a nuclear incident occurring during the transport of nuclear substances until such time as the substances are unloaded from the means of transport at the agreed location or at the delivery address or when the operator of another nuclear installation has assumed responsibility therefor [Section 6]. The carrier or shipping agent may take over the operator's liability with regard to the nuclear substances, provided he meets the requirements of the Act and any applicable regulations [Section 7]. Before each transport operation, the operator must supply a certificate indicating his name and address, the nature and quantity of the substances shipped and specifying the statutory amount of his liability. The certificate must be accompanied, *inter alia*, by a certificate from his insurer or financial guarantor [Section 10].

If the operator liable shows that the nuclear damage resulted wholly or in part from the fault or deliberate omission of the person having suffered the damage or from that person's gross negligence, the competent court may decide to relieve the operator wholly or in part from his obligation to compensate that person [Section 13].

The operator is not liable for a nuclear incident which is the direct consequence of war, invasion, insurrection or a natural disaster [Section 11].

The maximum amount of the operator's liability is established at Mexican pesos (MXN) 100 million for each nuclear incident [Section 14]. However, in view of Mexico's obligations under the 1963 Vienna Convention on Civil Liability for Nuclear Damage, to which it has been a Party since 25 April 1989, the nuclear operator's liability cannot amount to less than the minimum set by the Convention.

The Act has no special provision regarding the type of insurance or financial security the operator must take out to cover his liability. However, this obligation, also referred to in transport documents, appears indirectly in Section 23 which provides that public bodies are exempt from the

requirement to obtain such insurance of financial security to cover the nuclear damage referred to in the Act.

There is no provision for state funding.

The right to claim compensation for nuclear damage is extinguished ten years from the date of the incident [Section 19]. That term is extended to fifteen years in case of deferred personal injury [Section 21].

In accordance with the Federal Code of Civil Procedures, the Federal court of the domicile of the defendant will have jurisdiction to hear proceedings concerning implementation of the Act [Section 25].

II. INSTITUTIONAL FRAMEWORK

The Federal Government

The Federal Government is the supreme authority in Mexico regarding nuclear matters. However it acts through the Ministry of Energy in accordance with Article 33 of the Organic Law of the Public Federal Administration. This Article entered into force on 29 December 1994 and granted the Ministry of Energy jurisdiction to issue all Official Guidelines dealing with, *inter alia*, nuclear safety, safeguards and radioactive materials. The Ministry delegates some of its responsibilities to the National Nuclear Safety and Safeguards Commission pursuant to the 1984 Act on Nuclear Activities.

The 1984 Act on Nuclear Activities [Section 18] provides that the Federal Government, through the above Ministry, is responsible for:

- establishing the framework for the use and development of nuclear energy and technology, in accordance with the national energy policy;

- initiating, supervising and, as the case may be, approving the programmes of work of the Mineral Resources Board and the Commission for Mining Development in connection with radioactive ores so as to achieve congruity in the programmes and projects in the field of research, application and generation of nuclear energy and development of the nuclear industry;

- regulating nuclear and radiological safety and physical protection as well as safeguards and supervising the implementation thereof;

- establish the stages of the nuclear fuel cycle;

- regulating the import and export of nuclear material and fuels, together with the other competent authorities;

- establishing the nuclear industry's research and technological development policy;
- regulating the transport and storage of nuclear fuels and radioactive waste;
- implementing the international agreements concluded in the nuclear field.

1. Regulatory and Supervisory Authorities

a) Ministry of Energy

An Internal Regulation of the Ministry of Energy of 1 June 1995 (which entered into force on 2 June 1995) sets out the structure of the Ministry and the responsibilities which, in accordance with the 1984 Act on Nuclear Activities, as delegated by the Federal Government.

The Regulation specifies that the Ministry is responsible for [Section 5]:

- granting licences for, and authorising the establishment and operation of facilities for the treatment of radioactive ores, the siting, design, operation, dismantling and decommissioning of nuclear and radioactive installations and establish, together with other competent authorities, the policy for the import and export of radioactive ores and nuclear materials;
- directing, where necessary, the National Nuclear Safety and Safeguards Commission to temporarily assume control over any nuclear or radioactive installation which represents a hazard for workers or the general public.

The General Directorate for Energy and Nuclear Resources has several duties in the nuclear field. In particular, the General Directorate may [Section 15]:

- authorise those activities that are within the competence of the Ministry of Energy, under the applicable legislative provisions;
- conduct studies, inspections and verifications, as well as authorise and apply sanctions in relation to matters within the competence of the Ministry of Energy, provided such functions are not assigned to other administrative directorates.

The General Directorate for International Affairs and the National Nuclear Safety and Safeguards Commission are responsible for ensuring the proper application of Mexico's international agreements in the nuclear field [Section 12-I-k].

b) Ministry of Health

The Ministry of Health has responsibilities in the field of general health, including radiation protection, as specified in Articles 26 and 39 of the Organic Law of the Federal Public Administration, namely, when ionising radiation is used for medical purposes. In addition to the licences required for activities involving nuclear or radioactive substances, a health permit from the Ministry of Health is required for medical establishments using radiation sources [Decree of 14 June 1991, amending the General Health Act, Section 125].

As already mentioned, the Ministry has issued guidelines on radiation safety in establishments for medical diagnosis and treatment [Official Guidelines No. NOM-002-SSA2-1993 of 11 October 1994].

c) Ministry of Labour and Social Development

In relation to its responsibilities vis-à-vis workers and the workplace, and in accordance with Articles 26 and 40 of the Organic Law of the Federal Public Administration, the Ministry of Labour and Social Development issued technical directives, on 15 June 1994, on health and safety at workplaces where ionising radiation sources are used (see *supra* Section 6 "Radiation Protection").

d) Ministry of the Environment, Natural Resources and Fisheries

Pursuant to Articles 26 and 36 of the Organic Law of the Federal Public Administration, this Ministry is responsible, *inter alia*, for controlling pollution of the environment. In accordance with the 1988 Environmental Act, applicants for a licence to undertake activities in the nuclear field must first obtain approval of the environmental impact assessment from the Ministry, besides the assessment submitted to the National Nuclear Safety and Safeguards Commission.

e) Ministry of Communications and Transport

In accordance with Articles 26 and 36 of the Organic Law of the Federal Public Administration, this Ministry is responsible for the regulation of public transport. In addition to the licences required by the Ministry of Energy and the National Nuclear Safety and Safeguards Commission, licences for the transport by land of dangerous materials and wastes are issued by this Ministry [Official Gazette of 7 April 1993].

2. Public and Semi-Public Agencies

a) National Nuclear Safety and Safeguards Commission

i) Legal Status

The National Nuclear Safety and Safeguards Commission (*Comisión Nacional de Seguridad Nuclear y Salvaguardias*) is a semi-autonomous body, under the authority of the Ministry of Energy [1984 Act, Section 50].

ii) Responsibilities

The duties and responsibilities of the Commission are defined in the 1984 Act on Nuclear Activities [Section 50] are of very wide scope. In particular, it must:

- ensure the proper application of regulations and safeguards for nuclear and radiation safety and for physical protection in nuclear and radioactive installations to ensure public safety;

- ensure, with the other competent bodies, the proper implementation of international agreements in the field of nuclear and radiological safety, physical protection and safeguards to which Mexico is a Party;

- revise, evaluate and approve the bases for siting, design, construction, operation and decommissioning of nuclear and radioactive installations and propose the relevant regulations; this also applies with regard to the manufacture, handling, storage, reprocessing and transport of nuclear materials and fuels, radioactive materials and equipment containing such materials; and the processing, conditioning, disposal and storage of radioactive waste;

- provide opinions on the siting, construction, operation, etc. of nuclear installations prior to the delivery of a licence by the Ministry of Energy;

- deliver, renew, amend and suspend licences for radioactive installations;

- prior to the operation of nuclear or radioactive installations, approve the emergency plans; recommend and advise observance of nuclear and radiological safety measures and safeguards in emergency situations in such installations and close them down where required;

- establish and maintain the national system for registration and control of nuclear materials and fuels;

- give its opinion prior to the licensing of imports and exports of radioactive and nuclear materials, nuclear fuels and ionising radiation-emitting equipment;

- propose, revise and evaluate the regulations for the licensing of facilities for the treatment of radioactive ores;

- propose regulations governing nuclear and radiological safety, physical protection and safeguards in nuclear and radioactive installations and the safety and safeguards criteria for import and export of nuclear materials and fuels; and

- order and carry out inspections and verifications to ensure that the relevant regulations on nuclear and radiological safety, physical protection and safeguards are complied with.

iii) Structure

The Commission is headed by a director-general appointed by the Minister of Energy. It has the necessary personnel to carry out its tasks.

The Commission also has an advisory board chaired by the representative of the Ministry of Energy. The board includes representatives of the Ministries of the Interior; Foreign Affairs; National Defence; Marine; Agriculture and Hydraulic Resources; Communications and Transportation; Environment, Natural Resources and Fisheries; Health; and Labour and Social Development. With the agreement of the chairperson, representatives of other public bodies and experts in the nuclear field may also participate in the work of the advisory board.

The board, whose task is to advise the Commission, supplies the necessary technical co-operation and carry out the studies required.

iv) Financing

The Commission is financed from the budget of the Ministry of Energy.

b) National Nuclear Research Institute

The 1984 Act on Nuclear Activities also sets forth the status and duties of the National Nuclear Research Institute (*Instituto Nacional de Investigaciones Nucleares*) [Sections 41-49].

i) Legal Status

The Institute is a decentralised public body under the Federal Government and it has status as a separate legal entity.

ii) Responsibilities

The purpose of the Institute is to undertake research and development in the field of nuclear science and technology, promote the peaceful uses of nuclear energy, and disseminate the progress made, so as to include this work in the economic, social, scientific and technical development of the country.

To achieve these objectives, the Institute has been assigned the following tasks:

- to carry out and promote activities conducive to scientific and technological development in the nuclear field and to encourage the transfer of scientific knowledge in that area;
- to provide assistance to public and private bodies in the design, construction and operation of nuclear and radioactive installations and, as necessary, in relation to contracts for those services;
- to promote national technological development in the nuclear industry;
- to initiate research and development activities in nuclear science and technology in research institutes and universities;
- promote the application of radioisotopes in different fields;

- organise training programmes on the application of nuclear technology;

- with the agreement of the Ministry of Energy, make arrangements with foreign institutes and international organisations to undertake joint projects and information exchange in the field of nuclear science and technology;

- give its opinion on research and development agreements on nuclear science and technology concluded by the Ministry of Energy and generally advise the Federal Government in its field of competence.

iii) Structure

The Institute is managed by a board of directors, a director-general and a supervisory committee.

The board of directors is chaired by an under-secretary appointed by the Ministry of Energy, and is made up of the Directors-General of the Federal Electricity Commission, the National Science and Technology Council, the National Polytechnic Institute, and the Rectors of the National University of Mexico and the National Metropolitan University, as well as two persons appointed by the Ministry of Energy. The board members each have an alternate member.

The board, which is the directing body of the Institute, has many responsibilities, in particular:

- approving the international regulations of the Institute;

- establishing the general framework for carrying out the Institute's tasks;

- revising and approving the programmes of work;

- approving the budgets required to implement such programmes, checking the proper use of the economic resources and approving the financial accounts;

- evaluating the administrative operations and the results obtained, taking into account its own aims and the national objectives.

The Director-General of the Institute is appointed by the Ministry of Energy and:

- represents the Institute in all matters;

- implements the board of directors' decisions:

- proposes the measures required for operation of the Institute to the board;

- establishes and proposes the programmes of work to the board, and submits an annual activity report.

The supervisory committee is made up of one representative of the Institute, one representative of the Ministry of Energy and one representative of the Treasury. The latter co-ordinates the committee's activities and is responsible for reporting to the board of directors on the results of the committee's work.

The committee supervises the implementation of the approved programmes and budgets and the measures adopted for efficient management and handling of resources. For this purpose, it may undertake the inspections and audits it deems necessary.

iv) Financing

The Institute is financed by donations, Federal Government grants, remuneration for services rendered and other grants. It also owns property.

NETHERLANDS

I. GENERAL REGULATORY REGIME

1. Introduction

In the Netherlands, the basic legislation governing nuclear activities is set out in the 1963 Nuclear Energy Act [Stb.* 1963, No. 82], as amended (hereinafter referred to as "the Act"). This Act lays down the basic rules in the nuclear field, makes provisions for radiation protection, designates the different competent authorities and outlines their responsibilities. Responsibility for nuclear activities is not centralised, but is shared by several ministers who consult each other and issue regulations jointly, as required, in accordance with their area of competence. Detailed regulations to implement the Act are found in a series of decrees, the majority of which are listed below:

- Nuclear Energy Act (Definitions) Decree of 29 August 1969 [Stb. 1969, No. 358], as amended by a Decree of 20 October 1986 [Stb. 1986, No. 533];

- Nuclear Installations, Fissionable Materials and Ores Decree of 4 September 1969 [Stb. 1969, No. 403], amended by various decrees;

- Fissionable Materials, Ores and Radioactive Substances (Transport) Decree of 4 September 1969 [Stb. 1969, No. 405], as amended by various decrees;

- Fissionable Materials and Ores (Registration) Decree of 8 October 1969 [Stb. 1969, No. 471];

- Nuclear Energy Act (Registration of Radioactive Materials and Food and Drug Inspectorate Charges) Decree of 16 October 1969 [Stb. 1969, No. 472], amended by a Decree of 14 January 1993 [Stb. 1993, No. 42];

- Nuclear Energy Act, National Defence (Exemption) Decree of 20 October 1969 [Stb. 1969, No. 476], as amended by various decrees;

- Radioactive Materials Register (Plan) Decree of 5 December 1969 [Stb. 1969, No. 240];

- Nuclear Energy Act (Secrecy) Decree of 17 June 1971 [Stb. 1971, No. 420];

- Nuclear Energy Act (Contributions) Decree of 25 June 1981 [Stb. 1981, No. 455], as amended by a Decree of 20 December 1988 [Stb. 1988, No. 607];

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* Stb. = Bulletin of Acts, Orders and Decrees

- Radiation Protection Decree of 10 September 1986 [Stb. 1986, No. 465], as amended by various decrees.

The 1986 Radiation Protection Decree replaces the 1969 Radioactive Materials Decree [Stb. 1969, No. 404] and the Nuclear Energy Act (Devices) Decree of 10 September 1969 [Stb. 1969, No. 406]. It regulates the protection of the public and workers against the hazards of ionising radiation from radioactive materials and apparatus in accordance with the relevant Euratom Directive, establishes a licensing system for the use of radioactive materials and ionising radiation-emitting devices, and prescribes general rules for their use.

Together with the Radiation Protection Decree, the Nuclear Installations, Fissionable Materials and Ores Decree governs, in general, activities involving radioactive materials, ionising radiation-generating equipment and fissionable materials, while other decrees cover specific aspects, such as definitions, registration procedures, military exemptions, etc. The Transport Decree sets forth the regulations applicable to all forms of transport of radioactive materials and equipment. Finally, third party liability in the nuclear field is regulated by the 1979 Nuclear Incidents (Third Party Liability) Act, as amended in 1991.

Since the Nuclear Energy Act draws a distinction between fissile materials and ores on the one hand, and radioactive substances on the other, this distinction has been maintained in legislation based on the Act.

2. Mining Regime

Under the 1810 Mining Act, prospecting for ores is unrestricted, and the working of ores is authorised by government concession. The 1903 Mining Act provides that the government may reserve title and operate the mine itself.

Uranium and thorium ores are not mined at present in the Netherlands; however, the Nuclear Energy Act specifies that any person who establishes the presence of such ores in the ground must inform the Minister for Economic Affairs immediately. In addition, the Nuclear Installations, Fissionable Materials and Ores Decree lays down licensing requirements in connection with ores. Finally, the 1981 Decree amending the Nuclear Energy Act (Radioactive Materials) Decree [Stb. 1969, No. 404] sets up, in addition to other rules, a special procedure concerning the use of radioactive materials in mining operations (see under Section 6 “Radiation Protection” *infra*).

3. Fissionable Materials, Ores, Radioactive Materials and Equipment

As already mentioned, the 1963 Nuclear Energy Act as amended, together with the 1986 Radiation Protection Decree and the 1969 Nuclear Installations, Fissionable Materials and Ores Decree as amended (the latter being referred to hereinafter as “the Decree”) regulate dealings with radioactive materials and equipment and fissionable materials, while other decrees cover certain specific aspects such as, for example, devices, definitions, registration procedures, etc.

a) Fissionable materials and ores

Section 1 of the Nuclear Energy Act and the 1969 Definitions Decree define “fissionable materials” as materials, except ores containing 0.1% plutonium, 3% thorium or 0.1% uranium by

weight. “Ores” are: (a) ores, except monazite, containing at least 0.1% uranium or 3% thorium by weight; and (b) monazite containing at least 0.1% uranium or 10% thorium by weight.

The Act prohibits the possession or the transfer of fissionable materials or ores without a licence granted jointly by the Minister for Economic Affairs, the Minister for Social Affairs and Employment, and the Minister for Housing, Spatial Planning and the Environment [Section 15 of the Act and Section 3 of the Decree].

The procedure for applying for a licence and the information required of the applicant are laid down in Section 3 of the Nuclear Installations, Fissionable Materials and Ores Decree. Applications must be made in writing to the three appropriate ministers, and must include in particular a factual description of the uses to which the fissionable materials or ores will be put, the information required under the Decree, and an indication of the period for which the licence is sought. The information required includes a statement of the quantities, their chemical and physical properties, the form, content and degree of enrichment of materials and, for irradiated fissionable materials, their activity. Detailed conditions may be attached to the licence concerning, in particular, the protection of persons and property, national security, storage and surveillance of fissile materials and ores and supplies [Sections 15 and 19 of the Act].

The particulars of all fissionable materials and ores must be entered in a register kept by the Ministry of Economic Affairs. Any person who possesses, transfers or transports any fissionable materials or ores is required to keep a record and to give notice thereof for entry in the register [Sections 13 and 14 of the Act].

By way of exception, Sections 41 and 42 of the Nuclear Installations, Fissionable Materials and Ores Decree provide that no licence is required to hold non-irradiated fissionable materials which contain only natural or depleted uranium or thorium in quantities not exceeding 100 grams of each of these elements, and no plutonium. The Decree also exempts ores if packed in watertight metal containers or, if not packed in such a manner, provided their specific activity does not exceed 0.37 kilobecquerels per gram. Pursuant to the National Defence (Exemption) Decree, a licence is not required for fissionable materials, ores, establishments and equipment being used by or intended for the use of the Netherlands Armed Forces or the forces of an ally.

Under Section 43 of the Decree, the transfer of exempted materials does not require a licence, nor does the transfer of fissionable materials or ores to a person authorised to receive them.

b) Radioactive materials and equipment

Pursuant to Section 1 of the Nuclear Energy Act, “radioactive materials” are defined as any matter which emits ionising radiation as well as materials and objects containing such matter, with the exception of fissionable materials and ores.

In accordance with Section 29 of the Act and pursuant to the Radiation Protection Decree, the preparation, possession, use and disposal of radioactive materials are prohibited without a licence granted by the Minister for Social Affairs and Employment, the Minister for Health, Welfare and Sports, and the Minister for Housing, Spatial Planning and the Environment in consultation with any other ministers concerned, for example, the Minister for Agriculture and Fisheries and the Minister for Transport.

Applications for licences must include, in particular, a list of the radioactive materials indicating their activity, their chemical and physical state and their form, together with the operations for which the licence is sought, the total activity and the maximum quantity of radioactive materials likely to be present, as well as the protective measures to be taken [Sections 10 and 11 of the Radiation Protection Decree].

Since the implementation of the risk management concept in the Radiation Protection Decree [Stb. 1966, No. 44], installations in which radioactive materials are treated or ionising radiation-emitting apparatus is used, play an essential role. The installation is considered as a radiation source and the operators must obtain a licence in advance.

The risks which the installation could incur must be clearly evaluated [Sections 10 and 74(a) of the Radiation Protection Decree], new limits are introduced [Section 37(a) and (b)] and the responsible minister is given wider discretion to accept or reject applications for licences [Section 16(a)].

Under Section 28 of the Act, the detailed particulars of all radioactive materials which have been notified in accordance with its provisions must be entered in a register. Any person who prepares, possesses, uses or transfers radioactive materials is required to keep a record thereof and to give notice for the purpose of registration in the aforementioned registers. The implementation of Section 28 of the Act is governed by Sections 68 to 74(a) of the Radiation Protection Decree.

Ionising radiation-emitting equipment is also regulated by the Radiation Protection Decree, which applies to X-ray equipment, particle accelerators, etc. [Section 9]. The use of this type of equipment requires a licence from the Minister for Social Services and Employment, the Minister for Housing, Spatial Planning and the Environment, and the Minister for Health, Welfare and Sports [Sections 10-12]. The application must include, in particular, a description of the equipment, its purpose and the protective measures which will be taken [Section 11]. The implementation of the risk management concept in the Decree also applies to such equipment.

The Radiation Protection Decree provides for exemptions from licensing and registration in exceptional cases, on condition that radiation protection measures are observed. In addition, the Decree contains a number of specific exemptions, including that for radioluminous timepieces in compliance with the radiation protection norms adopted by the OECD Council [Section 54].

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

In the Netherlands, the construction and operation of nuclear installations are governed by the Nuclear Energy Act, whose basic provisions are further elaborated in the Nuclear Installations, Fissionable Materials and Ores Decree (the Installations Decree). In 1979 and 1993, these provisions were amended by the Environmental Protection (General Requirements) Act [Stb. 1979, No. 442 and Stb. 1992, No. 551].

In 1994, the General Administrative Law Act (hereinafter referred to as the “GALA”) came into force. In this Act all procedural aspects, including appeal, are laid down.

Under the Nuclear Energy Act, a licence is required to construct, commission, operate or alter any establishment where nuclear energy may be released. Such establishments include:

- land-based reactors;
- establishments where uranium or thorium are extracted from ores;
- establishments where natural uranium is enriched in the isotope-235 or where fissionable materials are separated in any manner;
- establishments where uranium or plutonium are processed into nuclear fuel elements or where uranium and thorium blankets for converter or breeder elements are manufactured;
- reprocessing plants;
- establishments where fissionable materials for non-nuclear purposes are treated or processed;
- establishments where research is carried out with fissionable materials;
- establishments where fissionable materials are stored, whether especially designed for the purpose of storage or whether used for temporary storage.

The ministers responsible for licensing nuclear installations are the Minister for Economic Affairs, the Minister for Housing, Spatial Planning and the Environment and the Minister for Social Affairs and Employment. There is no one government department or other body responsible for nuclear energy. In 1964, an Interministerial Nuclear Energy Committee was established to prepare decisions involving more than one ministry.

In accordance with Chapter II of the Installations Decree, the licensing procedure involves four principal stages:

- filing of the application;
- consultation of the parties concerned;
- granting of the construction licence;
- granting of the operating licence.

The amendments introduced by the 1979 Environmental Protection Act cover the detailed aspects of licensing procedures, in particular, provisions for greater access of the public to the relevant documentation, as well as greater public participation in the granting of licences.

Since 1994, the licensing procedure has been largely regulated by the GALA. It prescribes the procedure for the admissibility of an application for a licence and the time limit for a reply by the authorities. Within twelve weeks of the receipt of the application a draft decision must be made public [Section 3(1)(g) GALA]. Within the following four-week period anyone may raise objections [Section 3(22) GALA]. The minister concerned must, within six months of the receipt of the application, make a final decision [Section 3(28) GALA]. At the expiration of a six-week appeal period, the ruling will become final.

Several technical bodies are consulted during the various stages of the licensing procedure. After consultation with all interested parties, *i.e.* technical bodies and public and local authorities, the three responsible ministers issue a construction licence, subject to a number of conditions intended to ensure the protection of persons, animals and property, state security, the storage and supervision of fissionable materials and ores, energy supplies, the payment of compensation due to persons having suffered personal injury or property damage and compliance with international obligations. After construction has begun, an application for an operating licence is submitted to the responsible ministers. At this stage, the Reactor Safety Committee, on the basis of further detailed discussions with the applicant on design questions, issues a final statement on the safety of the installation and, if necessary, makes suggestions for conditions to be attached to the licence. Simultaneously, the licensing authorities consult with the various public bodies and ministries involved.

Pursuant to Section 58 of the Nuclear Energy Act, the ministers concerned are required to appoint officials responsible for the enforcement of the provisions of the Act and the decrees issued thereunder.

Accordingly, regular inspections, usually twenty times a year, are carried out by three different bodies: the Nuclear Safety Department and the Pressure Vessel Inspectorate (both under the aegis of the Minister for Social Affairs and Employment) and the Inspectorate for Environmental Control (under the aegis of the Minister for Housing, Spatial Planning and the Environment). Special inspections take place following any incident and in connection with proposed changes to the installation.

Concerning nuclear safety, it is relevant to note that the Netherlands accepted the 1994 Convention on Nuclear Safety on 16 October 1996.

b) Protection of the environment against radiation effects

The Environmental Protection (General Requirements) Act of 1979 is applicable to the licensing of any establishment where nuclear energy may be produced. Licences for the possession, use, transport and disposal of fissionable materials and ores, and radioactive material and equipment, as well as for the construction and operation of nuclear installations are granted by the Minister for Housing, Spatial Planning and the Environment, among others. Furthermore, inspections of nuclear installations are conducted by the Inspectorate for Environmental Control, under the Minister for Housing, Spatial Planning and the Environment. Dutch legislation requires notification of all radioactive releases into the environment and such releases are subject to regulatory limits. Under the co-ordinated monitoring programme involving several government ministries and services, radioactivity levels are monitored in relation to air, deposition, surface water, milk, grass and fish.

c) Emergency response

The Ministers for Health, Welfare and Sports, for Housing, Spatial Planning and the Environment and for Social Affairs and Employment are empowered to take emergency measures where persons or animals have been exposed to ionising radiation or contamination to such an extent that appreciable danger is feared. Furthermore, if the Minister for Agriculture and Fisheries considers that the soil, water or air is contaminated, he may take any measures he deems necessary. The same applies, if, in the opinion of the Minister for Transport, Water Control and Public Works, surface water is contaminated [Sections 40, 41 and 42 of the Nuclear Energy Act].

At the international level, the Netherlands is party to the 1986 Convention on Early Notification of a Nuclear Accident and the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, both of which it accepted on 23 September 1991.

5. Trade in Nuclear Materials and Equipment

Dutch legislation on nuclear trade is comprised partly of specifically nuclear-related texts and partly of general regulations concerning foreign trade: the Nuclear Energy Act, as amended, with its implementing decrees and the Act of 5 July 1962 on Imports and Exports [Stb. 1962, No. 295], amended on 24 March 1976 [Stb. 1976, No. 215], as implemented by the Export of Industrial Products Decree of 26 April 1963 [Stb. 1963, No. 128].

Pursuant to Section 15(a) of the Nuclear Energy Act, it is prohibited to transport, possess, import or export into or out of the Netherlands, or cause to be so imported or exported fissile materials or ores without a licence. However, under the 1969 Transport Decree as amended by the Decree of 4 June 1987, there are exemptions for the imports or exports carried out in performance of a transport contract, as well as in the case of non-irradiated fissile materials, if they consist entirely of natural or depleted uranium or natural thorium and contain no plutonium, and if the quantity brought into the Netherlands on any particular occasion contains not more than 100 grams of thorium or 100 grams of uranium; fissile materials that are held, or have been or may be imported, under a licence required by the national legislation of Belgium or Luxembourg, or in relation to which permission has been given to transit those countries, provided that the conditions attached to the licence are observed [Section 23 of the Transport Decree]; and special fissile materials not intended for Belgium or Luxembourg, which transit Netherlands territory, provided that the materials are not unloaded on such territory from the means of transport.

With a view to the protection of persons, animals, plants and property, the Transport Decree provides that a licence to import or to cause to be imported fissile materials into Netherlands territory may only be granted subject to certain conditions [Section 25]. Under Section 26, the responsible ministers (see under Section 4 “Nuclear Installations” *supra*) may grant exemptions, again subject to certain conditions or restrictions.

As noted above, nuclear trade in the Netherlands is also governed by the 1962 Act on Imports and Exports and the 1963 Decree on the Export of Industrial Products. The Decree determines the materials, articles and equipment subject to licensing and inspection, and specifies that the competent authority in this respect is the Minister for Economic Affairs.

Section 2 of the 1962 Act provides for the adoption, in the interests of the national economy and national security and in implementation of the international agreements concluded by the Netherlands, of regulations governing the import and export of specific articles or materials. The Act also provides for the adoption of regulations concerning the import and export of articles from or to certain countries.

Decrees relating to exports and imports, as well as any amendment or repeal thereof, are promulgated by the Minister for Economic Affairs in consultation with the ministers concerned (in particular, the Minister for Foreign Affairs), depending on the nature of the products in question. The ministers in turn consult other interested bodies [1962 Act, Sections 2(3) and (4)]. However, the consultation process is not required in cases involving national security or an international convention, if the ministers believe that consultation would be against the public interest [Section 2(5)]. Under Section 8, decrees involving imports and exports must be published in the Official Gazette.

The Decree on the Export of Industrial Products has been amended on numerous occasions due, in particular, to technological developments in the field of strategic materials. Section 2 of the Decree prohibits the export of articles and materials listed in Appendix A of the Decree without a licence from the Minister for Economic Affairs. Pursuant to Section 7, licences are subject to certain conditions, including the presentation of the licence to the responsible customs official at the time of export. Similarly, Sections 3 and 6 prohibit the export of items listed in Appendix B without a form signed on or on behalf of the exporter concerned, established in compliance with the conditions laid down by the minister, provided that the form is presented at the time of export to the customs official responsible for collecting customs duty.

International commitments made by the Netherlands concerning nuclear trade include participation in the work of the Zangger Committee and membership of the Nuclear Suppliers' Group (London Club). The Netherlands is party to the Treaty on Non-Proliferation of Nuclear Weapons. In relation to exports to non-nuclear weapons states, the Netherlands has undertaken to act in compliance with the principles adopted by the London Club applicable to the export of nuclear materials, equipment and technology [See communications to the Parliament of 30 March 1976, *Kamerstukken* II, 1975/76, 13865, No. 1; and 11 January 1978, Kamerstukken II, 1977/78, 13865, No. 2].

Finally, the Appendix to the Eighth Decree amending the Export Decree [Decree of 12 June 1981 relating to the export of strategic materials [Stb. 1981, No. 351] contains the Dutch version of the Trigger List of International Atomic Energy Agency (IAEA) Documents INFCIRC/209 and INFCIRC/254, completed by certain sections on ultracentrifugation technology. This list is revised regularly. Attached to the Decree is a note explaining the reasons for the amendment and also stipulating that it is prohibited to export the listed materials without permission from the Minister for Economic Affairs.

6. Radiation Protection

The Nuclear Energy Act makes provision for protection against the hazards of ionising radiation. These general principles are elaborated in the 1986 Radiation Protection Decree, as amended in 1988, 1991, 1993 and 1996, which implements at national level Council Directive 80/836/Euratom, as amended by Council Directive 84/466/Euratom, setting forth the Community's basic standards for radiation protection. The 1986 Decree replaces the 1969 Radioactive Materials Decree and the 1969 Apparatus Decree, thus regulating the protection of workers and the public against the hazards of ionising radiation from radioactive materials and equipment, while also establishing a licensing system and general rules for the use of radioactive materials and ionising radiation-emitting apparatus.

a) Protection of workers

The legislation provides that the number of persons exposed to radiation must be kept as low as possible and that appropriate measures must be taken to prevent external contamination. Furthermore, measures must be taken to prevent in so far as possible any internal contamination of persons by radioactive substances. Similarly, no harmful concentration of radioactive substances in the air is allowed in workplaces. The level of radiation, and the concentration of radioactive substances in the air, must be measured periodically [Section 31].

Persons may not carry out work involving ionising radiation unless they have passed a medical examination and they must be given a similar examination every time the physician deems it necessary

[Section 23(a)]. In addition, there exists a system of personal (dosimetric) monitoring [Section 25]. The total individual dose limit for workers is 50 mSv for whole-body exposure.

Finally, foreign workers are protected by the implementation of Council Directive 90/641/Euratom; those who work abroad shall have a radiological passport [Decree of 16 July 1994].

b) Protection of the public

The Nuclear Installations, Fissionable Materials and Ores Decree provides for a number of conditions attached to any licence granted under the Nuclear Energy Act with a view to the protection of persons, animals, plants and goods and, in particular, the following:

- irradiation or contamination of persons, animals, plants and goods shall be prevented to the maximum extent possible;

- in cases where irradiation or contamination are unavoidable, they shall be restricted to the minimum possible;

- in cases where irradiation or contamination are unavoidable, the number of persons exposed to ionising radiation shall be restricted to the minimum possible, taking into account the need to avoid an amount of radiation or contamination per person exceeding the maximum permissible level.

The total individual dose limit for members of the public is fixed at 1 mSv per year (a source limit of 0.1 mSv and a generic dose constraint for optimisation of protection of 0.04 mSv should be applied to each source category).

The Minister for Housing, Spatial Planning and the Environment has general responsibility for protection of the public against ionising radiation. If, in his opinion, the soil, water or air has been or is likely to be contaminated by radioactive materials to such a degree that appreciable danger is to be feared for public health, he and the Minister for Social Affairs and Employment may order the person who operates the establishment involved to close it down.

In addition, the mayor of a municipality where this establishment is situated may request the minister to take such action. Any order by the Minister to this effect is issued with the agreement of any other ministers involved.

The ministers concerned appoint officials charged with enforcing the Nuclear Energy Act in general and with measuring radiation doses. Similar duties are given to officials of the inspection services appointed by the mayors and municipal councils.

Pursuant to the Radioactive Materials Decree, the District Public Health Inspector may impose certain additional conditions on the use or disposal of radioactive substances.

In addition, the Radioactive Materials Decree (now the Radiation Protection Decree) was amended in 1973 to insert special provisions concerning the use of radioactive luminous paint on timepieces. This amendment, which became Part 4(a) and an Annex to the Decree, incorporates in the Netherlands legislation the OECD Radiation Protection Standards for Radioluminous Timepieces of 19 July 1966.

Following the adoption of the new European Union basic safety standards the Radiation Protection Decree will be modified accordingly.

c) Protection of individuals undergoing medical exposure

All uses of ionising radiation must ensure a wide safety margin. The protection of the individual undergoing medical exposure mainly aims at optimum diagnostic efficacy at reasonable dose to the patient and to reduce the number of inadequate exposures. The revised Directive 97/43/Euratom on Medical Exposures reaffirms those objectives, which are pursued by 4 types of requirements relating to: duties, responsibilities and qualifications of the medical staff; used equipment; procedural requirements; and special practices.

The Medical Exposures Directive is to be implemented in domestic legislation not later than 13 May 2000.

7. Radioactive Waste Management

In the Netherlands, the management of radioactive waste is governed in general by the Nuclear Energy Act as well as by the Radiation Protection Decree and the Nuclear Installations, Fissionable Materials and Ores Decree. Under the Act, a licence is required for the disposal of radioactive waste, with conditions imposed as to the method and location of disposal. In addition, the Act establishes a registration system to record the disposal of radioactive and fissile materials.

In 1984, the Netherlands Parliament accepted the government's waste management strategy as set forth in the Radioactive Waste Policy Paper. This Paper provided that:

- for the next 50-100 years all radioactive waste would have to be stored in a single above-ground storage facility;
- a special waste management organisation would be given complete and exclusive responsibility for all aspects of radioactive waste management in the Netherlands;
- research would be focused on deep geological disposal either within the Netherlands or in an internationally operated facility.

In 1982, the Netherlands Government created the Central Organisation for Radioactive Waste (*Centrale Organisatie Voor Radioactief Afval* – COVRA). At present, COVRA operates the transportation system for all low and intermediate-level waste; controls a number of waste treatment systems; and operates a storage facility for conditioned and packaged low and intermediate-level radioactive waste.

The Nuclear Energy Act establishes a system of registration to record the disposal of radioactive and fissionable materials [Sections 13 and 14]. A licence is also required for such disposal and its requirements may relate to the location and method of disposal [Section 32(2)].

No licence under the Nuclear Energy Act is required for the disposal of fissionable materials which are exempted from licensing because of their small quantities if, on discharge into the air or water, the concentrations do not exceed certain prescribed maximum limits [Section 41]. Similarly, no

licence under the Nuclear Energy Act is required for the disposal of radioactive materials if their activity is below certain prescribed maximum levels.

If radioactive materials are disposed of by being discharged into air or water, certain limits of radiation are imposed.

The disposal of radioactive waste by handing it to an approved waste collection service does not require a licence.

The Netherlands is party to the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, which it ratified on 2 December 1977.

8. Non-Proliferation and Physical Protection

The Nuclear Energy Act provides for national control and security measures, in the interests of the state, for any activity requiring licensing of the use of fissionable materials and ores. In particular, detailed regulations control the disclosure of information on nuclear activities. Conditions may be attached to licences with a view to ensuring state security or compliance with the Netherlands' international obligations [Section 19]. However, the implementing decrees contain no such requirement relating to fissile materials and ores, nor any provisions about conditions in licences relating to Section 19.

Pursuant to Section 68 of the Act, implementing decrees may also require that information, equipment or materials used to produce nuclear energy or relating to the storage, manufacture or processing of fissionable materials be treated as an official secret, if such information, equipment and materials have been obtained subject to an obligation of secrecy either directly from the government or with the approval of the competent authorities, or if the ministers concerned should so decide.

Anyone entrusted with the duty of applying the Nuclear Energy Act or with giving effect to international agreements and resolutions in the field of nuclear energy or ionising radiation adopted by international organisations is required to keep secret any information thus acquired.

Pursuant to Section 68 of the Act, the Secrecy Decree of 1971 lists the activities for which an obligation to maintain secrecy may be imposed. The scope of application of the Decree, designed to protect industrial secrets and to prohibit the export of sensitive information, was defined and broadened by a Ministerial Directive of 24 September 1971 [Stb. 1971, No. 107].

At the international level, the Netherlands ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 2 May 1975 and the 1996 Comprehensive Nuclear Test Ban Treaty on 23 March 1999. They also accepted the 1979 Convention on the Physical Protection of Nuclear Material on 6 September 1991. Requirements concerning physical protection are laid down during the licensing procedure for nuclear installations and are included in the 1987 amendments to the Transport Decree (see below).

9. Transport

The rules governing the transport of radioactive and fissionable materials in the Netherlands are contained in the Fissionable Materials, Ores and Radioactive Substances (Transport) Decree of 1969, as amended in 1983, 1987, 1988, 1993, 1997 and 1999. In addition to regulating the carriage of

radioactive materials by all modes of transport the Transport Decree also regulates activities closely associated with such carriage, for example the import and export of radioactive materials, and their storage during transport.

Under the Transport Decree, there are certain exemptions for fissile materials and ores if no licence is required pursuant to the regulations governing transport by road, rail and inland waterway, in which case it is sufficient that the packaging and approval procedures in the regulations be observed.

Given that in the Netherlands, the transport of radioactive materials implies the crossing of borders on a regular basis, particular care has been taken to ensure that the national transport regulations are in harmony with the regulations governing international transport. In fact, for all modes of transport, the international regulations have been incorporated into the national ones.

Thus, with regard to rail transport, the substance of the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) has been adopted in the national Regulations governing the Transport of Dangerous Goods by Rail (VSG). The Transport Decree provides that these Regulations are applicable to the carriage by rail of radioactive materials either directly or indirectly [Sections 7-10].

In respect of road transport, the Regulations governing the Transport of Dangerous Substances by Land (VLG), are based entirely on the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) and are applied pursuant to the Transport Decree to the transport by road in the Netherlands of radioactive materials [Sections 11 and 12].

Similarly, the national Regulations governing the Transport of Dangerous Substances by Inland Waterway (VBG) are taken from the Regulations for the Carriage of Dangerous Goods on the Rhine (ADNR). These same Regulations are applicable also to the transport of radioactive materials in the Netherlands' territorial waters [Sections 13-16].

With respect to international sea transport of dangerous goods the International Maritime Dangerous Goods Code (IMDG) is applied directly or indirectly for the Netherlands. Reference to the IMDG has been made in the Transport Decree.

With regard to air transport, the Technical Instructions for the Safe Transport of Dangerous Goods by Air of the International Civil Aviation Organisation (ICAO) are applied to the carriage of radioactive materials by air in the Netherlands.

In 1987, the Transport Decree was amended to take account of the extensive revisions of all the other international regulations since 1969, as well as the recommendations on maritime transport of radioactive materials issued by the IMO (the IMDG Code) and the rules on air transport promulgated by the ICAO. All these revisions, (except the ADNR) were based upon the 1973 Edition of the IAEA Regulations on the Safe Transport of Radioactive Materials. Further amendments concerned the implementation of physical protection requirements in compliance with the Convention on the Physical Protection of Nuclear Material. In essence, the modifications relate to licensing requirements, in particular to packaging and transport for the different levels of activity of the materials carried, certificates of approval, etc. and surveillance during transport.

In 1997, the Transport Decree was amended in order to incorporate the requirements of the European Union directives (for transport by rail: Council Directive 94/55/EC; for transport by road: Council Directive 96/49/EC). The 1999 edition of the ADR will also be applicable.

10. Nuclear Third Party Liability

The Netherlands ratified the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy on 28 December 1979, and the 1963 Brussels Convention Supplementary to the Paris Convention on 28 September 1979 [Act of 17 March 1979, Stb. 1979, No. 160]. The Act came into effect on 28 December 1979, bringing both Conventions into force on that date in the Netherlands. At the same time, the Nuclear Incidents (Third Party Liability) Act of 1979 [Stb. 1979, No. 225] laying down the regulations governing nuclear third party liability in the Netherlands also came into force on 28 December 1979, thereby repealing the Act of 27 October 1965 which contained regulations on third party liability in the field of nuclear energy.

On 1 August 1991, the Netherlands ratified the 1982 Protocols to the Paris Convention and Brussels Supplementary Convention [Stb. 1991, No. 368] and the 1988 Joint Protocol relating to the application of the Vienna Convention and the Paris Convention [Stb. 1991, No. 372]. On the same day, an Act amending the 1979 Nuclear Incidents (Third Party Liability) Act came into effect [Stb. 1991, No. 369], implementing the Paris and Brussels Protocols. Simultaneously, another Act amending the 1979 Act on Third Party Liability in implementation of the Joint Protocol was passed by Parliament [Stb. 1991, No. 373]. This Act came into effect on 27 April 1992 [Stb. 1992, No. 183].

On 1 August 1991, the Netherlands also ratified the 1971 Convention relating to Liability in the Field of Maritime Carriage of Nuclear Material [Stb. 1991, No. 371].

The 1991 version of the Third Party Liability Act incorporates the basic provisions of the Paris and Brussels Conventions and sets out additional provisions, differences or options applicable in national legislation.

Under the Netherlands legislation, the operator is not exonerated from paying compensation for damage caused by an incident due directly to a grave natural disaster [Section 3].

In relation to an incident on Netherlands territory, the consignor and carrier of the nuclear substances involved in the incident, as well as the person who was in possession of the substances at the time of the incident, shall be deemed to be the operator of a nuclear installation on Netherlands territory and shall be held jointly and severally liable for the damage, unless it be proved by them that some other person is liable under either the Paris Convention or the Joint Protocol [Section 17].

The limitations on the scope of the Paris Convention do not apply to the liability of an operator of a nuclear installation on Netherlands territory, for damage: (a) suffered on the territory of a state party to the Convention wherever the incident occurred; (b) suffered on the territory of a state not party to the Paris Convention, but party to the Joint Protocol, as the result of an incident in the territory of a state party to the Joint Protocol; or (c) wherever suffered, as the result of an accident on Netherlands territory [Section 15(1)].

In accordance with the Nuclear Incidents (Third party Liability) Act [Section 5(1) and (2)], the maximum liability of the operator under the Paris Convention has been raised to Dutch guilders (NLG) 750 million as from 1 January 1998 [Royal Decree of 14 November 1997, Stb. 1997, No. 577]. Under Section 5(3) a lower amount may be set for low-risk installations by ministerial order. For five installations, lower amounts between NLG 50 million and 100 million have been established. In so far as the funds available from the operator's financial security are insufficient to compensate for the damage, the state shall make available funds up to his maximum liability. In such cases, the minister is entitled to exercise the operator's rights of recourse [Section 10].

If, in the opinion of the Minister for Finance, an operator of a nuclear installation cannot obtain the financial security required by the Paris Convention or if such financial security is only available at an unreasonable cost, the Minister may enter into contracts on behalf of the state as insurer or provide other state guarantees up to the operator's liability limit [Section 9].

If the amount of damage caused by a nuclear incident in Netherlands territory exceeds the limit of the Brussels Convention, the government will make available supplementary funds to a maximum combined total of NLG 5 billion [Section 18(1)]. Under Section 18(4), these public funds will also be made available for damage suffered in the territory of Parties to the Brussels Convention, on condition of reciprocity.

The time limit for submission of claims resulting from personal injury is thirty years from the date of the accident; for other types of damage, this limit for submission of claims is ten years [Section 7(2)]. In both cases, the right to compensation shall be extinguished if an action is not brought within three years from the date on which the person suffering damage or his legal representative has knowledge of, or ought reasonably to have known of both the damage and the operator liable [Section 7(1)]. Claims filed within ten years of the date of the incident have priority over claims filed thereafter [Section 7(4)]. However, in so far as the state provides supplementary funds beyond the Brussels Convention limit, at least 10% of these funds will be reserved for personal injury claims filed after ten years [Section 27(2)]. If there are both personal injury claims and other claims and the total amount of those claims exceeds the NLG 5 billion limit, two-thirds of the total amount available will be reserved for personal injury claims [Section 27(1)].

If the damage caused by the nuclear incident is likely to exceed the operator's liability limit, claims must be brought before the District Court at The Hague, which has exclusive jurisdiction as the court of first instance [Section 22(1) and (2)]. A prohibition will be placed on the payment of damages and a committee will be established to settle claims under the authority of an examining judge [Section 22(2)]. The committee is entitled to appoint and consult experts [Section 23(2)]. If a claim is contested and the judge cannot reconcile the parties, he shall refer them to one or more court sessions for decision of the point at issue [Section 24(4)].

In respect of damage caused by nuclear substances for which there exists no liability under the Vienna and Paris Convention (*e.g.* the risk is more of a toxic or corrosive nature or the material is solely used for scientific, medical, agricultural, commercial, industrial or educational purposes), the person or entity which uses these materials on a professional basis, or which is the carrier of such materials, can be held liable under the national law of the Netherlands. This is set out in the Act of 30 January 1994 [Stb. 1994, No. 846] and the implementation Order of 15 December 1994 [Stb. 1994, No. 888]. This new legislation provides for strict liability for damage caused by dangerous substances (which include nuclear materials).

II. INSTITUTIONAL FRAMEWORK

In the Netherlands, responsibility for nuclear activities is not centralised. It is shared by several ministers who consult each other and issue regulations jointly, as the case may be according to their particular competence. The ministers are advised by a number of councils set up under the Nuclear Energy Act. The private sector and the universities, in co-operation with public administration, take an active part in the development of nuclear activities.

1. Regulatory and Supervisory Authorities

a) Minister for Housing, Spatial Planning and the Environment

All questions concerning the health and safety aspects of nuclear activities, including radiation protection, are within the competence of the Minister for Housing, Planning and the Environment. Together with the Minister for Economic Affairs and the Minister for Social Affairs and Employment, he is responsible for the licensing of nuclear installations and fissionable materials [Nuclear Energy Act, Section 15]. Together with the Minister for Social Affairs and Employment and the Minister for Health, Welfare and Sports, he also grants licences for radioactive materials and ionising radiation-emitting apparatus etc. [Section 29].

b) Minister for Economic Affairs

The Minister for Economic Affairs is competent for the licensing of nuclear installations and activities, together with the Minister for Housing, Spatial Planning and the Environment and the Minister for Social Affairs and Employment [Section 15].

c) Minister for Social Affairs and Employment

As mentioned, the Minister for Social Affairs and Employment is responsible jointly with the above Ministers for licensing matters. In particular, he is competent for questions of safety at work [Sections 15 and 29].

d) Minister for Health, Welfare and Sports

The Minister for Health, Welfare and Sports is responsible jointly with the Minister for Housing, Spatial Planning and the Environment and the Minister for Social Affairs and Employment for the licensing of radioactive materials and ionising radiation-emitting apparatus. [Section 29]. He is, in particular, responsible for the protection of individuals undergoing medical exposure.

e) Minister for Finance

The Minister for Finance is the competent authority in regard to nuclear third party liability and compensation of nuclear damage in the Netherlands.

f) Minister for Foreign Affairs

The Minister for Foreign Affairs is responsible for co-ordinating international co-operation in the nuclear field.

g) Other Ministers

The Ministers for Agriculture, Nature Conservation and Fisheries; Education, Culture and Science; Justice; and Transport and Public Works are also consulted concerning nuclear activities which come within their particular sphere of competence.

h) Interministerial Commission for Nuclear Energy

Established by Decree of the Ministers for Economic Affairs; Education, Culture and Science; Social Affairs and Employment; and Housing, Spatial Planning and the Environment, the Interministerial Commission is responsible for preparing and co-ordinating decisions in which many ministries are involved. It was set up for purposes of consultation and communication of information between ministries.

The Commission consists of representatives of the four Ministries referred to as well as all the other ministries concerned.

2. Advisory Bodies

A number of consultative councils advise or make recommendations to the ministers responsible for implementing nuclear energy policy.

a) Reactor Safety Council

The Reactor Safety Council was created pursuant to the Nuclear Energy Act as a body responsible for advising ministers on technical and or organisational matters relating to the safety of reactors [Nuclear Energy Act, Section 3].

The task of the Reactor Safety Council is to advise and make recommendations to the Minister for Social Affairs and Employment and the Minister for Housing, Spatial Planning and Environment, as well as to Parliament.

The Council consists of a maximum of twelve members appointed by the Minister for Social Affairs and Employment in agreement with the Minister for Housing, Spatial Planning and Environment.

The above Ministers may also appoint civil servants as advisors to the Council [Section 9].

b) Health Council of the Netherlands

The Health Council of the Netherlands, which was set up in 1919, informs the ministers of current scientific developments in the field of public health, and is called upon to give its advice as and where necessary.

3. Public and Semi-Public Agencies

a) Nuclear Research and Consultancy Group (NRG)

The Nuclear Research and Consultancy Group (NRG) was established in 1998 following the merger of business activities in the nuclear field of the Energy Research Centre of the Netherlands (*Energieonderzoek Centrum Nederland* – ECN) and the Research and Testing in Electrotechnical Materials Company (*N.V.tot Keuring van Electrotechnische Materialen* – KEMA).

i) Legal status

NRG is a joint venture whose capital is owned by ECN at 70% and by the KEMA at 30%.

ii) Responsibilities

The NRG undertakes, sponsors and co-ordinates research and development in the energy supply field, and its activities cover the technical, economic and social aspects of various sources of energy. The NRG offers a wide range of services not only to energy utilities, government organisations and various branches of industry, but also to financial services and the medical sector, being Europe's largest producer of radioisotopes.

In addition, the NRG operates under contract with the European Community the High Flux Reactor (HFR) which has a thermal power of 45 MW. The HFR forms part of the Petten Establishment of the European Community Joint Research Centre.

iii) Structure

NRG is administered by a board of partners (*Vennoten, directie ECN and the KEMA*), a board of management (*Directie*) and directors.

b) Research and Testing in Electrotechnical Materials Company (KEMA)

i) Legal status

The KEMA (*N.V. tot Keuring van Electrotechnische Materialen*) is a shareholding company. Its shares are held by city and provincial administrations and electric utilities. It has legal personality and reports to its shareholders.

ii) Responsibilities

The KEMA is a service agency which carries out tests, research and development for electric utilities and provides advisory services to the government, also in the nuclear field. In particular, it makes investigations in the economic use of nuclear energy in electricity-generating plants.

iii) Structure

The KEMA is administered by a board of directors appointed by its shareholders. The board is made up of eleven members nominated for a maximum of four years. The chairperson is elected from among its members.

The Company is made up of the five following Divisions:

- the Research and Development Division which is responsible for R&D work aimed at improving the quality of all aspects concerned with the generation, transport, distribution and application of electrical energy;

- the activities of the Mechanical and Chemical Testing Division concern quality control and advisory services. They cover installations for electricity generation – conventional as well as nuclear – the transport and the distribution of electrical energy, from the building stage to the commissioning stage and actual operation;

- the Engineering and Consulting Division carries out assignments in the fields of electrical, mechanical, civil and constructional engineering and control and automation. The activities include preparatory studies, the design and execution of complete projects for electricity supply as well as specialised advice for new constructions, improvement of existing plants, application of new techniques and energy saving;

- in particular, the Reactor Physics Division provides advice and assistance in the commissioning and operation of nuclear power plants;

- finally, the General Affairs Division comprises the departments providing services as part of the general administration of the KEMA.

iv) Financing

The KEMA is financed by income from services supplied to ministries and utilities.

c) Foundation for Fundamental Research on Matter (FOM)

i) Legal status

The FOM (*Stichting voor Fundamenteel Onderzoek der Materie*) is a foundation under the supervisory authority of the Minister for Education, Culture and Science and the Minister for Economic Affairs.

ii) Responsibilities

The FOM is active in the following areas:

- physics, including nuclear physics, plasma physics and high energy physics;
- fusion technology; isotope and ionising radiation applications.

The research sections of the FOM include five institutes and approximately fifty university groups.

iii) Structure

The FOM is administered by a board of governors and run by a director.

iv) Financing

The FOM is financed by government appropriations.

d) Central Organisation for Radioactive Waste (COVRA)

The Central Organisation for Radioactive Waste (*Centrale Organisatie Voor Radioactief Afval* – COVRA) was created by the Netherlands Government in 1982 to assume responsibility for all aspects of the management of radioactive waste in the Netherlands. By Decree of 31 August 1987 [Stb. No. 176] COVRA was approved as collector of nuclear waste, whether spent fuel or ore residues.

i) Legal Status

COVRA is a non-profit-making company operating under Dutch private law. Its shareholders are the two nuclear power stations GKN and PZEM, the Netherlands Energy Research Foundation (ECN) and the state. The role and the influence of the state and the other shareholders have been expressly set out in a separate agreement between the shareholders. As a private company, COVRA must comply with all regulatory requirements, laws and licensing procedures to be allowed to operate.

ii) Responsibilities

In brief, COVRA's statutory task is to ensure the long-term management of all radioactive waste, including collection and transportation, treatment and conditioning, temporary and/or permanent storage and disposal, including the necessary research activities in line with government policy.

The main responsibilities of COVRA are:

- the development of an appropriate waste management system;
- transportation of waste;
- waste treatment, conditioning and storage;
- interim storage, design and construction of new installations and facilities for treatment and storage of all kinds of waste on a new site;
- maintaining adequate quality assurance for all waste management;
- the preparation, construction, operation and closure of a disposal site;
- the development of appropriate short-term and long-term financial management for the management of all radioactive waste;
- informing the public about the radioactive waste for which it is responsible.

At present, COVRA operates the transportation system for all low and intermediate level radioactive waste. COVRA further manages a number of waste treatment and conditioning installations for low and intermediate level radioactive waste; including a super compactor, a grouting installation and incinerators at the Sloe site in Borsele. In addition, COVRA operates an interim storage facility for conditioned or packaged low and intermediate-level radioactive waste at the same site.

The spent fuel elements from the nuclear power stations which have been sent to France or to the United Kingdom for reprocessing are due to be returned as vitrified high-level radioactive waste to the Netherlands within the next five years, Currently COVRA is in the process of modifying its operating licence with a view to accommodating the vitrified high level waste in a vault type of storage facility. Construction of this new facility commenced in early 1999.

iii) Financing

Since COVRA is required to be self-financing, a detailed waste-fee system has been developed to charge radioactive waste generators for the waste they transfer to COVRA. Provision is made for activities that will be undertaken in the distant future, and eventual profits will be used to adjust the fee system.

For the interim storage facility for high level waste, a different system of financing has been chosen. Since the number of producers of high level waste is limited to the nuclear power stations and research reactors, each potential user of the high level waste facility is to procure the resources for the construction and operation of this facility in proportion to its storage capacity requirements on the basis of advance payments to COVRA.

NEW ZEALAND

I. GENERAL REGULATORY REGIME

1. Introduction

The first piece of legislation relating to ionising radiation sources was introduced in New Zealand in 1944 and prescribed the registration of X-ray equipment. A 1949 statute providing for controls on both radioactive materials and X-ray machines came into force with accompanying regulations in 1951. Comprehensive legislation governing ionising radiation uses has, therefore, been in place in New Zealand for approximately 50 years. The primary legislation in the field is the Radiation Protection Act 1965, as amended (hereinafter referred to as "the Act"), and the Radiation Protection Regulations 1982 (hereinafter referred to as "the Regulations").

2. Mining Regime

No nuclear materials are mined in New Zealand and there are, accordingly, no specific provisions in New Zealand law which deal with the prospecting for and mining of nuclear ores.

3. Radioactive Substances and Equipment

The Radiation Protection Act 1965 restricts the use of X-ray equipment or radioactive materials to persons holding a licence therefor or those who are acting on the instructions or under the supervision of a licensee [Sections 13 and 15 of the Act]. Similarly, the Act prohibits the sale of X-ray equipment, unless the purchaser is the holder of a licence to use the equipment or is exempt from obtaining such a licence [Section 14 of the Act]. The licensee is responsible for the safe use of X-ray equipment or radioactive materials [Regulation 11]. Applications for licences must be made in the prescribed manner to the Director-General of Health [Section 16 of the Act]. Licences, which are renewable annually [Sections 16(4) and 21 of the Act], may be issued for one or more purposes [Section 18 of the Act]. Licences may be granted subject to special conditions, in addition to any conditions prescribed in respect of licences generally, and such special conditions may be varied at any time by the Director-General of Health [Section 17 of the Act].

The Director-General may, at his discretion, cancel or suspend for such period as he thinks fit, any licence granted under the Act if the licence holder commits an offence under the Act or breaches any of the conditions of the licence, or if he considers it in the public interest to do so [Section 20 of the Act]. Subject to the right of appeal under Section 23 of the Act, the decision of the Director-General in this respect is final.

For the more common purposes, which include the majority of licensees, codes of practice prepared by the National Radiation Laboratory (NRL) are issued to licensees and compliance with the relevant code is a condition of the licence. In the case of licences issued for the use of unsealed

radioactive materials, the radioactivity levels of radionuclides which may be ordered at one time are set out as licence conditions and are dependent on the qualifications and expertise of the licensee, its support staff and facilities.

The codes of practice prepared by the NRL to date are as follows:

- NRL C1: Code of safe practice for the use of unsealed radioactive materials, revised 1996.
- NRL C2: Code of safe practice for the use of sealed radioactive materials in industry, revised 1997.
- NRL C3: Code of safe practice for the use of unsealed radioactive materials in medical diagnosis, therapy and research, revised 1994.
- NRL C5: Code of safe practice for the use of X-rays in medical diagnosis, revised 1994.
- NRL C6: Code of safe practice for the use of X-rays in diagnosis (chiropractic), revised 1997.
- NRL C7: Code of safe practice for the use of X-rays in dentistry, 1991.
- NRL C8: Code of safe practice for use of X-rays in diagnosis (veterinary), 1984.
- NRL C9: Code of safe practice for the use of X-rays and radioactive material in industrial radiography, revised 1997.
- NRL C10: Code of safe practice for the use of X-rays in podiatry, 1990.
- NRL C11: Code of safe practice for the treatment of cats for thyroid disorders with iodine-131, revised 1997.
- NRL C12: Code of safe practice for the use of irradiating apparatus in medical therapy, 1992.
- NRL C13: Code of safe practice for the use of strontium-90 ophthalmic applicators, 1997.

Under the Regulations, the owner of a facility is responsible for ensuring that there is a licensee for X-ray equipment or radioactive materials at all times [Regulation 9]. It is also required that in any organisation employing more than one licensee the owner clearly defines the areas of responsibility of each licensee. Applicants for a licence under the Act may be required to have qualifications and facilities in relation to the specific purpose involved [Section 18 of the Act].

Exemptions from licensing are granted for the production, sale, storage, transport or use of radioactive materials in certain categories or which contain a quantity or concentration of a radionuclide below the level required for licensing. The Act defines [Section 2] a radioactive material as any article containing a radioactive substance giving it a specific radioactivity exceeding 100 kBq per kg and a total radioactivity exceeding 3 kBq. The Regulations exempt radioactive material with levels of radioactivity below those set out in Schedules 1, 2 and 3 to the Regulations [Regulation 4]. These levels were calculated on the basis of the smaller of two levels of radioactivity, one derived from an external radiation limit and the other based on toxicity.

The Regulations also exempt from licensing clocks, watches and other instruments containing radioactive luminous material in the form of specified radionuclides, with activities up to prescribed limits, which would otherwise exceed the exemption levels. Similar exemptions apply to smoke detectors, radiation source educational kits, ionisation and electron capture detectors used in gas chromatography, and tritium beta lights [Regulation 4(3)].

Any person who has radioactive material under his control is required to keep a record of the quantity, nature and location of the radioactive material. In addition, every purchaser of radioactive materials must keep accurate records specifying the purposes to which the materials are put. These records are open for inspection by an authorised representative of the Director-General of Health and must be retained for 10 years [Regulation 16].

Sales of irradiating apparatus are required to be notified to the National Radiation Laboratory, and may be made only to persons who are licensed for a purpose for which the equipment has been designed [Section 14 of the Act].

Pursuant to the Act, any officer of the Department of Health (or of any area health board) who is properly authorised by the Minister, has the right to enter at all reasonable hours any premises, vehicle, ship, or aircraft in order to examine or test any radioactive material or to examine or calibrate any irradiating apparatus which is located there [Section 24 of the Act].

4. Nuclear Installations

New Zealand has no nuclear installations and no legislation in this respect.

5. Trade in Nuclear Materials and Equipment

Control of radioactive material entering and leaving the country is maintained through a requirement of prior consent of the Minister of Health [Section 12 of the Act]. This allows surveillance of quantities imported and ensures that material is acquired and used only by licence holders.

In practice, for the majority of orders the authorisation procedure is streamlined through agreements between overseas suppliers, the New Zealand agents and the National Radiation Laboratory. Under these agreements, the agents are required to process orders only from licensees and to advise the NRL promptly of all orders forwarded. Material from suppliers with whom agreements have been reached (referred to as “approved suppliers”) are forwarded directly to the licensee through Customs at the place of entry into the country.

Most radiopharmaceuticals for medical use, radiochemicals for other uses and industrial radiography sources are imported from approved suppliers. In other cases, an “authorisation to import radioactive materials” document is required for each shipment, to obtain its release from Customs.

Radioactive material shipments imported into the country per year total about 3 000, 80% of which are destined for hospitals and medical laboratories.

6. Radiation Protection

Provisions of the legislation in force in New Zealand are generally consistent with recommendations of the International Commission on Radiological Protection (ICRP) and the International Basic Safety Standards (BSS) for Protection against Ionising Radiation and for the Safety of Radiation Sources. They include:

- licensing of users (see Section 3, *supra* "Radioactive Substances and Equipment");
- notification of sales of X-ray equipment (see Section 3, *supra* "Radioactive Substances and Equipment");
- notification and authorisation of importation of radioactive materials (see Section 5, *supra* "Trade in Nuclear Materials and Equipment");
- a system of exemption from licensing requirements for radioactive materials (see Section 3, *supra* "Radioactive Substances and Equipment"); and
- requirements governing dose limits and exposure monitoring, as well as transport, disposal, labelling and records of radioactive materials.

The legislation is administered by the National Radiation Laboratory, a unit of the Ministry of Health, which also acts in an advisory and investigative capacity in radiation protection matters, as well as providing personal monitoring and other services to users. The National Radiation Laboratory additionally maintains national radiation exposure standards, operates an environmental radioactivity monitoring programme, and provides measurement services and advice on health aspects of non-ionising radiation.

Part III of the 1982 Regulations sets out the obligations of owners and licensees for radioactive materials or irradiating apparatus they may own or for which they have responsibility, general safety precautions to be taken or observed by licensees, and requirements for the storage and labelling of radioactive materials and for the disposal of waste materials and containers.

Dose limits are prescribed in the Regulations for persons employed to work with radioactive materials or irradiating apparatus, and also dose limits for other categories of persons [Regulation 18]. These limits are compatible with the 1977 Recommendations of the ICRP.

The Regulations set out the requirements for the monitoring of occupational exposures and prescribe actions to be taken in the event of exposures exceeding the occupational dose limit [Regulations 19 and 20]. The ICRP Recommendations were revised in 1991 and it is intended that the legislation in New Zealand be amended to incorporate these revisions, in particular the changes to dose limits.

Licensees are responsible for dealing with events which might give rise to on-site contamination as a result of a spill or other incident [Regulation 11]. The potential for inadvertent public exposure is low, but incidents involving the loss of a source, or a transport incident could conceivably occur. In the case of the latter, the possibility of public exposure is limited by virtue of the packaging requirements of the International Atomic Energy Agency (IAEA) Transport Regulations [in force in New Zealand under Regulation 3]. In order to provide local capability for monitoring in the event of an incident, the NRL maintains a set of survey instruments in the care of health protection officers

throughout the country. Basic training in radiation safety and use of the instruments is provided by the NRL to allow radiation monitoring to be carried out if an incident is reported.

New Zealand acceded to the 1986 Convention on Early Notification of a Nuclear Accident and to the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, in both cases on 11 March 1987.

7. Radioactive Waste Management

The 1982 Regulations set out the obligations of owners and licensees in respect of the disposal of waste materials and containers [Regulations 14 and 15].

In the absence of nuclear installations or mining of nuclear materials, the main source of nuclear waste in New Zealand consists of nuclear materials used for radiochemicals and nuclear medicine. A variety of radioactive materials is used for these purposes, but four radionuclides predominate in these applications: iodine-125, iodine-131, technetium-99m and phosphorous-32. These nuclides are relatively short lived, with half-lives of 60 days, 8 days, 6 hours and 14 days, respectively. Most of the radioactivity has disappeared by the normal process of radioactive decay during its use, before it becomes waste.

The NRL rules applying to such waste are based on the IAEA International Basic Safety Standards for Radiation Protection. Thus, NRL C1 “Code of Safe Practice for the Use of Unsealed Radioactive Material” limits the concentration of radioactivity in any waste entering the environment to less than the exempt concentration listed for each nuclide in the Basic Safety Standards, at the point where it enters the environment before any further dilution occurs, and at the time it enters the environment before any further decay occurs. Licensees are permitted to dispose of waste below those limits without further approvals. Authorisation for disposal of higher concentrations of waste, or abnormal volumes within limits, could be considered if the need arose, but any such approval would be subject to additional conditions.

Unsealed radioactive waste can be in solid, liquid or gaseous form, and, if contaminated with radioactivity above the limit for uncontrolled disposal, its disposal is subject to Regulation 14.

A sealed radioactive source is a quantity of radioactive materials sealed in a metal capsule. The radioactive material is itself securely contained, but ionising radiation can be emitted. Historically, sealed radioactive sources were used for medical applications in the treatment of cancer. However, a variety of industrial uses now predominate. The most common use of sealed radioactive sources in New Zealand is in domestic smoke alarms, which because of the small quantity of radioactivity involved, are exempted from the Act’s licensing requirements. In industrial and medical applications with radioactivity levels above the exemption levels in the Basic Safety Standards, uncontrolled disposal is not permitted for any of these encapsulated sources.

The primary emphasis of the NRL’s policy for the management of these encapsulated sources is to ensure that each source is always accounted for. Responsibility for keeping track of all licensed radioactive sources is vested in the licensees, but the NRL maintains a database of all such sources and continually updates it on the basis of advice from licensees. An important NRL service is the receipt of all sealed radioactive sources which are obsolete, damaged or unwanted for any reason. National Radiation Laboratory assumes responsibility for supervision, storage and ultimate disposal of these sources. The only significant exception to this service is in the case of high activity sources (in

practice cobalt-60 which is being replaced), which are exported back to the supplier of the replacement source.

On 30 April 1975, New Zealand ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter.

8. Non-Proliferation and Physical Protection

The 1982 Regulations contain general provisions regarding the safe storage and marking of materials, containers and places where the materials are stored. Every licensee is required to take all reasonable steps to ensure the safekeeping of radioactive material for which he is responsible, to ensure its proper labelling and to store the material in a fire-resistant container. Every person who stores radioactive material must erect a warning sign in the prescribed form, unless the material is packed and labelled in accordance with the IAEA Transport Regulations or is adequately protected against unauthorised removal [Regulation 12].

New Zealand became a Party to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (NPT) on 10 September 1969 and to the 1996 Comprehensive Nuclear Test Ban Treaty, not yet in force, on 19 March 1999.

9. Transport

The 1982 Regulations require radioactive materials to be transported, and packaged and labelled for transport, in accordance with the IAEA Regulations for the Safe Transport of Radioactive Materials [Regulation 3]. These IAEA Regulations form the basis of two other sets of international regulations governing transport of radioactive materials: the International Air Transport Association (IATA) Restricted Articles Regulations, and the Dangerous Goods Code of the International Maritime Organisation (IMO).

10. Nuclear Third Party Liability

New Zealand is not a party to any of the international conventions on nuclear third party liability and has no specific legislative provisions on the subject.

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities

National Radiation Laboratory (NRL)

In New Zealand the advisory, investigative, surveillance and regulatory functions are all combined in the National Radiation Laboratory (NRL).

The NRL is a unit of the Ministry of Health and performs the following principal functions:

a) Administration of the Radiation Protection Act 1965 and Radiation Protection Regulations 1982 and provision of statistical or scientific data for use in promoting changes to legislation as may be required.

This includes in particular:

(i) licensing users of radioactive materials and irradiating equipment and ensuring that each use is under the responsibility of a suitably qualified person; and

(ii) controlling the import, export, manufacture, transport and disposal of radioactive materials.

b) Developing and maintaining national standards for radiation exposure measurement and providing for calibration of clinical dosimeters, equipment used in radiotherapy, and other radiation-measuring instruments.

c) Assessing, advising and providing information on hazards and risks associated with human activities involving ionising and non-ionising radiation and radioactive materials, and acting as a national centre of reference on such matters. In recent years, there has been a substantial advisory component related to non-ionising radiation, particularly radiofrequency radiations and ELF fields.

d) Undertaking surveys and research aimed at assessing ionising and non-ionising radiation doses arising from various sources and improving radiation protection measures and programmes.

e) Monitoring of radiation doses received by medically examined persons, and operation of inspection and advisory services to educate radiation users and to promote and maintain safe working practices. This includes provision of codes of practice and training courses where appropriate. Field work is held to be an important component of the safety assessment and advisory function.

f) Operation of a personal monitoring service to monitor radiation doses received by persons occupationally or otherwise exposed, and investigation of any case of real or suspected over-exposure.

g) Monitoring and assessing radioactivity in the environment, undertaking food certification with respect to its radioactive content, and acting as a collaborating laboratory with the WHO International Reference Centre in the field of environmental radioactivity.

In respect of (c) above, the NRL produces a quarterly publication, *Radiation Protection News and Notes,* which provides information and comment on items and events of radiation protection interest. Scientific studies are reported in the NRL report series and specialist scientific journals.

2. Advisory Bodies

Radiation Protection Advisory Council

Pursuant to the Act, the Council's function is to advise and make recommendations to the Minister of Health on radiation protection matters and to the Director-General of Health in respect of applications for licences which are forwarded by him for advice and recommendation [Section 10 of the Act].

The Council consists of the Director-General of Health, the Director of the National Radiation Laboratory, the Director of the Institute of Nuclear Science in the Department of Scientific and Industrial Research, two persons (each of whom is either a radiologist or a radiotherapist), a medical practitioner and a qualified physicist [Section 5].

3. Public and Semi-Public Agencies

Research Institutes

Some research on radiation protection and nuclear physics is carried out by the Institute of Geological and Nuclear Sciences and by certain universities in New Zealand.

NORWAY

I. GENERAL REGULATORY REGIME

1. Introduction

Although at present there are no plans for nuclear power projects in Norway, it was one of the first countries to embark upon a nuclear research programme and to enact legislation governing nuclear activities.

As far back as 1938, an Act on the Use of X-rays and Radium, etc. was passed to establish rules governing the use of radioactive substances, and this legislation is still in force [Act No. 1 of 18 June 1938]. However, this Act is due to be replaced by a new Act in 2000. Other regulations adopted pursuant to more recent legislation provide for the control and supervision of nuclear activities.

The nuclear sector is now regulated by Act No. 28 of 12 May 1972, as amended, on Nuclear Energy Activities which establishes a licensing regime for nuclear installations, nuclear fuels and radioactive substances and which also sets out a third party liability regime for compensation of nuclear damage. In addition, the Regulations of 1 March 1983 on the production, import and sale of radioisotopes were adopted pursuant to the 1938 Act, the Act of 26 June 1964 on Medicinal Goods [repealed and replaced by the Act of 4 December 1992] and the Act of 11 June 1976 on Product Control. Radiation protection aspects are regulated by the 1938 Act and by regulations adopted pursuant to that Act.

With respect to the authorities responsible for the different fields of nuclear activities, the 1972 Act, as amended, provided that the Norwegian Nuclear Energy Safety Authority (*Statens Atomtilsyn*) set up by Royal Decree of 9 February 1973 under the aegis of the Ministry of Industry and Energy, was the supervisory authority for the licensing of nuclear materials [Section 10], and that the State Institute of Radiation Hygiene (*Statens Institutt for Stralehygiene* – SIS) set up by Royal Decree of 25 September 1953 under the aegis of the Ministry of Health and Social Affairs was also responsible for radioactive substances. On 1 January 1993, the Nuclear Energy Safety Authority and the State Institute of Radiation Hygiene were merged into one single body: the Norwegian Radiation Protection Authority (*Statens Strålevern*), placed under the authority of the Ministry of Health and Social Affairs [1972 Act, as amended by the Act of 18 December 1992].

2. Mining Regime

Under the General Concessions Act on the acquisition of waterfalls, mines and other real estate, general prospecting activities may be carried out by the state, local authorities and Norwegian nationals and companies [Act No. 16 of 14 December 1917, Chapter II]. A mine may not be operated without authorisation from the Ministry of Trade and Industry; the state and local authorities are

exempted from this requirement. While existing legislation contains no express provisions giving the state direct control over the ownership and distribution of products obtained from mining, the Ministry of Trade and Industry, when granting mining concessions, enjoys wide powers to impose conditions it deems necessary in the public interest. In practice, uranium prospecting in Norway is almost entirely carried out by the state. There is at present no activity in this field.

3. Radioactive Substances, Nuclear Fuel and Equipment

Act No. 28 of 12 May 1972 on Nuclear Energy Activities establishes the general regime governing nuclear fuels, radioactive products and nuclear substances. Pursuant to the 1972 Act, "nuclear fuels" mean fissionable materials in the form of uranium or plutonium metal, alloy or chemical compound; "radioactive products" mean other radioactive materials (including waste) which are produced or have become radioactive through exposure to ionising radiation incidental to the production or use of nuclear fuels; "nuclear substances" mean nuclear fuels, other than natural or depleted uranium, as well as radioactive products, with the exception of radioisotopes used for industrial, commercial, agricultural, medical or scientific purposes [Section 1(a), (b) and (c)].

The 1972 Act provides that it is unlawful to manufacture, own, store, handle, transport, sell or otherwise dispose of nuclear substances without a permit from the Ministry of Health and Social Affairs [Section 5(1) and (2)].

Permits may be granted for a limited or indefinite period and may cover one or more of the above activities involving nuclear substances [Section 5(2)]. The conditions subject to which permits are granted may be amended where necessary for safety reasons or to ensure that compensation will be provided [Section 8(2)].

The Ministry may make exceptions to the obligation to obtain a permit, provided that certain conditions are complied with [Section 5(1)]. A permit may be revoked if its requirements are being substantially or repeatedly disregarded or for safety reasons [Section 9].

The King may decide that any activities involving nuclear fuels or radioactive products other than nuclear substances should be subject to notification or licensing [Section 5(3)]. He may issue rules regarding the manufacture, handling, packaging, storage, etc. of nuclear fuels or radioactive materials [Section 6].

The manufacture of radioisotopes is subject to a permit issued by the Norwegian Radiation Protection Authority [Regulations of 1 March 1983, Section 2].

The Regulations of 1 June 1979, made pursuant to the 1964 Act on Drugs and Poisons, exempt radioisotopes produced for medical use by the Institute for Energy Technology (*Institutt for Energiteknikk* – IFE) from the above-mentioned procedure [Section 3(1)(c)].

4. Nuclear Installations

Although no nuclear power plant has ever been established in Norway, there is a comprehensive legal framework for licensing the construction and operation of nuclear installations. This legal regime is laid down by Act No. 28 of 12 May 1972 on Nuclear Energy Activities and its relevant provisions are described below.

a) Licensing and inspection, including nuclear safety

The 1972 Act provides that it is prohibited to construct, own or operate a nuclear installation without a licence [Section 4].

The competent authority in matters of licensing is the Ministry of Health and Social Affairs; the Norwegian Radiation Protection Authority advises the Ministry in connection with the safety aspects of nuclear installations and makes recommendations on licensing applications [Section 10]. However, the Minister of Petroleum and Energy is responsible for the licensing of nuclear power plants.

The licence for a nuclear installation covers both construction and operation. However, before the installation is put into operation, the operator concerned must fulfil certain requirements which require the approval of the Norwegian Radiation Protection Authority [Section 11]. The Authority exercises continuous supervision over all operations and ensures that all the conditions prescribed by the licence are being complied with [Section 13].

Licences are granted for a specific site and are, as a rule, limited in duration. A separate licence is required for the transfer of a nuclear installation to a new owner or operator [Section 4].

A licence is granted when [Section 11(2)]:

- the technical standards of the installation, the operating regulations, safety measures and accident emergency plans are satisfactory;
- the management and personnel of the installation have the necessary qualifications and clearly defined spheres of responsibility;
- all the necessary authorisations have been obtained in accordance with other legislative provisions.

Concerning the inspection of nuclear installations, the Norwegian Radiation Protection Authority may at any time demand access to any such installation and its surrounding area [Section 14].

Norway ratified the 1994 Convention on Nuclear Safety on 29 September 1994.

At present, only one licensee has been granted permission to own and operate nuclear installations in Norway, namely the Institute for Energy Technology, which operates research reactors at Kjeller and Halden.

b) Emergency response

The 1972 Act provides for public safety precaution measures. The King may decide that municipal and county authorities in the area in which a nuclear installation is or will be situated must collaborate with the operator of that installation in respect of safety measures for protection of the public in that area. In accordance with rules to be issued by the King, a plan should be prepared for safety and relief measures in the event of an incident including, where necessary, compulsory evacuation [Section 49].

Where an incident has occurred within the national territory, the Ministry of Health and Social Affairs may order all persons who were in the danger area at the time of the incident to identify themselves to the Municipal Medical Officer or the police within a given time-limit and supply the information necessary to register the damage. They must also undergo a medical examination where considered necessary by the health authorities [Section 50].

On 26 September 1986, Norway gave its consent to be bound by the provisions of the 1986 Convention on Early Notification of a Nuclear Accident.

5. Trade in Nuclear Materials and Equipment

Nuclear trade in Norway is governed by several basic principles, namely nuclear non-proliferation (*i.e.* safeguards), nuclear safety, physical protection and radiation protection. These considerations are reflected in the legislation in force and such trade is subject to a licensing regime, pursuant to the legislation governing nuclear energy, radiation protection and export/import control. These three complimentary approaches mean that several authorities are involved in the licensing procedures for trade in nuclear materials and equipment.

a) Trade governed by nuclear energy legislation

The 1972 Act covers trade in nuclear fuel products and radioactive substances (for an explanation of these terms, see *supra*, Section 3 "Radioactive Substances, Nuclear Fuel and Equipment"). The Act provides that it is unlawful to manufacture, own, store, sell, or otherwise hold or dispose of nuclear substances without a permit from the Ministry of Health and Social Affairs [Section 5(1)]. The permit may be granted for a limited or indefinite period, or on an individual basis, and may be restricted to a special authorisation for one of the above activities [Section 5(2)]. The granting of a permit to handle, own or sell radioactive substances is subject to such safety conditions as are deemed necessary [Section 8(1)]. In addition, the Regulations for the Physical Protection of Nuclear Material, laid down by the Royal Decree of 2 November 1984, provide that persons responsible for nuclear materials must establish a system for physical protection of such materials during their storage and transport [Section 12]. The sender, in co-operation with the Norwegian Radiation Protection Authority and the recipient, must ensure in advance that during shipment the nuclear material will be subject at least to the minimum level of physical protection set out in Appendix 3 to the Regulations [Section 17].

b) Trade governed by radiation protection legislation

The Regulations of 1 March 1983 issued by the Ministry of Health and Social Affairs regulate the manufacture, import and sale of radioisotopes used for industrial, commercial, agricultural, medical or scientific purposes, in order to ensure radiation protection [Section 1]. These Regulations were issued pursuant to Act No. 1 of 18 June 1938 on the Use of X-rays and Radium, etc.

The import and sale of radioisotopes require a permit from the Norwegian Radiation Protection Authority [Sections 3 and 4]. Generally, applications for such permits are made by those involved in such trade, but end-users may also apply. Permits are issued on a case-by-case basis, but may also be granted as a general permit covering several years. The main criteria applied in respect of the issue of a general permit aim to prove the necessity of such activity observance of the relevant radiation

protection regulations. The Institute for Energy Technology has a general permit for the import and sale of all types of radioisotopes.

The Norwegian Radiation Protection Authority is empowered to issue detailed rules concerning registration and reporting of imports and sales of radioisotopes and such conditions are set out in a document of 20 June 1984 entitled "Conditions for Production, Import and Sale of Radioactive Material in Norway". These conditions are general and concern, in particular, safety procedures, quality control and the requirements concerning reporting to the Authority.

c) Trade governed by export/import control legislation

Act No. 32 of 6 June 1997 on import and export control authorises the King to regulate the import or export of any article, and to establish such licensing regimes as may be appropriate for the article or product in question [Section 1]. The Act is general in its scope, and thus it applies equally to nuclear or radioactive materials of any kind.

Regulations issued to implement the two previous Acts of 13 December 1946 on import and export control are still in force. They authorise the Ministry of Foreign Affairs to establish a list of goods that require an import licence [Regulation No. 1596 of 1 November 1983] and a list of goods that can be exported without restriction [Regulation No. 52 of 10 January 1989]. At present these regulations do not specify licensing requirements for nuclear or radioactive materials.

In addition, Act No. 93 of 18 December 1987 sets out stringent measures governing export control for strategic or sensitive goods, services and technology. The Ministry of Foreign Affairs has established an export control regime to implement this Act. Through its Regulation No. 51 of 10 January 1989, it set out a list of goods requiring an export licence. Any nuclear material, technology or equipment that is strategic or may have a military use (dual purpose use or which may be converted to military use) is covered by this export control regime.

Finally, Regulation No. 157 of 10 March 1989, adopted pursuant to Act No. 93 of 18 December 1987, prohibits generally the export of heavy water from Norway. The Ministry of Foreign Affairs may, however, grant an export licence when the heavy water concerned is of insignificant quantity and will be used exclusively for medical, research or industrial purposes. Since 1980, Norway exports nuclear materials and equipment only to those countries where all nuclear activities are covered by the International Atomic Energy Agency safeguards.

6. Radiation Protection

Legislation on radiation protection in Norway is made up of a series of laws and regulations, the most important of which is Act No. 1 of 18 June 1938 on the Use of X-rays and Radium, etc. which provides the basis for protection in this field.

The Ministry of Health and Social Affairs is the competent authority in matters of radiation protection [1938 Act] and the Norwegian Radiation Protection Authority under the aegis of this Ministry is responsible, *inter alia*, for ensuring that work involving ionising radiation is properly carried out. In this respect it co-ordinates its activities with the Labour Inspectorate [Royal Decree of 25 September 1953 and Royal Decree of 23 January 1976].

Regulations No. 1157 were issued on 14 June 1985 by the Ministry of Local Government and Labour in implementation of Act No. 4 of 4 February 1977 on the protection of workers and their working environment. They prescribe protective measures during work with ionising radiation and provide that employees may not be assigned to work involving radiation where the effective dose equivalent exceeds 50 millisieverts (mSv) over a period of twelve months; it is planned to lower the limit to 20 mSv. For adolescents between sixteen and eighteen years of age, the dose limit is set at 5 mSv for that same period [Section 4]. Pregnant women and children below the age of sixteen may not be assigned to work which involves exposure to ionising radiation [Sections 4 and 6]. Other provisions of the Regulations provide for medical examinations, duties of employers, etc. The Regulations also apply to offshore petroleum activities in accordance with the Regulation on the protection of workers and their working environment in relation to petroleum activities. Regulations No. 1157 repeal and supersede Regulations of 1978 dealing with the same question.

Several regulations issued in implementation of the 1938 Act provide for radiation protection in a number of activities, in particular for industrial radiography, industrial gauges and well logging. Other regulations concern the use of ionising radiation and approval of radiographs respectively [Regulations of 24 June 1977]. The latter were made in pursuance of Act No. 47 of 14 June 1974 on approval of health personnel.

The Royal Decree of 23 January 1976, issued pursuant to the 1938 Act, prescribes regulations on the supervision and use of installations, apparatus, materials and substances which release ionising or other radiation representing a danger to health.

The Royal Decree of 23 January 1976, issued pursuant to the 1938 Act, lays down detailed provisions on the supervision and use of installations, apparatus, materials and substances which release ionising and other radiation representing a hazard to health. The text specifies the authority competent in supervisory matters in accordance with the 1938 Act, namely the State Institute of Radiation Hygiene (now the Norwegian Radiation Protection Authority), as well as the type of devices concerned and the duties of the persons using them [Sections 1, 3 and 5].

The following are subject to supervision by the Norwegian Radiation Protection Authority:

- all installations, apparatus, materials and substances which produce ionising radiation and are used for medical, veterinary, scientific, industrial or other purposes;
- waste and discharges of substances which produce ionising radiation; and
- use of lasers, radar, microwaves and other electromagnetic radiation representing a danger to health.

Such equipment and materials cannot be sold or used without prior notification to the Authority, which may prohibit transactions or use before it has granted a licence to this effect [Section 4]. Furthermore, the Authority must be notified of new installations or extensions or major alterations to existing facilities; it must grant permission before they are used.

Certain installations, facilities and other devices may be exempted from these obligations by the Minister of Defence [Section 3].

A Royal Decree of 2 November 1979 prescribes the qualifications required for using X-ray devices for medical purposes.

In November 1988, the State Institute of Radiation Hygiene (now the Norwegian Radiation Protection Authority) issued Guidelines on radon measurements in dwellings, based on the results of large-scale surveys carried out in Norway and on conclusions reached by national experts and competent international organisations (International Commission on Radiological Protection, World Health Organisation). The Authority concluded that radon was the main source of collective exposure to ionising radiation in the country and made recommendations on the permissible average yearly radon concentration, in existing and future dwellings. In the first case if the concentration is higher than 200 Bq/m^3 (becquerel), consideration should be given to lowering that level, and if higher than 800 Bq/m^3, remedial action should be taken. A maximum level of 200 Bq/m^3 is recommended for future dwellings. Similar Guidelines on radon measurements for building grounds were also issued in November 1988.

7. Radioactive Waste Management

The 1972 Act on nuclear energy activities specifies that the Norwegian Radiation Protection Authority (NRPA) must exercise continuous supervision over the operation of nuclear installations, including the disposal of radioactive waste [Sections 11 and 13], while the 1983 Regulations on Production, Import and Sales of Radioisotopes provide that the NRPA prescribes the conditions governing radioactive waste disposal operations and issues the required permits [Sections 2 and 4].

At the international level, Norway ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter on 4 April 1974, and the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, on 12 January 1998.

8. Non-Proliferation and Physical Protection

The 1972 Act provides that the King may take the necessary measures to ensure that nuclear installations, equipment, fuel, radioactive products and other materials used for nuclear energy purposes, which are subject to international safeguards pursuant to agreements to which Norway is a party, are used only for non-explosive, peaceful purposes [Section 51]. The Act also specifies that persons engaged in activities in accordance with the Act have an obligation to preserve secrecy concerning confidential technical information acquired in the course of their work [Section 53].

As regards non-proliferation, Norway has been a Party to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons since 5 March 1970 but has not adopted domestic legislation in this respect. It also ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 15 July 1999.

As regards physical protection, Norway ratified the 1979 Convention on the Physical Protection of Nuclear Material on 15 August 1985, although it had already enacted legislation on this subject. A Royal Decree of 2 November 1984 issued pursuant to the 1972 Act lays down Regulations for the Physical Protection of Nuclear Material. These Regulations aim to establish conditions which will minimise the possibilities of theft of nuclear materials and sabotage of nuclear installations. They lay down detailed provisions concerning the obligations of nuclear operators and specify the powers of the competent authorities regarding physical protection.

The Act provides that the Norwegian Radiation Protection Authority (NRPA) is the competent body for the physical protection of nuclear materials and is empowered to make rules in this respect.

If theft or sabotage is reported, the Ministry of Health and Social Affairs acts as the co-ordinating body for the steps to be taken by the Ministry of Justice and the Ministry of Foreign Affairs; the former Ministry is responsible for initiating the operations to counteract such theft or sabotage while the latter Ministry is in charge of notifying other countries in accordance with the Convention on the Physical Protection of Nuclear Materials [Annex II].

Persons responsible for nuclear materials and equipment (operators pursuant to the 1972 Act) must establish and maintain a system for physical protection of the equipment and materials during storage, processing and transport. They must prepare a safety report on physical protection for the approval of the Ministry of Health and Social Services. This report must take into account radiation protection aspects and criticality hazards and be kept up to date regarding any changes or any acquisition of nuclear materials requiring stricter safety measures [Section 12].

Operators must also appoint one or more persons to be responsible for the physical protection aspects of stored material or material being processed or shipped. They are responsible for ensuring that the physical protection system operates in accordance with the rules issued by the NRPA [Section 12].

The Regulations lay down specific requirements for protecting nuclear material in storage and for nuclear equipment, and it divides the materials into three categories (I, II and III) according to their radioactivity and weight [Section 14]. The premises where they may be housed are also divided into three areas for surveillance purposes: restricted, protected and vital; access to these areas differs according to their classification and detailed instructions are provided for the setting up of protection and alarm systems for each type of area, aside from the general alarm system, directly connected to the police through a continuously manned guard centre [Section 15].

The Regulations also provide for the preparation of a contingency or emergency plan, also for transport, in consultation with the police. The plan must take into account the division of responsibility between the different bodies involved and must include the necessary protective equipment to be made available to the police. The safety report prepared by the operator must also include arrangements for effective action by personnel and the police in the event of theft or sabotage of nuclear material [Section 13].

Adoption of the Regulations gave rise to an amendment of the Penal Code [Section 152(a)] to include a provision dealing with unlawful possession, utilisation, transfer or distribution of plutonium or uranium, thereby endangering human life, health or property or the environment. Such acts are liable to a fine or a term of imprisonment of up to four years. Acts which may result in loss of human life or extensive damage to property are punishable by the penalty prescribed in Section 148 of the Penal Code, namely imprisonment ranging from two to twenty-one years, but not less than five years where death or serious injury has occurred.

The provisions on the physical protection of nuclear material during transport are discussed *infra* under Section 9 “Transport”.

9. Transport

The basic framework for the rules governing the transport of nuclear fuels and certain radioactive materials is established in the 1972 Act on Nuclear Energy Activities; the transport of radioactive materials not covered by that Act falls within the scope of the 1938 Act on the Use of X-rays and Radium, etc.

The Norwegian Radiation Protection Authority (NRPA) is the competent authority for the transport of radioactive materials by road and rail. The Maritime Directorate of the Ministry of Foreign Affairs is the authority responsible for issuing regulations on the maritime transport of dangerous goods; regulation of the transport by air of radioactive materials is the responsibility of the Civil Aviation Administration [Act of 11 June 1993 on Civil Aviation, Section 9(1) and (4); this assignment of authority was confirmed by the Ministry of Transport and Communication's decision of 25 March 1994].

The different modes of transport are regulated by provisions specific to each mode as summarised below. It should be noted that the international regulations applying to the different modes of transport of radioactive materials is based on the IAEA's Regulations for the Safe Transport of Radioactive Materials.

The Directorate for Fire and Explosion Prevention, as the competent authority for the transport of dangerous goods by road and rail in Norway, works in co-operation with the NRPA as regards class 7 (radioactive) materials. The Regulations of 20 December 1996 on the transport of dangerous goods by road and rail state that the international regulations for carriage of dangerous goods by road (ADR) and rail (RID) shall apply to both international and domestic transport of dangerous goods.

As regards maritime transport, the relevant provisions of the International Maritime Dangerous Goods Code issued by the International Maritime Organization (IMO) and the provisions of the International Convention for the Safety of Life at Sea (SOLAS) are applied in Norway pursuant to Regulations issued by the Maritime Directorate on 30 November 1979.

Pursuant to the Regulations of 15 May 1979 issued by the Civil Aviation administration, air transport of radioactive materials is carried out in accordance with technical instructions governing safety for the air transport of dangerous goods of the International Civil Aviation Organisation (ICAO).

The 1984 Regulations on the Physical Protection of Nuclear Material contain provisions establishing basic rules for physical protection of nuclear material during transport by road, rail, sea and air. These provisions apply in addition to the different regulations referred to above.

The physical protection of all shipments must be approved and authorised in advance by the NRPA. The licences specify the conditions applying to each particular shipment. The Authority may only grant a general permit for shipments of categories II and III material, in which case no further notification is required for individual shipments [Section 17(c)].

Only authorised persons may carry out shipments and the operator and the authorities concerned must be cautious in dealing with information which could jeopardise physical protection [Section 17(a)].

Shipments of nuclear materials are subject to agreements being concluded prior to the shipment between the sender and the recipient, and the sender and the transport firm, respectively [Section 17(f)]. The operator must also ensure that the shipment remains as short a time as possible in transit, that as few reloadings as possible occur and that shipments do not take place at regular, known times [Section 17(a)].

The operator must establish an external transport executive body for the transport operation and inform the parties concerned accordingly; that body must maintain telephone or radio contact with the

transport vehicle and/or the escort vehicle and based on the information received, give appropriate instructions relating to irregularities during the transport to the transport personnel, the police or the road authorities as the case may be [Section 17(e)].

The Regulations set out special provisions in connection with the transport of Category I material (with the highest fissile content) for the different modes of transport. These are summarised below [Section 18].

As regards road transport, the transport vehicle must be constructed and equipped to resist attack, be equipped with a two-way communication system and be manned by at least two persons. The transport must also have a police escort and the position of the vehicle must be reported to the transport executive body several times an hour.

Transport by rail must be carried out in a freight train or a separate carriage in a passenger train. The transport must have a police escort and the accompanying guard must be equipped with a two-way communication system.

The sea transport of Category I material must be carried out with a police escort and the consignment placed in a locked and sealed room or container.

Transport by air must take place in an especially selected aeroplane, with a police escort.

10. Third Party Liability

The regulations governing nuclear third party liability are set out in the Act of 12 May 1972 on nuclear energy activities, as amended. This Act, which enabled Norway to ratify the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy (on 2 July 1973) and the 1963 Brussels Supplementary Convention (on 7 July 1973), applies the principles of the Paris Convention, including the strict liability of the operator, which is limited in amount and in time. The Act applies to nuclear damage caused by an incident occurring in Norway or in another country Party to the Paris Convention.

The Ministry of Health and Social Affairs may exempt from the provisions of the Act, certain types of nuclear installation, nuclear fuel, radioactive products or substances which in its opinion, constitute no significant hazard [Section 2(1)].

Liability under the Act is vested exclusively and strictly in the operator of a nuclear installation [Sections 20–28]. Therefore, claims for compensation for nuclear damage for which the operator is liable may not be brought against any person other than the operator himself, or his insurer or guarantor [Section 27].

The liability of an operator for one and the same nuclear incident is limited to Special Drawing Rights (SDR) 60 million [approximately Norwegian kroner (NOK) 500 million] [Section 30(1)]. However, the King may, if the size and nature of the installation or operation so warrant, lower that amount to SDR 5 million (approximately NOK 42 million).

To cover his liability, the operator of a nuclear installation must take out and maintain insurance or such other security as the Ministry of Health and Social Affairs authorises [Section 35(1) and (2)]. The Ministry may approve separate insurance or other security to cover liability for incidents occurring during transport [Section 35(3)].

Whenever a nuclear substance is transported to or from a foreign country, the operator liable under the Act must supply the carrier with a certificate of financial security for the carriage issued by or on behalf of the guarantor [Section 38(1)].

If claims for compensation against a nuclear operator cannot be satisfied by the maximum amount of that operator's liability, but are valid under the Act, the Act provides for the claims to be paid out of government funds up to a total amount of SDR 300 million [Section 40(1)].

A claim is extinguished if it is not acknowledged or if legal action is not instituted within ten years of the date of the nuclear incident [Section 34(1)]. If the incident is attributable to nuclear substances which have been stolen, lost or abandoned, the time-limit for bringing claims is twenty years from the date of the theft, loss or abandonment [Section 34(2)].

Norwegian courts have jurisdiction to hear cases on the liability of an operator in respect of nuclear damage if the nuclear incident occurred wholly or partly on Norwegian territory, if it occurred on the high seas at a time when the substances in question were being carried between countries not party to the Paris Convention, or if the place of the incident cannot be determined with certainty and the installation of the operator liable is situated in Norway [Section 45(1)].

Lastly, Norway ratified the 1988 Joint Protocol relating to the Application of the Vienna Convention and the Paris Convention on 11 March 1991, and it ratified the 1971 Convention relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material on 16 April 1975.

II. INSTITUTIONAL FRAMEWORK

In Norway, responsibility for nuclear matters is vested mainly in the Ministry of Health and Social Affairs. The Ministry is assisted in its work by bodies which have advisory and supervisory authority.

Several other ministries also have certain responsibilities in the nuclear field when related activities are within their competence.

1. Regulatory and Supervisory Authorities

A. Ministerial Level

a) Ministry of Health and Social Affairs

The Ministry of Health and Social Affairs is the competent authority pursuant to the 1972 Act on Nuclear Energy Activities and the 1984 Regulations for the Physical Protection of Nuclear Material. The Ministry issues licences for nuclear installations.

The Ministry is also responsible for the protection of public health and is therefore competent to deal with questions of radiation protection [1938 Act on the Use of X-rays and Radium, etc.]. In this capacity, it is not only in charge of drafting legislation in this field but also of ensuring that work involving ionising radiation is properly carried out.

The Ministry performs its licensing and control functions and, to some extent, drafts regulations through the NRPA for which it has administrative responsibility [1972 Act on Nuclear Energy Activities, as amended by the Act of 18 December 1992].

b) Ministry of Trade and Industry

The Ministry of Trade and Industry has general co-ordinating functions and deals with budgetary matters concerning research and development in the field of nuclear energy.

The Ministry also deals with matters concerning prospecting for deposits of uranium, thorium and other ores or minerals which may be of use for the exploitation of nuclear energy [1917 General Concessions Act on the Acquisition of Waterfalls, Mines and other Real Estate].

c) Ministry of Foreign Affairs

The Ministry of Foreign Affairs is the competent authority under Act No. 32 of 6 June 1997 on export and import control, and thus has responsibility under that legislation for export and import of nuclear materials. It is also responsible for the export control regime established by Regulation No. 51 of 10 January 1989, made pursuant to Act No. 93 of 18 December 1987 on export control for strategic goods, services and technology, which also applies to sensitive nuclear material. The Ministry of Foreign Affairs is also empowered to grant exceptional export licences for heavy water under Regulation No. 157 of 10 March 1989, adopted pursuant to Act No. 93 of 18 December 1987.

The Ministry is responsible for international relations and agreements in the nuclear field. It also co-ordinates Norwegian participation in this field in international organisations.

d) Other Ministries

The Ministries of Justice, Agriculture, Transport and Communications, the Environment, Culture and Science, and Local Government and Labour may also be called upon to deal with legislative or administrative questions in the nuclear field.

B. Subsidiary Level

a) The Norwegian Radiation Protection Authority (NRPA)

The NRPA (*Statens Strålevern*), as explained earlier in this study, was established in 1993 through a merger of the Nuclear Energy Safety Authority and the State Institute of Radiation Hygiene. The NRPA is placed under the Ministry of Health and Social Affairs for administrative purposes [1972 Act, as amended in 1992] and has taken over the responsibilities of both previous bodies.

The Authority advises the Ministry of Health and Social Affairs in its capacity as the highest specialised agency on questions of nuclear safety and is the supervisory authority in that field [1972 Act, Section 10].

The Authority may, on its own initiative, put into effect all the measures it deems necessary from the safety viewpoint and is responsible for ensuring that all rules and conditions connected with safety precautions are complied with. It is responsible for the licensing aspects of nuclear installations and must exercise continuous supervision over the construction and operation of such installations [1972 Act, Sections 11 and 13].

It is also empowered to license and control all equipment and apparatus emitting ionising radiation with regard to radiation protection and public health and may issue the necessary regulations for that purpose [1938 Act, Royal Decree of 23 January 1976]. In addition, it grants permits for the production, import and sale of radioisotopes, and issues conditions governing their production, storage, labelling and quality control, as well as conditions regarding disposal, radiation protection and facilities and equipment connected with such materials [Regulations of 1 March 1983 on the production, import and sale of radioisotopes, Sections 2, 3 and 4].

Furthermore, the NRPA is responsible for research and educational activities in the fields of dosimetry, radiation hygiene and other related topics. The research work covers the following sectors: medical radiation physics, industrial radiation physics and medicine.

The NRPA has five departments: Nuclear Safety, Health Physics, Radiation Medicine, Environmental Protection and Administration and Information.

It is funded by the ordinary budget allocated to the Ministry of Health and Social Affairs and through project contracts with other ministries, *i.e.* the Ministry of Foreign Affairs and the Ministry of the Environment.

b) The Norwegian Nuclear Emergency Organisation

Based on the Royal Decree of 26 June 1995 the government decided to establish the above Organisation made up of representatives of the following entities:

- the ministries involved;
- the Ministerial Co-ordination Committee;
- the Crisis Committee for Nuclear Accidents;
- the Advisors to the Crisis Committee for Nuclear Accidents;
- the Secretariat for the Crisis Committee;
- the regional emergency organisations.

The ministries are entirely responsible for emergency preparedness in their respective areas of competence. In order to deal effectively with the early phase of a nuclear accident, the Ministries have transferred responsibility for remedial actions to the Crisis Committee for Nuclear Accidents.

The Ministerial Co-ordination Committee is responsible for ensuring co-operation and co-ordination between the different ministries and ensuring that the necessary resources are made available for this purpose. Its members are the Ministries of Health and Social Affairs, Justice, Defence, Foreign Affairs, Environment, Agriculture, Trade and Industry, Education, Research and Church Affairs, Transport and Communications and Fisheries. The Committee is headed by the Ministry of Health and Social Affairs.

The Crisis Committee for Nuclear Accidents is made up of representatives of the following institutions:

- Norwegian Radiation Protection Authority (NRPA);
- Directorate of Civil Defence and Emergency Planning;
- Norway Military Headquarters;
- Police Department of the Ministry of Justice;
- Norwegian Board of Health;
- Norwegian Food Control Authority.

It is headed by the NRPA representative.

The Committee is responsible for establishing and implementing remedial actions in the event of a nuclear accident or an impending nuclear accident representing a potential threat to Norway. It must organise the evacuation of the population if the situation represents a direct threat to health and life; provide shelter, administer stable iodine, block and secure contaminated areas; impose short-term restrictions on production and distribution of foodstuffs; and advise on the consumption of dairy products.

Wherever possible, the Committee must discuss its decisions with the Ministries before acting on them.

The Advisors to the Crisis Committee for Nuclear Accidents are representatives of 12 organisations and institutions with the expertise and competence required to organise emergency measures, both as regards the management of nuclear accident situations and for further development and maintenance of emergency preparedness. They are representatives from the Norwegian Defence Research Establishment, the Institute for Energy Technology, the Norwegian Meteorological Institute, the Geological Survey of Norway and the Norwegian Agricultural Inspection Service, etc. During accident situations, their tasks are:

- to submit and make available all information, data and measurements relevant to emergency situations, and to make forecasts for radioactive dispersion, fallout and radiation doses to the public;
- to advise on preventing or reducing the radiological and economic consequences of a nuclear accident in Norway.

The Secretariat for the Crisis Committee (the Nuclear Safety Department in the NRPA) is responsible, *inter alia,* for alerting the Nuclear Emergency Organisation and for warnings in a

emergency situation; it also organises a telephone watch so that the Organisation can be alerted at all times.

The regional emergency organisations are established under the direction of the Chief Administrative Officers in the Norwegian counties.

2. Public and Semi-Public Agencies

Institute for Energy Technology (IFE)

i) Legal Status

The IFE (*Institutt for Energiteknikk*) was set up by Royal Decree of 30 May 1947 as the *Institutt for Atomenergi* (IFA) and became an independent foundation in 1953. It reports to the Ministry of Petroleum and Energy. In 1980, its name was changed into its present one, in line with developments in its work in recent years and adapted to national goals, as specified by the authorities.

ii) Responsibilities

The Institute's mandate, as defined in 1980, is to conduct research and development, analyses, etc. within the field of energy, including nuclear research and other fields particularly suited to the Institute's competence.

The IFE is the national centre for nuclear research and development, and as such, it carries out work in nuclear safety, environmental protection, waste management and materials technology.

The IFE owns and operates the JEEP II reactor, a 2 MW, heavy water-cooled and moderated research reactor, as well as the 20 MW Halden Boiling Water Reactor which is used in an International Project, set up in 1958 under the auspices of the OECD Nuclear Energy Agency (OECD/NEA) for the purpose of carrying out a joint programme of research and experiments between national centres and nuclear power manufacturing industries from OECD Member countries in connection with the operation of a boiling water reactor.

IFE also produces and distributes radioisotopes; it has a gamma radiation plant in operation and arranges courses in data processing and isotope applications.

The activities of IFE are geographically divided between two sites, Kjeller, which is the main research centre, and Halden, where the OECD/NEA Halden Reactor Project is located.

The research and development activities are performed in the following sectors:

- energy and systems technology;
- petroleum technology;
- OECD/NEA Halden Reactor Project;

- materials technology;
- isotopes and chemistry;
- industrial chemistry;
- physics.

The Institute operates a waste treatment plant which processes radioactive waste from its own activities and from outside sources, as well as the Combined Storage and Disposal Facility for low and intermediate level waste in Hindalen.

iii) Structure

The Institute is managed by a board consisting of six members, one appointed by the government, one by the firm Norsk Hydro A/S and two by the Royal Council of Scientific and Industrial Research. The remaining two members are chosen by and from among the staff and are appointed by the government.

A managing director, appointed by the board, is entrusted with the day to day running of the Institute which has a staff of about 550 people.

iv) Financing

The Institute's yearly expenditure is covered by grants from the Ministry of Trade and Industry and by income from research and development work undertaken on a contractual basis with other national and foreign firms and institutions.

In connection with the OECD/NEA Halden Reactor Project, the majority of the programmes are financed by contributions from the Parties and Associated Parties to the Halden Agreement.

POLAND

I. GENERAL REGULATORY REGIME

1. Introduction

There are no nuclear power plants in Poland at present. There are, however, two research reactors: the EWA reactor, the decommissioning of which commenced on 24 February 1995, and the MARIA reactor. In addition, there is a radioisotope processing centre and a spent fuel storage facility in Swierk and a radwaste facility at Rozan. In view of the current estimation of nuclear energy costs and the level of public concern, which remains high, no projects for nuclear power plants are expected to be carried out in the near future.

The Atomic Energy Act of 10 April 1986 [Dz. U.* No. 12, poz. 70, hereinafter referred to as "the Act"), which entered into force on 1 July 1986, is a framework Act governing all nuclear activities in Poland. It establishes the main supervisory body in the nuclear field, the National Atomic Energy Agency (*Panstwowa Agencja Atomistyki*, hereinafter referred to as "the NAEA"), a government body directly under the authority of the Prime Minister, who appoints its President. In addition, there are various other competent bodies, such as the Central Laboratory for Radiological Protection (see *infra* Part II, Section 3 "Research Institutes").

The Act recognises the need to develop nuclear energy for peaceful purposes, but in a manner which protects life, health, property and the environment. It establishes a licensing system which applies to:

- nuclear installations (from site selection to decommissioning) [Part 2];
- manufacture, use of and trade in nuclear materials [Part 3];
- manufacture and use of ionising radiation sources [Part 4];
- construction and operation of radioactive waste depositories [Part 5]; and
- transport of nuclear materials, radioactive sources and waste [Part 6].

In addition, the Act covers training and protection of workers, third party liability issues and penalties. The functions of the NAEA and its President, particularly as regards the licensing procedure for nuclear installations, are further detailed in Decrees issued by the Council of Ministers on 23 February 1987, 11 January 1988 and 21 November 1995.

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* Dz. U.: *Ddziennik Ustaw* = Law Bulletin of the Republic of Poland.

The Act has been amended several times (1987, 1991, 1994, 1995 and 1996), and is supplemented by several orders, ordinances and decrees. One of the amendments to the Act with potentially broad application is the amendment of 24 June 1994 [Dz. U. No. 90, poz. 418], which provides for the possibility of obtaining assistance from the state budget for any expenditure required in the interests of the safe use of nuclear energy. On 6 December 1994, the Council of Ministers issued a Decree specifying the type of activities which could benefit from such financial assistance [Dz. U. No. 131, poz. 661].

Furthermore, a new Criminal Code entered into force in Poland on 1 September 1998 [Dz. U. No. 88, poz. 2677]. Two new provisions governing nuclear energy and ionising radiation have been introduced into Chapter XX of this Code. Article 163(4) provides that a person responsible for an event which poses a threat to the life and health of a significant number of persons or considerable damage to property, through release of nuclear energy or ionising radiation, will be liable to imprisonment for a period of one to ten years. The second of these provisions provides that whoever, without permission or contrary to stipulated conditions, possesses, uses, produces, reprocesses, collects or deals with explosion devices or substances, radioactive materials, ionising sources or other objects dangerous to the life or health of a significant number of persons or subject to cause considerable damage to property, will be liable to imprisonment for a period of six months to eight years [Article 170(1)].

2. Mining Regime

There is no legislation dealing specifically with the prospecting for and mining of radioactive ores in Poland. These activities are therefore governed by the Mining and Geological Act of 4 February 1994 [Dz. U. No. 67, poz. 342].

3. Radioactive Substances, Nuclear Fuel and Equipment

a) Licensing

Section 4 of the Act provides that a licence from the competent nuclear safety and radiation protection authority is required to carry out activities related to the application of atomic energy. Amongst the activities listed in that Section are the production, conversion, storage or use of nuclear materials and radioactive sources. Also specified are the manufacture and use of devices incorporating radioactive sources or emitting ionising radiation, as well as the manufacture of dosimetric equipment and equipment and devices for protection against ionising radiation. The President of the NAEA may also exempt certain activities from the licence requirements [Section 4(5)].

"Nuclear materials" are defined in the Act as materials containing fissile nuclides or nuclides which could become fissile following nuclear reactions, and in particular isotopes of uranium, plutonium and thorium [Section 3(1)]. The Act states that licences to manufacture, convert, store, make use of and trade in nuclear materials shall be granted by the President of the NAEA [Section 20].

"Radioactive sources" are defined in the Act as radioactive substances prepared in such a manner as to allow use to be made of the ionising radiation they emit [Section 3(4)]. Licences in respect of "sources of ionising radiation" [defined in Section 3(5) of the Act as being radioactive sources or devices emitting ionising radiation] are provided for under the Act [Section 22]. Licences in respect of sources of ionising radiation are granted by the President of the NAEA [Section 22(1)], with

the exception of licences to manufacture, purchase, install and use X-ray apparatus emitting radiation of energy equal to or less than 300 keV, which are granted by the local State Public Health Inspector [Section 22(2)].

In addition to the licensing requirements, the Act requires that nuclear materials and radioactive sources be registered and monitored [Section 5] as described in the following sub-sections.

b) Registration and Monitoring of Nuclear Materials

The Act requires any organisational unit licensed to manufacture, convert, store, use and trade nuclear materials, to register and monitor such materials [Section 21(1)]. The rules governing such registration and control are established by the President of the NAEA, in agreement with the Minister for Industry and Trade, the Minister for Internal Affairs and Administration, the Minister for Foreign Affairs and the Minister for Transportation and Maritime Administration.

Such rules are established under the Regulation of 20 October 1987 of the President of the NAEA [Mon. Pol.** No. 33, poz. 285]. The rules set out the principles which apply to the keeping of records and the control of nuclear materials during manufacture, processing, use, removal from one place to another and storage on national territory. Nuclear materials passing in transit through Polish territory are excluded from the application of these rules.

The system for recording and controlling nuclear materials includes internal plant records and audits of nuclear materials, as well as central record keeping and audit by the National Atomic Energy Agency. The Regulation of 20 October 1987 sets out the type of documentation which must be kept and details of inspections to be conducted.

c) Registration and Monitoring of Radioactive Sources

The Act provides that the President of the NAEA shall determine the rules applicable to the registration and control of radioactive sources, as well as the rules governing the control of devices incorporating radioactive sources and emitting ionising radiation [Section 25]. This provision is implemented through the Regulation of 28 July 1987 of the President of the NAEA [Mon. Pol. No. 27, poz. 214]. This Regulation stipulates the principles for keeping records of and controlling radioactive sources, although it expressly states that these principles do not apply to such sources while they are in transit.

As well as stipulating the type of information to be maintained in respect of radioactive sources, the Regulation also contains several appendices setting out model forms for the maintenance of registers. Entities responsible for maintaining the records must, by 15 January each year, submit a list of radioactive sources available at 1 January of that year. The list must be submitted to the Central Laboratory for Radiological Protection and to local State Public Health Inspectors.

The Regulation of 28 July 1987, governing record-keeping in respect of radioactive sources, provides for regular inspections to check on the storage conditions of radioactive sources and sets out the reporting requirements in respect of those inspections. In addition, provision is made in the Regulation for verifying radiation protection in respect of equipment containing radioactive sources, prior to putting the equipment into operation. This verification is to be done by the entity authorised to

** Mon. Pol.: *Monitor Polski* = Bulletin of the Council of Ministers.

install the equipment, which must advise the Central Laboratory for Radiological Protection of the verification results.

d) Requirements for Dosimetric Equipment

The Act provides that the President of the NAEA shall determine the standards which dosimetric equipment used for radiation protection must meet, together with the requirements relating to the recording of dosimetric readings [Section 35]. These standards and requirements are set out in the Regulation of 25 January 1988 of the President of the NAEA [Mon. Pol. No. 6, poz. 59].

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

"Nuclear installations" are defined in the Act as installations or devices in which nuclear materials are manufactured, applied, converted, stored or transported in sufficient quantities to allow a self-sustained fission reaction [Section 3(2)]. This definition is further elaborated in Section 14 of the Act, which refers, in particular, to nuclear power plants producing electricity or heat or both; establishments using nuclear reactors as a source of thermal energy or radiation for technological purposes; establishments for producing, converting and storing nuclear materials; and nuclear reactors used for research and experiments. Installations or devices are classified as nuclear installations on the basis of a decision of the President of the NAEA.

The Act includes amongst the activities subject to licensing the construction, start-up, operation or decommissioning of nuclear installations [Section 4(2)]. The licences are granted by the President of the NAEA on the request of the investor or the operator [Section 17]. A major licensing activity currently carried out by the Department of Nuclear and Radiation Safety of the NAEA is in respect of the operation of the MARIA research reactor.

A protection zone, subject to land-use restrictions, must be established around nuclear installations in order to reduce the risk from ionising radiation [Section 18(1)]. The detailed rules governing protection zones are set out in the Regulation of 1 June 1988 of the President of the NAEA [Mon. Pol No. 20, poz. 180]. Pursuant to this Regulation, the boundaries of a protective zone must be established so as to ensure that during the normal operation of a nuclear installation the effective annual dose equivalent emitted from the installation is less than 0.25mSv (25 mrem).

Inspection powers are described in Part 10 of the Act, as part of a wider nuclear surveillance function. Pursuant to Ordinance No. 3 (4 July 1996) of the President of the NAEA, the former Nuclear Inspectorate for Radiation and Nuclear Safety was abolished and its functions and employees transferred to the NAEA as two new Departments of the Agency. These two departments are, respectively, the Department of Nuclear and Radiation Safety and the Department of Control of Applications of Ionising Radiation Sources.

The nuclear surveillance tasks, including inspections, are performed by the President of the NAEA, the Principal Inspector for Nuclear Surveillance and other inspectors responsible for nuclear surveillance. The Principal Inspector for Nuclear Surveillance is appointed by and responsible to the President of the Agency, and directs the work of the inspectors responsible for nuclear surveillance [Section 52]. The President of the Agency may entrust the surveillance tasks to officials of

organisational units subject to nuclear surveillance, who will have the same rights as inspectors responsible for nuclear surveillance [Section 53].

Under Section 54 of the Act, the inspectors are entitled to:

- conduct visits, at any hour of the day or night, at locations (including means of transport) where nuclear materials, sources of ionising radiation or radioactive waste are used, produced, stored or transported;

- examine documents dealing with nuclear safety or radiation protection in the nuclear installation or unit subject to control;

- verify that the licensed activities comply with the nuclear safety and radiation protection provisions and conditions laid down in the licences; and

- to undertake, as necessary, independent technical and dosimetry measures.

The President of the NAEA may require that any breaches of nuclear safety and radiation protection provisions, or any shortcomings in the performance of conditions laid down in the licences, be rectified within a given period [Section 57].

The procedure to be followed in matters arising out of the surveillance are governed by the Code of Administrative Procedure [Section 58]. Any decision involving nuclear safety and radiation protection may be contested before the Supreme Administrative Court (*Naczelny Sad Administracyjny*) [Section 59].

"Nuclear safety" is defined in the Act as the state in which, during the normal operation of a nuclear installation and on the appearance of any disturbances, the limits of exposure to ionising radiation laid down by law for persons working in nuclear installations and for other persons, will not be exceeded [Section 3(7)]. Nuclear safety is made a priority under the Act, as can be seen from the numerous references to this issue throughout the legislation [*e.g.* Sections 4(4), 12(1), 17(2), 19, 27(2), 28 and Part 10].

Poland is party to the Convention on Nuclear Safety, which it ratified on 14 June 1995.

b) Emergency response

If nuclear safety is endangered by the operation of the installation, the Act empowers the President of the NAEA to order a reduction in its production of power or its withdrawal from service [Section 19]. The authorisation of the President is required to return the installation to full power or to bring it back on line.

If an inspection of the installation reveals a direct threat to nuclear safety or radiation protection, the President of the NAEA, the Principal Inspector for Nuclear Surveillance or the inspectors responsible for nuclear surveillance (see, *infra*, Section 6 "Radiation Protection") are required to impose emergency measures designed to eliminate the danger [Section 55].

Poland is party to the following international conventions dealing with emergency response:

- 1986 Convention on Early Notification of a Nuclear Accident (ratified on 24 March 1988);

- 1986 Convention on Assistance in Case of a Nuclear Accident or Radiological Emergency (ratified on 24 March 1988);

- Bilateral agreements on early notification of a nuclear accident and on co-operation in nuclear safety and radiological protection concluded with: Denmark (1987), Austria (1987), Norway (1989), Ukraine (1993), Belarus (1994), Russian Federation (1995), Lithuania (1995) and Slovak Republic (1996).

By order of the President of the NAEA, the International Contact Point (ICP) of the early warning system has been established. The ICP operates on a 24-hour basis and serves as a channel for the exchange of information on radiation emergencies with the International Atomic Energy Agency (IAEA) in Vienna and neighbouring countries, in accordance with international conventions and bilateral agreements.

5. Trade in Nuclear Materials and Equipment

Under the Act, a licence is required for the import into, the export from and transit through Poland of nuclear materials, radioactive sources and devices incorporating such sources, as well for the import of everyday articles emitting ionising radiation [Section 6]. The conditions governing such trade are set out in the Regulation of 25 February 1988 of the President of the NAEA [Mon. Pol. No. 9, poz. 82]. The licences are issued by the President of the NAEA pursuant to his authority under the Act [Sections 20 and 22].

Nuclear materials, radioactive sources and equipment containing radioactive sources may be imported from abroad by an entity that has been licensed under Section 4 of the Act to:

- use such items;

- deal in nuclear materials or radioactive sources;

- manufacture and process nuclear materials and radioactive sources;

- manufacture devices containing radioactive sources; or

- manufacture articles of general use which emit ionising radiation.

Similarly, nuclear materials, radioactive sources or devices containing radioactive sources may be exported to foreign countries by an entity that has been licensed under Section 4 of the Act to:

- distribute nuclear materials or radioactive sources;

- manufacture devices containing radioactive sources;

- use nuclear materials and radioactive sources; or

- manufacture nuclear materials and radioactive sources.

An Act of 2 December 1993 provides for special control rules for the import, export and transit of certain goods and technologies in accordance with international agreements concluded by Poland [Dz. U. No. 129 of 24 December 1993]. These control rules apply to a variety of goods and

technologies, including those belonging to the nuclear fuel cycle and those capable of producing nuclear explosive devices. The list of such goods and technologies is established by the Minister for the Economy and the Minister for Foreign Affairs. Import and export certificates are issued by the Minister for the Economy after the licence has been granted. Permits for the transit of such goods are issued by the directors of customs offices. Control teams appointed by the Minister for the Economy, and which include a member of the National Atomic Energy Agency, carry out checks on Polish territory. The Minister for the Economy issued an Order on special controls in foreign trade pursuant to the 1993 Act [Dz. U. No. 19 of 25 March 1994]. This Order contains provisions relating to articles capable of producing nuclear explosive devices.

6. Radiation Protection

Ongoing surveillance of nuclear safety and radiation protection is dealt with in Part 10 of the Act, with general responsibility being given to the President of the NAEA, the Principal Inspector for Nuclear Safety and other inspectors responsible for nuclear surveillance [Section 52]. If an inspection of the installation reveals a direct threat to nuclear safety or radiation protection, the President of the NAEA, the Principal Inspector or the inspectors responsible for nuclear surveillance are required to impose emergency measures designed to eliminate the danger [Section 55]. For further details of the nuclear surveillance tasks of the Principal Inspector and the inspectors, see *supra*, Section 4 "Nuclear Installations", sub-section (a) Licensing and Inspections".

Detailed rules for this surveillance function are set out in the Decree of the Council of Ministers of 11 January 1988 [Dz. U. No. 4, poz. 30].

The Principal Inspector and the other inspectors examine the documentation relating to nuclear safety and radiation protection submitted by applicants in licensing proceedings, provide opinions on the siting of nuclear plants and waste disposal facilities, review training programmes for employees in nuclear installations and give periodic reports on the nuclear safety and radiation protection situation in the country.

Part 7 of the Act deals with training and health protection of workers in the nuclear industry. Workers may only carry out activities involving nuclear materials, sources of ionising radiation or radioactive waste if they have adequate knowledge of nuclear safety and radiation protection requirements, in light of their position. Medical examinations are required to ensure that the worker is suitable for the post and training programmes must be organised periodically to educate workers on nuclear safety and radiation protection issues. The training programmes must be submitted to the President of the NAEA for approval [Section 32]. The Minister for Health and Welfare is responsible for establishing the general content and principles of the training programme for persons responsible for ensuring protection against ionising radiation in X-ray centres [Section 33(4)]. The Act also requires medical surveillance of workers likely to be exposed to ionising radiation, and provides for compulsory systematic dosimetric readings as part of this surveillance [Section 34].

The standards for such medical surveillance and dosimetric recordings in the workplace are set out in the Regulation of 25 January 1988 of the President of the NAEA [Mon. Pol. No. 6, poz. 59]. Under that Regulation, the results of measurements concerning the level of exposure for individuals must be kept for at least 30 years after termination of the work involving exposure to ionising radiation. Similarly, the results of atmospheric dosimetric measurements taken at the workplace must be kept for at least 30 years, unless such results have been handed over to the state nuclear safety and radiation protection surveillance body.

The relevant radiation dose limits are set out in the Regulation of 31 March 1988 of the President of the NAEA [Mon. Pol. No. 14, poz. 124]. These dose limits are for workers employed under conditions where there is a likelihood of exposure to ionising radiation and for persons residing in the neighbourhood of ionising radiation sources, including nuclear installations.

The Appendices to the Regulation of 31 March 1988 set out the formulas used to calculate the applicable dose limits under the Regulation. Generally, to identify ionising radiation hazards for workers, there is an annual limit on intake corresponding to one of the following:

- overall effective dose equivalent of 50 mSv;
- 150 mSv for lenses of the eyes;
- 500 mSv for other tissues or organs, including skin (when assessing skin exposure reference is made to a skin surface not exceeding 10 sq. cm).

There are more stringent dose limits specified for women workers up to 45 years of age and for workers generally between 16 and 18 years of age.

The dose limit for a 12-month period for those residing in the neighbourhood of ionising radiation sources, including nuclear installations, is 1 mSv.

In 1965, Poland ratified the 1960 ILO Convention No. 115 on Workers Protection against Ionising Radiation. As a result, the international safety standards for radiation protection and their amended versions were implemented in Poland. The present law is based on the 1994 Basic Safety Standards for Protection against Ionising Radiation and for the Safety of Radiation Sources (BSS) as approved by the IAEA. The recent revision of the BSS is the basis for bringing the existing regulations in Poland into line with European Union directives. In 1995, the President of the NAEA issued regulations on permissible levels and intervention measures in respect of radon concentrations in the air in dwelling places.

In 1995, an Act was passed amending several pieces of legislation, including the Atomic Energy Act of 1986, in order to establish more severe sanctions for breach of the rules on nuclear safety and radiation protection through the performance of regulated activities without a valid licence or through illegal possession of nuclear materials [Dz. U. No. 104, poz. 515].

In 1996 the Act was amended twice:

- On 2 February 1996 [Dz. U. No. 24, poz. 110], Section 10 of the Act was deleted and Section 9(1) was modified. The latter section was modified to allow workers, in the event of an accident, to refuse to obey an order requiring them to participate in tasks which could cause them to receive more than the permitted dose of ionising radiation under that section. Section 10, which was deleted, previously provided that there was no maximum dose limit for volunteers taking part in emergency operations following a radiological accident. The Act no longer permits such exposure and is in line with international standards.
- On 8 August 1996 [Dz. U. No. 106, poz. 496], Section 63 was amended to empower the Minister for Defence, the Minister for the Interior and Administration and the Office for National Security, in agreement with the President of the NAEA, to determine the principles and rules for applying the Act to enterprises and institutes under their control and which are engaged in the use of atomic energy.

7. Radioactive Waste Management

Part 5 of the Act sets out the general framework for the regulation of radioactive waste. Radioactive waste from the manufacture, conversion, temporary or final storage or use of nuclear materials and radioactive sources, and from the operation and decommissioning of nuclear installations, must be treated in such a way as to prevent their constituting a risk to persons or the environment [Section 26(1)].

Radioactive waste must be registered at the place where it is produced or stored, and the rules governing the classification of waste, its characterisation and registration, and the conditions for its treatment and storage are determined by rules made by the President of the NAEA [Section 26(4)]. Licences for the construction and operation of radioactive waste repositories are granted by the President of the NAEA [Section 27(1)]. Pursuant to an amendment of 24 June 1994 [Dz. U. No. 90, poz. 418], the President of the NAEA ruled upon the National Radioactive Waste Repository by Regulation of 2 September 1994. This repository is to be used for the final storage of all radioactive waste produced in Poland [Section 27(a)]. The 1994 amendment to the Act provided that the local council on whose territory the National Radioactive Waste Repository is located is entitled to an annual payment from the National Atomic Energy Agency budget. The payment is fixed under the Act at the level of 200% of the local council income obtained in the previous year by virtue of property tax, adjusted for inflation [Section 27(b)].

The rules governing classification, registration and conditions for treatment and storage of the waste, referred to in Section 26 of the Act, are set out in the Regulation of 19 May 1989 of the President of the NAEA [Mon. Pol. No. 18, poz. 125].

At the international level, Poland ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter on 23 January 1979.

8. Non-Proliferation and Physical Protection

For details of the system for registration and monitoring of nuclear materials and radioactive sources, see Section 3(b) and (c) of this study.

Poland is party to the following international conventions, treaties and agreements dealing with non-proliferation and physical protection in the nuclear field:

- 1968 Treaty on the Non-Proliferation of Nuclear Weapons (ratified on 12 June 1969);
- Safeguards Agreement with the IAEA (ratified in 1972; published in INFCIRC/179);
- 1979 Convention on the Physical Protection of Nuclear Material (ratified on 5 October 1983); and
- 1996 Comprehensive Nuclear Test Ban Treaty (ratified on 25 May 1999);

Poland is also a Member country of the Nuclear Suppliers Group (NSG – London Club) and, as a result, observes the NSG guidelines set out in IAEA publication INFCIRC 254/rev.2/Part 1 and Part 2 (export and import control by the state, as laid down by the Act of 2 December 1993; see below).

As discussed *supra*, under Section 5 "Trade in Nuclear Materials and Equipment", an Act of 2 December 1993 provides for special control rules for the import, export and transit of certain goods and technologies in accordance with international agreements concluded by Poland [Dz. U. No. 129 of 24 December 1993].

Under the Act, the physical protection of nuclear materials is the responsibility of the organisational unit to which a licence has been granted to manufacture, convert, store, use and trade in those materials [Section 21(1)]. The President of the NAEA is required to establish the rules governing physical protection by the licensee of nuclear materials. These rules are made in agreement with the Minister for Industry and Trade, the Minister for Internal Affairs, the Minister for Foreign Affairs and the Minister for Transportation and Maritime Administration [Section 21(2)]. They are set out in the Regulation of 6 June 1988 of the President of the NAEA [Mon. Pol. No. 20, poz. 181].

Pursuant to the Regulation of 6 June 1988, the licensee is required to establish an "Industrial Guard" with watchmen to control access to those places in which the nuclear materials are located. The nuclear materials must be guarded and escorted when moved and details of the exact date, place and conditions for the transfer must be established between the suppliers, receivers and carriers of the nuclear material. The nature and extent of physical protection will vary according to the categorisation of the nuclear materials as defined in the Appendix to the Regulation. There are three categories within this Appendix, of which Category I nuclear materials are subject to the strictest safety measures in line with the Regulation.

Physical protection during transport for nuclear materials in quantities smaller than those falling into Category III, and for natural uranium, are governed by separate regulations relating to the carriage of hazardous materials, or measures adopted under separate regulations relating to the protection of goods during their manufacture, processing, application and storage.

9. Transport

Part 6 of the Act deals in particular with the transport of nuclear materials and radioactive sources and waste. Licences to transport nuclear materials and radioactive sources are granted by the President of the NAEA. The nuclear materials must be prepared for transport and transported in such a way as to prevent any possibility of a self-sustained fission reaction [Section 29]. To the extent that they are not regulated by separate provisions, the conditions for the safe transport of nuclear materials and radioactive sources and waste are determined by the Minister responsible for the mode of transport in question, in agreement with the Minister for Internal Affairs and the President of the NAEA [Section 30]. The radiation doses to which persons involved in the transport operation are exposed must be monitored and must not exceed the dose limits specified under the Act [Section 30(3)].

As discussed above under Section 8 "Physical Protection", the Regulation of 6 June 1988 of the President of the NAEA contains specific provisions to ensure the safety during transport of nuclear material falling into one of the three categories set out in the Appendix to that Regulation. Category I nuclear materials (2 kg or more of unirradiated plutonium; 5 kg or more of unirradiated ^{235}U where enriched by 20% or more in ^{235}U; or 2 kg or more of unirradiated ^{233}U) have the highest security measures and are required to have a separate vehicle in the case of road transport, a special train in the case of rail transport or a special aircraft in the case of transport by air.

The conditions and requirements applying to transport within the site of the entities which produce, store or use nuclear materials or radioactive sources and waste are to be specified by the President of the NAEA in the licence for the activity authorised.

10. Nuclear Third Party Liability

Poland acceded to the 1963 Vienna Convention on Civil Liability for Nuclear Damage and the 1988 Joint Protocol on the Application of the Vienna Convention and the Paris Convention on 23 January 1990. The legislative provisions to meet its obligations under the Convention were already largely in place under Part 8 of the Act, although there are provisions in the Convention which are not specifically addressed under the Act. As a matter of basic principle, however, the Act, like the Convention, channels liability for nuclear damage to the operator of a nuclear installation [Sections 36(1) and 39(1)].

In the event of nuclear damage occurring during the transport of nuclear materials, the operator sending the material remains liable for third party damage until the material is handed over to the consignee [Section 37(1)]. When nuclear damage occurs during international transport, third party liability lies solely with the operator sending the nuclear material or the operator to whom the material was delivered, depending on the terms of the consignment agreement. If the agreement makes no such provision, the consignor retains liability until the nuclear materials are handed over to the authorised person at the border of the state in which the package is to be delivered [Section 37(2)].

The operator of a nuclear installation, or consignor when appropriate, is not liable for nuclear damage if the damage results from an act of war or exclusively from an intentional fault on the part of the victim [Section 38]. In such a case, the operator, or the consignor when appropriate, has a right of recourse against the persons whose intentional fault caused the damage.

Compensation for nuclear damage includes:

- for the victim, losses suffered as a consequence of personal injury or damage to health, or as a result of the destruction or deterioration of property, or, for other persons, losses suffered as a result of the death of the victim;
- earnings the victim could have made had he not suffered the damage; and
- the essential expenses which have been or will be incurred following the accident, in order to prevent persons and the environment from being exposed to ionising radiation [Section 39(2)].

The compensation for nuclear damage also covers compensation for damage to common property following damage to the environment. The State Treasury is entitled to request compensation for such damage and any compensation obtained shall be paid into the Environmental Protection Fund *(Fundusz Ochrony Srodowiska)* [Section 39(3)].

The operator of a nuclear installation is required to take out third party liability insurance against nuclear damage. Under the Regulation of 26 August 1986 of the Minister for Finance [Mon. Pol. No. 28, poz. 201], the State Enterprise for Insurance (*Panstwowy Zaklad Ubezpieczen* – PZU) is appointed as the sole authorised insurer in Poland for civil liability for nuclear damage. The insured party must pay 0.5-1% of the value of the coverage as a premium. If the nuclear damage suffered by any person exceeds the compensation provided by insurance, the victim may request

payment from the State Treasury of the excess amount. The Council of Ministers are to determine the method of compensating damage to property and the environment in excess of the insurance cover [Section 40].

There is no time limit for the right to compensation for nuclear damage suffered by persons, while the right to compensation for nuclear damage to property or the environment is subject to a prescription period of ten years from the date on which the accident occurred [Section 41(1)].

To the extent not covered by Part 8 of the Act, the provisions of the Civil Code apply to liability for nuclear damage [Section 42]. Similarly, the provisions of Part 8 of the Act do not prejudice the application of other provisions on benefits for work-related accidents or occupational diseases [Section 43].

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities

a) National Atomic Energy Agency (NAEA)

The National Atomic Energy Agency – NAEA (*Panstwowa Agencja Atomistyki*) is the governmental agency responsible for the use of nuclear energy in Poland. As such, it is responsible for the co-ordination and control of activities related to the research and safe use of nuclear energy, safeguards for nuclear materials, storage of radioactive waste, education and information of the public, as well as international co-operation in the field of nuclear energy.

The NAEA is directed by its President, who is appointed by and reports to the Prime Minister under the terms of the Atomic Energy Act of 1986. The President of the NAEA is assisted by an advisory body, the Atomic Energy Council.

The NAEA was established under the Act [Part 9] and its powers and responsibilities, as well as those of its President, have been defined by various decrees and regulations made pursuant to the Act. In particular, the NAEA powers and functions, along with those of the President of the NAEA, are detailed in the Decree of the Council of Ministers of 23 February 1987 [Dz. U. No. 9, poz. 55].

The President of the NAEA has a particularly important role under the legislative scheme, particularly in relation to the granting of licences and the overall supervision of the nuclear sector [Section 47]. The President is responsible for governmental supervision of all aspects of the peaceful uses of atomic energy related to nuclear safety and radiation protection. He is responsible for radiological emergency preparedness and for decontamination measures. In the event of a radiation emergency, the President puts the emergency plan into operation and establishes protective zones around nuclear facilities. He also supervises the control over foreign trade in and transit through Polish territory of nuclear materials and equipment. The President, in co-operation with the Minister for Foreign Affairs, co-ordinates international relations in the field of the peaceful and safe use of atomic

energy. He represents the Government of Poland in the governing bodies of specialised international organisations.

b) Minister for Health and Welfare

The Minister for Health and Welfare is responsible under the Act for making regulations laying down the conditions for the safe application of ionising radiation for medical purposes [Section 13(1)]. Pursuant to the Act, the President of the NAEA, in agreement with the Minister, establishes the dose limits for ionising radiation, including the permissible emission of ionising radiation by everyday articles [Section 13(2)]. The Minister for Health and Welfare lays down the conditions applying to X-ray centres and the rules governing work and training involving the use of X-ray equipment [Section 22(3) and 33(4)].

c) Minister for Transportation and Maritime Administration

The President of the NAEA, in agreement with the Minister for Transportation and Maritime Administration (as well as with the agreement of the Minister for Industry and Trade, the Minister for Internal Affairs and the Minister for Foreign Affairs) establishes the rules governing the registration, surveillance and physical protection of nuclear materials [Section 21(2) of the Act]. Similarly, the President of the NAEA, in agreement with the Minister for Transportation and Maritime Administration (as well as with the agreement of the Minister for the Economy) lays down the conditions for the import into, export from and transit through Poland of nuclear materials, radioactive sources and devices incorporating such sources.

2. Advisory Bodies

Atomic Energy Council

The Atomic Energy Council is an advisory body which assists the President of the National Atomic Energy Agency by providing its opinion on questions relating to the NAEA's activities [Section 49]. It comprises a chairperson appointed by the Prime Minister on the recommendation of the President of the NAEA, together with members of the Council appointed by the President of the NAEA.

3. Research Institutes

a) Central Laboratory for Radiological Protection

The Central Laboratory was founded by Regulation No. 164 of 13 July 1957 of the Prime Minister. Its Statute was approved by the President of the NAEA on 12 February 1993. Its main activities include supervision and control of radiation hazards, the scientific research programme in radiation protection, the formulation of standards on radiation protection and safe handling of radioactive sources, the personal dose monitoring service. It also serves as an Emergency Service Centre and an International Contact Point of the early warning system, in the event of a nuclear accident.

b) Institute of Atomic Energy

The Institute was founded by Regulation No. 31 of 13 December 1982 of the Prime Minister. Its Statute was approved by the President of the NAEA on 29 January 1993. Its main activities include VVER reactor safety studies, fuel and structural material studies for gas-cooled reactors, analysis of nuclear safety and radiological protection, processing of radioactive wastes and production of equipment applied in reactor technology.

c) Institute of Nuclear Physics

The Institute was founded by decision of the Council of Ministers of 20 July 1960. Its Statute was approved by the President of the NAEA on 7 April 1992. It is responsible for conducting research in high and low energy physics, condensed matter physics, accelerator techniques and applied nuclear physics.

d) Institute of Nuclear Chemistry and Technology

The Institute was founded by Regulation No. 31 of 13 December 1982 of the Prime Minister. Its Statute was approved by the President of the NAEA on 14 July 1992. Its main fields of activity include material studies, studies on the use of radioisotope instruments and research and studies in the areas of radiochemistry, radiobiology and health protection, chemical engineering, metallurgy, hydrology and environmental protection.

e) Institute for Nuclear Studies

The Institute was founded by Regulation No. 31 of 13 December 1982 of the Prime Minister. Its Statute was approved by the President of the NAEA on 8 October 1996. Its main fields of activity include basic and applied physics and work on nuclear electronic instrumentation and nuclear apparatus.

f) Radioisotope Centre

The Centre was founded by Regulation No. 8 of 18 September 1989 of the President of the NAEA. Its Statute was approved by the President of the NAEA on 30 May 1997. The activities of the Centre consist of production of radioactive materials for biochemical and industrial purposes and research work in the fields of radioimmunology, radioactive preparations, ionising radiation sources, metrology and analysis.

g) Institute of Plasma Physics and Laser Microfusion

The Institute was founded by Regulation No. 44 of 25 July 1975 of the Prime Minister. Its Statute was approved by the President of the NAEA on 1 July 1993. Its main fields of research are basic and applied sciences in the nuclear field.

PORTUGAL

I. GENERAL REGULATORY REGIME

1. Introduction

There is no single framework Act governing the nuclear sector in Portugal; instead, a series of laws, regulations and decrees contain detailed provisions governing nuclear activities. Responsibility for these activities is shared between the Ministry for Economic Affairs, the Ministry for Health and the Ministry for the Environment and Natural Resources.

The institutional framework for nuclear activities in Portugal has undergone a number of successive changes, the most recent of which took place in 1998. These changes are summarised below.

The Ministry for Industry was reorganised in 1977, with new departments being created and others closed down, including the *Junta de Energia Nuclear* (JEN) [Decree-Law No. 548/77 of 31 December 1977]. The tasks of the JEN were re-distributed both amongst existing departments and new bodies created for that purpose [Order No. 126/78 of 31 May 1978]. The latter included the Protection and Nuclear Safety Bureau (*Gabinete de Protecção e Segurança Nuclear* – GPSN), the National Industrial Engineering and Technology Laboratory (*Laboratorio Nacional de Engenharia e Tecnologia Industrial* – LNETI), and the General Directorate for Energy (*Direcção Geral de Energia* – DGE), all of which were placed under the responsibility of the Ministry for Industry. In 1996, another reorganisation took place: the Ministry for Industry and Energy and the Ministry for Trade and Tourism were merged together to form the Ministry of Economic Affairs.

The LNETI was reorganised in 1979, by Decree-Law No. 361/79 of 1 September 1979, following which it was transformed into a public institute, the National Industrial Engineering and Technology Institute (*Instituto Nacional de Engenharia e Tecnologia Industrial* – INETI) by Decree-Law No. 240/92 of 29 October 1992.

In 1995, control over INETI and the DGE was transferred from the Ministry for Industry to the Ministry for Economic Affairs [Decree-Law No. 296/95 of 17 November 1995].

In 1987, the GPSN was transferred to the Ministry for the Environment and Natural Resources [Decree-Law No. 329/87 of 23 September 1987]. Following the reorganisation of the Ministry for the Environment by Decree-Law No. 189/93 of 24 May 1993, the GPSN was merged with other directorates into a new General Directorate for the Environment (*Direcção Geral do Ambiente* – DGA). Under the provisions of this same Decree-Law the Department of Radiological Protection and Safety of INETI was also transferred to the DGA.

Under Decree-Law No. 10/93 of 15 January 1993, the General Directorate for Fundamental Health Care (*Direcção Geral dos Cuidados de Saúde Primários*) and the General Directorate for

Hospitals were merged into a single directorate, the General Directorate for Health (*Direcção Geral de Saúde*). The Statute of this new general directorate was established by Decree-Law No. 345/93 of 1 October 1993.

Finally, Decree-Law No. 122/93 of 16 April 1993 restructured the General Directorate for Geology and Mines into a public institute, the Institute for Geology and Mines (*Instituto Geologico e Mineiro* – IGM).

For consistency, these bodies will generally be referred to by their new names in this study.

The main legislative instruments regulating nuclear activities are as follows: the above-cited Decree-Law No. 548/77, Decree-Law No. 49.398 of 24 November 1969 which lays down the licensing system for nuclear activities, Decree No. 487 of 5 December 1972, adopted in implementation of Decree-Law No. 49.398, which provides specifically for the licensing of nuclear power plants, Decree-Law No. 348/89 of 12 October 1989 setting out the framework for radiation protection as implemented by Decree No. 9/90 of 19 April 1990 and amended by Decree No. 3/92 of 6 March 1992 and, to a certain extent, Decree-Law No. 186/90 on environmental protection of 6 June 1990.

2. Mining Regime

In Portugal, a number of decree-laws have been issued since 1950 to regulate the prospecting for and exploitation of radioactive ores, and in 1955, the Minister for Finance was authorised by decree-law to fix export taxes for radioactive materials and their concentrates [Decree-Law No. 37.986 of 27 September 1950; Decree-Law No. 40.135 of 20 1955].

Decree-Law No. 426/83 of 7 December 1983 and Decree No. 34/92 of 4 December 1992 regulate radiation protection and environmental impacts in respect of uranium mining activities. The 1992 Decree sets out the radiation protection standards to be applied to such activities [Chapter III]. This Decree, which repeals Decree No. 78/84 on the same subject, was adopted to take into account more recent international radiation protection standards. It sets out the obligations of persons in charge of such activities [Section 6] and those of workers performing such activities [Section 7]. It specifies that any unnecessary exposure to radiation or contamination of the environment must be avoided; it also provides that such exposure levels must be as low as possible and in any event always below the limits fixed by the national radiation protection standards [Section 9]. All mining projects or related treatment and recovery facilities must be for approved by the Institute for Geology and Mines [Section 43].

Two Decisions define, respectively, the rules to be complied with when concluding contracts for the prospecting and exploitation of radioactive ore deposits and for the licensing of bodies engaged in such activities [Decisions Nos. 2 and 3 of 19 March 1971 of the JEN Presidency].

According to Decrees Nos. 348/89, 34/92, 187/93, 189/93 and 345/93 the responsible authorities for uranium mining and related activities are the Institute for Geology and Mines, the General Directorate for Health and the General Directorate for the Environment.

3. Radioactive Substances, Nuclear Fuel and Equipment

Activities involving production of and trade in radioactive substances and nuclear fuel are regulated by Decree-Law No. 49.398 of 24 November 1969.

The Institute for Geology and Mines (*Instituto Geologico e Mineiro* – IGM) is responsible for controlling the production of and trade in nuclear fuel for industrial uses [Order No. 126/78 of 31 May 1978, Section 1 and Decree No. 7/93 of 19 March 1993, Section 2].

The import, production, use and transport of radioactive substances and radiation-emitting equipment are subject to prior authorisation by the General Directorate for Health, in accordance with the conditions laid down by Sections 6, 7 and 8 of Decree-Law No. 348/89 and Section 34 of Decree No. 9/90 of 19 April 1990.

In accordance with Decree No. 9/90 [Section 35] substances and apparatus whose radioactivity does not exceed certain levels specified in Annex II of the Decree are exempted from prior authorisation or licensing; such exemptions do not apply to radioactive substances for medical or diagnostic purposes or to radioactive substances added to toys, cosmetics or household products [Section 36 as amended by Decree No. 3/92 of 6 March 1992].

The import and export of concentrates of radioactive substances, the fabrication, import and export of nuclear fuel, the treatment of and trade in irradiated fuel and other activities of an industrial nature are subject to licensing [Decree-Law No. 49.398, Sections 1 and 2]. Licences are issued for a limited period on a case-by-case basis, upon proof that the establishment concerned has the necessary technical knowledge and financial resources. Its premises are subject to inspection by the competent authorities, being the regional delegations of the Ministries for Economic Affairs, Health and the Environment**.** In addition, contracts whose purpose is the establishment, modification or transfer of associations concerned with the above activities are subject to ministerial approval [Section 4].

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

The licensing and operation of nuclear installations in Portugal are governed by Decree-Law No. 49.398 of 24 November 1969 which lays down the licensing system for all nuclear industrial activities. Decree-Law No. 487 of 5 December 1972 made in implementation of Decree-Law No. 49.398, sets out the licensing procedure for nuclear power plants. Decree-Law No. 48.568 of 4 September 1968 establishes the nuclear installations inspection regime. (These provisions are not, however, applied at present as there are no nuclear power plants in Portugal).

The General Directorate for Energy (*Direcção Geral de Energia* – DGE) under the Ministry for Economic Affairs and the General Directorate for the Environment (*Direcção Geral do Ambiente* – DGA) under the Ministry for the Environment and Natural Resources, are the authorities responsible for the licensing, operation and inspection of nuclear installations [Decree-Law No. 548/77, Section 7].

According to Decree No. 487/72 [Section 1], nuclear power plants must be established in compliance with Decree-Law No. 49.398 of 1969. The licensing procedure takes place in three stages, each one of which results in delivery of a preliminary licence for site approval, construction and operation, respectively.

The application for a preliminary licence for site approval must contain all the information required to assess the technological, economic and safety aspects of the installation concerned, and the local population must be informed of the application by notification in the Official Gazette [Sections 2

and 3]. When a preliminary licence is granted, the applicant must then apply for a construction licence and attach a preliminary safety report [Section 6]. Requests for a construction licence are examined from the viewpoint of the design of the facility, construction techniques, etc. The operating licence is then issued on the basis of a final safety report.

Nuclear facilities must be inspected regularly, in accordance with the provisions of Decree-Law No. 48.568 of 4 September 1968. The inspections are scientific and technical and are intended to check the effectiveness of radiation protection and nuclear safety measures. The DGA is the authority in charge of inspections from the viewpoint of nuclear safety [Decree-Law No. 425/91, Section 1].

The General Directorate for Health, with the support of the General Labour Inspectorate and technical assistance from other bodies is responsible for inspections and controls from the radiation protection point of view [Decree No. 9/90, Section 54].

At the international level, Portugal is a Party to the 1994 Convention on Nuclear Safety which was ratified on 20 May 1998.

b) Protection of the environment against radiation effects

Act No. 11/87 of 7 April 1987 on the environment provides the basis for the environmental policy in Portugal. Section 25 of the Act deals with radioactive substances and specifies that control of any contamination likely to be caused by such substances should be undertaken as follows, with a view to preventing its effects on the health and welfare of the population:

- the effects of radioactive substances on ecosystems should be assessed;
- disposal limits should be set for chemical and physical radioactive effluents resulting from activities involving extraction, transport, conversion and use of radioactive substances;
- preventive measures should be established to respond immediately to any radioactive contamination;
- the effects of transfrontier contamination should be assessed and monitored;
- rules should be set governing the transit, transfer and deposit of radioactive substances on the national territory, in the territorial seas and the exclusive economic zone.

Decree-Law No. 186/90 of 6 June 1990 was made in implementation of Council Directive 85/337/EEC on assessing the effects of certain public and private projects on the environment. It provides that approval of nuclear power plant projects and other nuclear reactor projects, as well as radioactive waste repositories, is subject to a prior environmental impact assessment [Section 2 and Annex I]. Decree No. 38/90 of 27 November 1990, made in implementation of the Decree-Law, specifies the procedure to be followed for environmental impact assessments. Prior to any licence being granted, the licensing authority, according to the type of project being assessed, must be provided with an environmental impact study of the planned project. The authority competent to direct the study is designated by order of the Minister for the Environment and Natural Resources [Section 3]. The study must include, *inter alia*, a description of the project, its site, operational characteristics, physical, geological, hydrogeological, ecological, and demographic data, as well as information on the quality of the environment (water, soil, etc.) [Section 2]. The public is consulted on the study and must provide its views within a given time limit [Section 4].

c) Emergency response

Decree No. 9/90 of 19 April 1990 provides for emergency response in case of an accident or emergency. In the context of the radiation protection plan for installations to be submitted to the General Directorate for Health, the person responsible for the installation involved must include a plan of action in the event of accidental exposure to radiation or emergency situations in accordance with the intervention plan specified in the Decree [Section 7]. The General Directorate for Health, on its own initiative or on proposal of the competent authority, the General Directorate for the Environment, and following consultation with the National Radiation Protection Commission, establishes intervention plans including measures to be adopted in emergency or accident situations likely to involve abnormal radiation levels for workers and members of the public [Section 46(1)]. Those measures must take into account radiation protection rules so as to be fully effective [Section 46(2)]. In an accident situation, the General Directorate for Health immediately informs the competent authorities, namely the Civil Protection Office, on the methods of intervention in terms of personnel and equipment it considers necessary for protecting public health [Section 46(3)].

Where the magnitude of the accident so warrants, the competent authorities inform the Community Member States likely to be affected by its occurrence [Section 46(4)].

Portugal is a Party to the 1986 Convention on Early Notification of a Nuclear Accident, which was ratified on 30 April 1993.

5. Trade in Nuclear Materials and Equipment

The regulations on trade in nuclear materials and equipment in Portugal can be found in Decree-Law No. 375/90 which provides for the physical protection of nuclear materials on the national territory. As already mentioned, the Decree-Law designates the General Directorate for the Environment (*Direcção Geral do Ambiente* – DGA) as the competent authority regarding physical protection matters [Section 3].

Accordingly, the import, manufacture, possession, purchase, sale or transfer of nuclear material, as well as its transport whether national or international when it takes place on the national territory, are subject to prior licensing by the DGA, without prejudice to the competence assigned to other authorities [Section 3].

Also, Decree No. 9/90 on radiation protection provides that the import of radioactive materials and that of equipment emitting radiation for scientific, medical or industrial purposes as well as for any activity involving the production of ionising radiation requires a prior licence from the General Directorate for Health following consultation of the National Radiation Protection Commission [Section 34].

In accordance with Decree-Law No. 72/91 on medical products and equipment for human use, the marketing of medical products containing radionuclides requires a licence from the Ministry of Health, following consultation with the General Directorate for Pharmaceutical Questions [Sections 2 and 30]. Applications for such licences are described in Section 6 “Radiation Protection” *infra*.

6. Radiation Protection

The radiation protection of workers and the public is governed by several texts. In particular, Decree-Law No. 348/89 of 12 October 1989, which establishes the National Radiation Protection Commission as an advisory body to the General Directorate for Health, sets out the institutional framework for radiation protection. Decree No. 9/90 of 19 April 1990, made in implementation of Decree-Law No. 348/89 [Section 15], establishes the basic principles of radiation protection applicable to occupationally exposed persons, to individuals and to the public at large. It implements Council Directives 80/836/, 84/467/ and 84/466/Euratom which contain basic radiation protection standards and lay down safety measures for radiation protection of persons undergoing medical treatment. Radiation protection provisions are also to be found in Decree No. 34/92 relating to uranium mining and related activities, referred to under Section 2 "Mining Regime" *supra*.

Decree-Law No. 348/89 provides that the rules and directives laid down therein and made in its implementation apply to all activities likely to involve exposure to ionising radiation and radioactive contamination, in particular in radioactive and nuclear installations, and during the exploitation of radioactive minerals and the production, treatment, handling, use, storage, transport and disposal of radioactive substances and radiation-emitting equipment [Section 1].

As mentioned above, the Decree-Law provides that the General Directorate for Health within the Ministry for Health is responsible for radiation protection on the national territory [Section 2] and sets up a National Radiation Protection Commission to advise the General Directorate on radiation protection matters and related legislation [Sections 4 and 5]. The operation of radiation-emitting devices or equipment is subject to a prior licence delivered by the General Directorate for Health [Section 7].

Decree No. 9/90 defines the duties of persons responsible for installations or activities likely to involve exposure to radiation [Sections 3-6]. In particular, they must submit to the General Directorate for Health, for approval, a radiation protection plan to be applied in their installations or which will cover their activities, as the case may be; the plan must include measures for regular control of all radiation protection devices [Section 7].

Nuclear third party liability is also covered by some special provisions of the Decree-Law No. 153/96 of 10 August 1996 concerning the use of sealed radioactive sources. Under these provisions licence holders are strictly liable for damage caused to persons, to property and to the environment by a sealed radioactive source, even if they have complied with applicable legal requirements [Section 3].

The Decree makes a distinction between occupationally exposed persons, individual members of the public and the population as a whole [Section 2] and provides for different annual dose limits according to each category as specified in annex [Section 31]. The annual dose limit for occupationally exposed persons is 50 mSv (5 rem), while that for members of the public is 5 mSv (0.5 rem) [Annex IV].

The Decree allows certain exemptions from the prior licensing requirements provided under Section 7 of Decree-Law No. 348/89 [Section 36]; these exemptions are listed in Annex II. Decree No. 3/92 of 6 March 1992 amends Section 36, specifying that such exemptions do not apply to radioactive substances administered for diagnosis, research or treatment or to foodstuffs, medical products, household articles, cosmetics or toys containing radioactive substances.

Order No. 53/71 of 3 February 1971, approving general health and safety regulations for workers in industrial facilities provides that premises where radioactive substances or radiation-emitting devices are used, handled or produced must comply with the special safety regulations in force [Section 28].

As explained under Section 2 "Mining Regime" *supra*, Decree No. 34/92 of 4 December 1992 regulates radiation protection in uranium mining and related activities. Persons in charge of such activities must submit to the General Directorate for Health the protection and safety plan to be applied in their installations, or which will cover their activities, as the case may be; in particular, the plan must include measures for regular monitoring of radiation protection devices. Such persons must also inform workers of the possible risks and the measures to be complied with to avoid exposure to radiation, and ensure that they are observed [Section 6]. For their part, workers must comply with such measures and use the equipment and dosimeters provided for their protection; they must also take every precaution to keep such equipment in good condition [Section 7].

This Decree also calls for an administrative service to ensure compliance with the safety provisions required by the Decree as well as with specified radiation levels [Section 27]. The Radiological Protection Service must be made up of at least one technician specialised in radiation protection who will co-ordinate the Service, one physician and one ventilation specialist [Section 28].

Decree-Law No. 72/91 of 8 February 1991 lays down regulations for the manufacture, marketing and quality control of medical products and apparatus for human use. The regulations take account of a series of Directives on this subject issued by the European Community and establish a licensing system for medical products and apparatus, including those containing radioisotopes [Section 4].

The manufacture of medical products containing radioactive substances and their marketing is subject to prior licensing [Sections 30-32]. In addition to information to be provided in licence applications for all medicines (*e.g.* information on the applicant, composition of medicine, intended use, etc.), applications for licences to market irradiating apparatus must also contain a general description of the system and the qualitative and quantitative characteristics of the radioactivity released [Section 31]. The Decree-Law provides that its provisions are without prejudice to the application of the radiation protection legislation in force [Section 35].

Decree-Law No. 36/95 of 14 February 1995 implements into national law Council Directive 89/618/Euratom of 27 November 1989 on informing the general public of the health protection measures to be applied and steps to be taken in the event of a radiological emergency.

Decree-Law No. 153/96, adopted on10 August 1996, regulates activities involving the use of sealed radioactive sources which could pose a risk of ionising radiation exposure or of radioactive contamination, so as to ensure the protection of the public and of the environment (published in *Diario da Republica*, 30 August 1996).

Persons responsible for the possession, use, transport and import of sealed sources must submit a request for a preliminary licence to the General Directorate for the Environment in accordance with the prescribed conditions of this Decree and the criteria set forth jointly by the Ministers for Health, Environment and Science and Technology or on the advice of the General Directorate for Health. A public register of all licensees is to be kept.

7. Radioactive Waste Management

Decree-Law No. 348/89 of 12 October 1989 provides that the storage and disposal of radioactive products or waste require a licence from the General Directorate for Health, following consultation with the National Radiation Protection Commission [Section 8].

Decree No. 9/90, which implements Decree-Law No. 348/89, specifies the principles governing radioactive waste management. It provides that the disposal and storage of radioactive waste must be planned in such a way as to avoid or reduce its dispersal into the environment, whether under normal or emergency conditions [Section 44]. Furthermore, in order to obtain a licence from the General Directorate for Health, the applicant must submit an environmental impact assessment, information on the planned radiation protection and nuclear safety measures and operations as well as storage conditions, whether temporary or final [Section 45(1) and (2)]. The General Directorate for Health grants a licence, provided that all the radiation protection and nuclear safety measures it has approved have been complied with, and also fixes a dose limit for radioactive releases, taking into account the need to keep radioactivity levels in the environment as low as possible [Section 45(3) and (4)].

In accordance with Decree No. 34/92 of 4 December 1992 on radiation protection in uranium mining and related activities, products resulting from prospecting deposited in slag heaps must be monitored to control their radioactivity levels; adjacent areas must also be monitored so as to detect the quantity of radionuclides released into bodies of water, sediments or the air [Section 64(1)]. Premises where radioactive residues from uranium treatment are stored must be kept in such a way as to ensure that dust releases are reduced to a minimum [Section 64(2)]. Repositories for radioactive waste must be established in accordance with the most recent recommendations of the International Atomic Energy Agency. Plans for repositories must provide guarantees that they will remain stable for periods running from 200 to 1 000 years, taking into account extreme technical and meteorological phenomena [Section 65(1)]. The disposal into the environment of radioactive materials from facilities for the treatment of ores and uranium recovery must be carried out in compliance with the radiation dose limits set by the General Directorate for the Environment (*Direcção Geral do Ambiente* – DGA) [Section 67].

Also, Order No. 16/90 of 21 August 1990 provides for the treatment of solid hospital residues of all types. It specifies that radioactive waste must be disposed of in accordance with the regime established by Decree-Law No. 348/89 and Decree No. 9/90 [Section 3(5)].

Decree-Law No. 138/96 of 25 July 1996 aims to incorporate into Portuguese domestic law Council Directive 92/3/Euratom on the monitoring and control of shipments of radioactive waste between Member States, as well as their entry into and exit from the European Community (published in *Diario da Republica*, 14 August 1996). The Decree describes in detail the licensing procedure for each import, export or shipment of radioactive waste within the Community, between a third country and the Community, or between two third parties where part of the shipment crosses the territory of a Member State of the Community. The DGA is, in principle, the agency with jurisdiction to grant licences and to define the transfer of procedures. Permission may be given to return waste resulting from the reprocessing of irradiated fuel to the country of origin where such fuel originated in that country or it was agreed in advance by the parties that such waste would be returned.

Finally, Portugal is a Party to the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and other Matter, which it ratified on 14 April 1978.

8. Non-Proliferation and Physical Protection

Portugal has no domestic legislation on non-proliferation. However, it is a Party to the 1968 Treaty on the Non-Proliferation of Nuclear Weapons, which it ratified on 15 December 1977, and has concluded the subsequent safeguards arrangement with the International Atomic Energy Agency on 7 August 1978 [IAEA INFCIRC/272]. Also, Decree-Law No. 425/91 of 30 October 1991 designates the Bureau for Nuclear Protection and Safety (*Gabinete de Protecção e Segurança Nuclear* – GPSN) as the authority competent in safeguards matters [Section 1].

Portugal is also a Party to the 1979 Convention on the Physical Protection of Nuclear Material, ratified on 6 September 1991. Following the adoption of Presidential Decree No. 14/90 of 15 March 1990 authorising ratification of the Convention, Decree-Law No. 375/90 of 27 November 1990 designates, in accordance with the Convention, the GPSN as the competent authority in relation to physical protection matters [Section 2].

9. Transport

The Regulations for the Transport of Dangerous Goods [Order No. 977/87 of 31 December 1987] deal with radioactive substances under Class 7, in accordance with the recommendations of the International Atomic Energy Agency.

Decree-Law No. 210-C/84 of 29 June 1984 and Orders No. 686/88 and 695/88 of 14 and 15 October 1988 lay down provisions for the transport of radioactive substances by road.

Decree-Law No. 348/89 provides that the regulations on radiation protection in force apply to the transport of radioactive substances [Section 1]. Decree No. 9/90, made in implementation of this Decree-Law specifies that the transport of radioactive materials requires a licence delivered by the General Directorate for Health, following consultation of the National Radiation Protection Commission [Section 34].

Conditions for the safe transport of fresh or spent nuclear fuel and for the transport of radiation sources for nuclear installations as well as radioactive waste from such installations must be assessed and examined by the General Directorate for the Environment [Decree-Law No. 425/91, Section 3(e)].

Decree-Law No. 72/91 on medical products and apparatus for human use specifies, as regards medicines containing radionuclides and irradiating apparatus, that they must be packed in accordance with the requirements set out in the International Atomic Energy Agency's Regulations for the Safe Transport of Radioactive Materials, and that their labels must indicate their levels of radioactivity [Section 33].

10. Nuclear Third Party Liability

Portugal has not yet enacted specific nuclear third party liability legislation. However, Decree-Law No. 348/89 on radiation protection provides that the person responsible for installations, equipment or materials emitting ionising or non-ionising radiation is liable for damage resulting from their use, unless it is proved that at the time the damage was caused, the installations, equipment or materials had been used in conformity with the technical rules in force and were in perfect condition, or the damage was due to a case of force majeure [Section 10]. Such persons, with the exception of the

state or public entities, must cover their liability through an insurance company authorised to operate in Portugal, in accordance with regulations to that effect, to be established by decree [Section 11].

At international level, Portugal is a Party to the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy, which it ratified on 29 September 1977.

II. INSTITUTIONAL FRAMEWORK

In Portugal, responsibility for the control and management of nuclear activities is vested in the Minister for Economic Affairs, the Minister for the Environment and Natural Resources and the Minister for Health as mentioned in Part I of this Study. Decree-Law No. 358/76 of 14 May 1976 provides for the general organisation of the Ministry for Industry and Energy and also provides for greater involvement of the state in such matters. Based on that Decree-Law, Decree-Law No. 548/77 of 31 December 1977 set up new departments within the Ministry and closed down others, in particular the *Junta de Energia Nuclear*.

Order No. 126/78 of 31 May 1978 reorganised the energy sector, in particular to combine nuclear energy with the overall energy sector and to merge nuclear activities with other industrial and research activities.

1. Regulatory and Supervisory Authorities

a) Minister for Economic Affairs

The Minister for Economic Affairs is responsible for nuclear policy in Portugal. He is empowered to prepare and propose the energy and industry plan within the general national development programme; he supervises and directs the management of public and nationalised companies in the industry and energy sector, without prejudice to the competence of other ministers concerned, and he promotes research and development in that sector as well as agreements on technical and scientific co-operation; he also controls activities in the industrial and energy sectors [Decree-Law No. 358/77, Section 1].

More generally, he makes proposals in respect of industrial and technological policy and is responsible for the implementation of these policies in the framework of the general policy determined by the government [Sections 3 and 15]. The minister may also establish specialised institutes under his authority in order to encourage industrial and energy development. In addition, he has established within his Ministry a number of research and development services in the nuclear field, covering *inter alia* nuclear physics and instrumentation, reactors, nuclear fuel, radioisotopes, radiochemistry and radiobiology [Ordinance No. 204/79 of 16 July 1979].

b) Minister for Health

The Minister for Health is competent for all questions of radiation protection through the General Directorate for Health [Decree-Law No. 348/89, Section 2]. The Minister is empowered to make regulations in his field of competence [Decree-Law No. 10/93 of 15 January 1993, Section 1].

c) Minister for the Environment and Natural Resources

The Minister for the Environment and Natural Resources is empowered to make regulations in his field of competence, which includes uranium mining activities [Decree No. 34/92 of 4 December 1992] and physical protection [Decree-Law No. 375/90 of 27 November 1990]. The Minister is also the supervisory authority over the General Directorate for the Environment, which now includes the ex-GPSN. Through that Directorate, he is responsible for ensuring compliance with nuclear third party liability guarantees and safeguards (IAEA) as well as for radioactive waste management requirements. The Ministry of the Environment and Natural Resources was reorganised in 1993 by Decree-Law No. 187/93 of 24 May 1993.

d) Minister for Finance

The Minister for Finance is generally competent, together with the Minister for Economic Affairs, for financing public industrial activities [Decree-Law No. 40.135 of 20 April 1955], and for establishing customs duties in connection with radioactive ores and products made therefrom.

As regards the National Uranium Enterprise (*Empresa Nacional de Urânio* – ENU), the Minister for Finance, jointly with the Minister for Economic Affairs had originally fixed by decree the authorised capital of the Company [Decree No. 490/76 of 23 June 1976], before it was transformed into a private limited company (see *infra*, under Section 3 "Public and Semi-Public Agencies").

In connection with the National Industrial Engineering and Technology Institute (*Instituto Nacional de Engenharia e Tecnologia Industrial* – INETI), the Minister for Finance and the Minister for Economic Affairs are empowered to establish by order the conditions of operation of the INETI Administrative Board [Decree-Law No. 361/79 of 1 September 1979, Section 13].

2. Advisory Bodies

a) National Radiation Protection Commission (CNPCR)

The National Radiation Protection Commission (*Comissão Nacional de Protecção contra Radiações* – CNPCR) was set up within the General Directorate for Health by Decree-Law No. 348/89 [Section 4]. It has an advisory task and is made up of representatives of the following:

- the General Directorate for Health, which holds the chair;
- the General Directorate for the Environment;
- specialists in nuclear medicine, radiology, radiotherapy and dermatology from departments at the Faculty of Medicine;

- the General Directorate for Hygiene and Safety at Work.

The CNPCR advises the General Directorate for Health on all questions within its competence. The Chairman of the CNPCR may set up working groups made up of members of the Commission and other specialists to study and assess specific questions in its field [Section 4(4)].

b) Commission for Radiological Protection and Nuclear Safety

Decree-Law No. 311/98 of 14 October 1998 established the Commission for Radiological Protection and Nuclear Safety (*Comissão para a Proteccão Radiologica e Segurança Nuclear*) whose principal objective is to minimise risks to public health and to the environment as a result of ionising radiation, radioisotopes and nuclear installations.

This Commission comprises representatives from the three ministries competent in this field, namely the Ministry for the Environment, the Ministry for Health and the Ministry for Science and Technology.

The Decree-Law entrusts the Commission with the following duties:

- to draft bills and regulations in the above-mentioned sectors;
- to verify compliance with conditions set out in licenses for the storage, production or transport of radioactive material and equipment or for nuclear installations which generate radioactive residues or nuclear waste;
- to guarantee the respect of international obligations related to radiological protection and nuclear safety;
- to co-operate with similar bodies working in these fields in other countries and with the competent international organisations;
- to assist in the preparation of national radiological and nuclear emergency plans.

Technical assistance is provided to the Commission by the Technological and Nuclear Institute (*Instituto Technológico e Nuclear* – ITN), through its Department of Radiological Protection and Nuclear Safety. This Department was formerly part of the General Directorate for the Environment, before its transfer to the ITN pursuant to Section 4 of Decree-Law No. 311/98 mentioned above. The tasks assigned to this Department are listed in the Decree-Law and are of a strictly technical nature in order to guarantee its complementarity with the Commission's duties.

3. Public and Semi-Public Agencies

The different departments under the Ministries for Economic Affairs, Health and Environment and Natural Resources enjoy a certain extent of autonomy and, in view of their responsibilities, it is appropriate to discuss them in this part of the study.

a) General Directorate for Energy (DGE)

The General Directorate for Energy (*Direcção Geral de Energia* – DGE), previously under the authority of the Ministry for Industry and Energy [Decree-Law No. 548/77, Section 7], is now under the authority of the Ministry for Economic Affairs [Decree-Law No. 296/95 of 17 November 1995]. It covers the operational aspects of the overall energy sector, namely, the production, transport, distribution and use of various forms of energy, including nuclear energy. The DGE was reorganised by Decree No. 7/93 of 19 March 1993, and its tasks were redefined as follows:

- to encourage the preparation of legislation governing activities in its field of competence;
- to establish the technical conditions for facilities and equipment which produce, use, transport or store energy products, and contribute to the preparation of appropriate technical regulations, taking into account environmental aspects;
- to license activities related to the production, transport and distribution of electricity.

The DGE is run by a director general and an administrative board. Its services include a Nuclear Energy Division which is responsible for keeping under review the technical and economic tendencies in the development of fuel and equipment for nuclear power plants, and the problems in the field of radioactive waste management. To this effect, the Nuclear Energy Division must in particular [Section 15];

- maintain up-to-date information on the nation's uranium reserves and the situation of nuclear fuels on the world market;
- prepare studies on the technical development of nuclear power plants;
- ensure that Portugal's rights and obligations under international treaties in the nuclear field are observed;
- encourage information of the public on nuclear matters.

b) Institute for Geology and Mines (IGM)

As explained in Part I, Section 1 "Introduction" *supra*, the General Directorate for Geology and Mines was restructured into the Institute for Geology and Mines (*Instituto Geologico e Mineiro* – IGM) by Decree-Law 122/93 of 16 April 1993. The IGM is under the authority of the Ministry of Economic Affairs and is generally responsible for the management of mineral resources [Decree-Law No. 548/77, Section 7]. In particular, it is responsible for prospecting for, inventorying and assessing radioactive ores [Decree-Law No. 122/93 of 16 April 1993, Section 18].

c) General Directorate for the Environment (DGA)

As explained in Part I, Section 1 "Introduction" *supra*, Bureau for Nuclear Protection and Safety (*Gabinete de Protecção e Segurança Nuclear* – GSPN) merged with other departments into the General Directorate for the Environment (*Direcção Geral do Ambiente* – DGA) [Decree-Law No. 189/93]. Section 19 of this Decree-Law specified that further regulation was not necessary for this purpose.

Hence, the following paragraphs describe the activities of the ex-GSPN which subsequently became the DGA, as originally provided by Decree-Law No. 425/91 of 30 October 1991.

The DGA is placed under the authority of the Ministry for the Environment and Natural Resources [Decree-Law No. 425/91]. It is responsible for safety assessments, controls and inspections of the peaceful uses of nuclear energy, as well as for monitoring the environment for radioactivity [Section 1].

The following tasks have been assigned to the DGA [Section 2]:

- assessment and examination of the radiological impact of nuclear and radioactive installations, including radioactive waste management and extraction and treatment of radioactive ores;
- assessment and examination of the safety of nuclear and radioactive installations;
- ensuring that nuclear third party liability guarantees and non-proliferation safeguards are complied with;
- collaboration with national and international authorities in radiation emergency responses;
- promotion and establishment of the laws and regulations required to fulfil its tasks.

The DGA has also been designated as the competent authority for the physical protection of nuclear materials [Decree-Law No. 375/90 of 27 November 1990, Section 2].

In fulfilment of its tasks the DGA must in particular [Decree-Law No. 425/91, Section 3]:

- elaborate proposals for regulations, national standards and technical rules in its area of competence;
- give its opinion on radiological impact studies required by the law;
- give its opinion on safety assessments and quality controls for nuclear installations, materials, systems and components;
- carry out inspections and supervision and propose the corrective measures required to guarantee protection of workers and the public against the risk of exposure to radiation;
- assess and inspect the safety conditions for the transport of fresh or spent nuclear fuels;
- ensure that monitoring of radioactivity in the environment is carried out;
- promote co-operation with foreign institutions of the same type and specialised international agencies and act as the national representative in groups or committees in its area of competence;
- ensure compliance at the national level with the international commitments undertaken by Portugal in the fields of third party liability for nuclear or radioactive damage, physical protection of nuclear material and safeguards;

- participate in the preparation of international agreements for scientific and technical co-operation in its area of competence;

- inform public opinion and interested national or foreign agencies about the country's radio-ecological status, whether in normal conditions or in case of an accident.

d) National Industrial Engineering and Technology Institute (INETI)

The National Industrial Engineering and Technology Institute (*Instituto Nacional de Engenharia e Tecnologia Industrial* – INETI), previously under the authority of the Ministry for Industry and Energy [Decree-Law No. 548/77], is now under the authority of the Ministry for Economic Affairs [Decree-Law No. 296/95 of 17 November 1995]. It incorporates the Nuclear Energy and Engineering Institute, formerly the Research Centre of the JEN.

As already explained, the National Laboratory of Industrial Engineering and Technology was merged into the above Institute (INETI) by Decree-Law No. 240/92 of 29 October 1992. Order No. 592-A/93 of 15 June 1993 sets out the internal organisation and operation of the Institute.

i) Legal Status

The INETI is an institute for technological research and development which provides support to the different industrial sectors in the ambit of the Ministry of Economic Affairs [Section 24]. It is endowed with the status of a separate legal entity, owns property and enjoys administrative and financial autonomy [Decree-Law No. 361/79 of 1 September 1979, Sections 1 and 2].

ii) Responsibilities

The responsibilities of the INETI are the following [Decree-Law No. 548/77, Section 24]:

- to undertake applied research in accordance with the objectives of the national programme;

- to provide technological assistance to industrial undertakings, with a view to improving manufacturing processes and supplying innovative techniques;

- to provide the analytical assistance required for quality control of products and related inspection and technical surveillance;

- to collect, co-ordinate and disseminate information of interest to the ministerial services and undertakings concerned;

- to train specialists in techniques of interest to the different industry sectors.

In particular, the INETI co-ordinates and carries out research and development programmes and projects directly related to industrial development, through contracts with industrial undertakings or in association with national or international bodies [Decree-Law No. 361/79, Sections 5 and 6]. INETI is also responsible for promoting, participating in and ensuring co-operation with similar foreign and international agencies in the technological, energy and industrial fields, and participates in international scientific and technical co-operation agreements [Ordinance No. 172/79].

iii) Structure

The INETI is made up of institutes, technical and scientific services, central services and regional delegations [Order No. 592-A/93, Annex, Section 4].

The governing bodies of INETI are the Board of Management, the Technical Board and the Inspectorate [Section 2].

iv) Financing

In addition to funds allotted from the general state budget, the revenue of INETI is derived from remuneration for services supplied to public and private undertakings as well as income from property and profits from patented inventions.

e) Technological and Nuclear Institute (ITN)

Decree-Law No. 324-A/94 of 30 December sets up the Technological and Nuclear Institute (*Instituto Technológico e Nuclear* – ITN) to replace the Nuclear Energy and Engineering Institute (ICEN).

i) Legal Status

The new Institute has the status of a separate legal entity and was given scientific, technical, administrative and financial autonomy under the supervising authority of the Ministry for Land Planning and Administration. Following the establishment of the thirteenth Portuguese constitutional government in 1995, supervision over ITN was transferred to the Ministry for Science and Technology [Decree-Law No. 296-A/95 of 17 November 1995].

ii) Responsibilities

The ITN is, in particular, responsible for:

- promoting and undertaking scientific research and technical development in the peaceful applications of nuclear energy;
- providing scientific and technical assistance to the government when implementing its policies on nuclear safety, pharmaceutical and meteorological control, as well as in the application of both radioisotopes and ionising radiation;
- organising and undertaking training in the above fields;
- ensuring technology transfers to public and private agencies;
- establishing exchanges with national, international and foreign institutes pursuing the same objectives; and

- studying and implementing bilateral and multilateral co-operational programmes in its field of competence.

iii) Structure

The structure and internal organisation of ITN are to be established by decree.

iv) Financing

The ITN is financed in two ways: partly through the General State Budget that allocates funds yearly, and partly through the incomes from the supply of services to public and private organisations (see Decree-Law No. 324/94 of 30 December 1994, Sections 1 and 5).

f) National Uranium Enterprise (ENU)

i) Legal Status

Originally the National Uranium Enterprise (*Empresa Nacional de Urânio* – ENU) was a public corporation pursuant Decree No. 67/77 of 6 May 1977 which established this Enterprise. However, Decree-Law No. 376/90 of 30 November 1990 of the Minister for Economic Affairs converted it into a private limited company, with the majority of shares held by the state [Section 1]. It retains its legal personality and the rights and obligations it held when it was converted [Section 2].

ii) Responsibilities

According to its Statute [Decree-Law No. 376/90, Annex, Chapter I, Section 3], the purpose of ENU is to prospect for uranium and other nuclear ores, market those substances and provide related services and supplies, study the advantages of other natural and energy sources and related activities.

iii) Structure

The governing bodies of ENU are a General Assembly, made up of its shareholders which hold voting rights (one hundred shares equal one vote), a board of directors, made up of a chairperson, and a maximum of six members and a board of controllers made up of one chairperson, two members holding voting rights and an alternate member, elected by the General Assembly [Statute of the ENU].

The General Assembly examines the reports of the board of directors and the board of controllers, and studies the application of measures requested; it elects from among the shareholders and other persons the directors and members of the board of controllers. It may furthermore authorise the setting up of companies and deals with any business for which it has been convened, within the limits of its legal attributions [Statute of the ENU, Section 10].

The General Assembly is convened and chaired by the Chairperson of the Assembly's Bureau, made up of the chairperson and vice-chairperson and a secretary, elected by the General Assembly [Section 11(1)]. It is convened at thirty days' notice, and has a specific agenda [Section 11(2)]. It meets at least once a year; extraordinary meetings are held if the board of directors or the board of

controllers consider it necessary, or at the request of shareholders representing at least 20% of the authorised capital [Section 12]. Decisions are adopted by a majority of the votes present or represented [Section 10(2)].

The board of directors is responsible for managing the assets of ENU and may acquire or sell all ENU's physical or real property, represent ENU in court proceedings, set up companies or participate in established ones, set up the technical and administrative organisation of the Enterprise and internal operating rules, determine salaries of personnel, etc. [Statute of the ENU, Section 14(1)].

The board sets the dates and frequency of its ordinary meetings; extraordinary meetings are held at the request of the chairperson or that of two directors or two members of the board of controllers [Section 16(1)].

The board of controllers may be assisted by experts or auditors nominated specifically for this purpose. Its decisions are adopted by a majority of the votes expressed, the majority of members being present; the chairperson has a casting vote [Statute of the ENU, Section 19]. Every three months, the board of controllers must send to the Ministries for Finance and Economic Affairs a report on the controls carried out, the anomalies detected and the differences noted as compared to the estimates [Decree-Law No. 376/90, Section 6(2)].

On 2 October 1992, ENU was merged with the holding company entitled Development Mining Enterprise (*Empresa de Desenvolvimento Mineiro* – EDM).

iv) Financing

The authorised capital of ENU is set at Portuguese Escudos (PTE) 1 billion at present entirely subscribed by the state and made up of one million shares, each with a nominal value of PTE 1 000 [Statute of the ENU, Section 4]. The board of directors may increase the authorised capital up to a maximum of PTE 3 billion [Section 5].

SPAIN

I. GENERAL REGULATORY REGIME

1. Introduction

After the end of World War II, Spain was aware that nuclear energy production would play an important role in the next decade, and therefore set up a public body, entitled *Junta de Energía Nuclear* (Nuclear Energy Commission) by a Decree-Law of 22 October 1951, with full powers over nuclear matters. At the same time, Spain extended its legislation in the field of atomic energy and in particular, on 29 April 1964, adopted the Nuclear Energy Act [Act No. 25/1964]. This is a framework Act, allowing the introduction and development of a general programme of action in the nuclear field.

Since the early 1970s or so, the Spanish authorities have been amending the previous legal and institutional regime. The nuclear sector was reorganised by separating research from industrial and commercial activities of nuclear energy [Decree No. 2967 of 7 December 1979, Act No. 15 of 22 April 1980, Act No. 13 of 14 April 1986]. The Research Centre for Energy, the Environment and Technology (*Centro de Investigaciones Energeticas, Medioambiantales y Tecnologicas* – CIEMAT; the *Junta de Energía Nuclear* became the CIEMAT in 1986), was given responsibility for research and development whereas the Nuclear Safety Council (*Consejo de Seguridad Nuclear)* was entrusted with tasks relating to nuclear safety control and radiation protection. The National Uranium Enterprise (*Empresa Nacional del Uranio S.A.* – ENUSA) was given responsibility for industrial activities in the nuclear fuel cycle, except for radioactive waste management, which was to be dealt with by the National Enterprise for Radioactive Waste Management (*Empresa Nacional de Residuos Radioactivos S.A.* – ENRESA).

More recently, Law No. 40 of 30 December 1994 relating to the re-organisation of the country's electricity industry confirmed the suspension of certain nuclear power plant construction projects (Lemoniz, Valdecaballeros and Unit 2 at Trillo) and recognised the right of the owners of these projects to receive compensation for the losses that they sustained. Decree No. 2202 of 28 December 1995 implemented this Law and established a mechanism for indemnifying investors affected by the moratorium.

On 27 November 1997, Parliament adopted Act No. 54 governing the electricity sector in Spain. This Act regulates all activities related to the distribution of electrical energy, in particular its production, transport, distribution and commercialisation, and international and Community-wide trade in this field. The Act sets out the principle of free enterprise in respect of the production and distribution of electrical energy. These activities must, from now on, be pursued in a manner which guarantees access to electrical energy for all interested consumers on the national territory.

2. Mining Regime

Since the adoption of the Act of 17 July 1958, referred to as the Freedom of Mining Act, radioactive ore prospecting and mining activities may be carried out by any private individual.

Until then, Spain had had a system whereby the *Junta de Energía Nuclear* held exclusive mining rights [Decree-Law of 22 October 1951, Sections 3 and 4], whilst prospecting activities remained unrestricted.

Individuals and firms wishing to prospect for and mine radioactive ores must now apply to the Ministry of Industry and Energy for a prospection licence and a mining concession. The applications are accompanied by a report drawn up by ENUSA and are governed by the general law on mining. ENUSA is responsible for supervising these activities and may submit proposals for any suitable measures to the Ministry of Industry and Energy. The Ministry keeps a record of the quantities of radioactive ores mined.

These rules do not apply to ENUSA, which has taken over the mining activities formerly carried out by the *Junta de Energía Nuclear*. ENUSA may purchase from private individuals an annual quota of radioactive ores, fixed by the Minister of Industry and Energy. Ores are classified under two categories, depending on whether or not the uranium is combined with another mineral.

3. Radioactive Substances, Nuclear Fuel and Equipment

Under Section 22 of the Nuclear Energy Act of 29 April 1964, private companies are allowed to produce and market nuclear material and equipment.

Since in theory the *Junta de Energía Nuclear* was not empowered under its own rules to carry out nuclear industrial and marketing activities, a company was set up in 1971 [Decree No. 3322 of 23 December 1971] for this purpose: the National Uranium Enterprise (ENUSA). This is a company established under private law which, among other things, is responsible for producing and constituting emergency stockpiles of nuclear substances.

The Minister of Industry and Energy authorises the manufacture of nuclear or radioactive components after examining a report drawn up by the Nuclear Safety Council [Act No. 15 of 22 April 1980, Section 3].

In relation to ENUSA, the Minister of Industry and Energy approves the standard form contracts for agreements between the company and third parties, and is consulted in respect of the sale price of nuclear substances to be applied by ENUSA [Decree No. 2967 of 7 December 1979, Section 11].

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

In Spain, there is no state monopoly for the production of nuclear power, and private industrial concerns (notably electricity-producing companies) may also become nuclear operators. The first legal instrument governing the operation of nuclear facilities appeared in 1963 as a Decree regulating industry in general [Decree No. 157 of 26 January 1963]. However, it was not until 29 April 1964,

when the Nuclear Energy Act was adopted, that special regulations concerning nuclear installations were issued. The Decree of 27 July 1968 [Decree No. 2072] establishing a licensing system for industries producing and using nuclear power was superseded by a Decree of 21 July 1972 [Decree No. 2869/1972] concerning the approval of the Regulations on nuclear and radioactive installations.

These instruments were followed by the Act of 22 April 1980 [Act No. 15/1980] setting up a Nuclear Safety Council, which is now the basic law in force, and replaces the regulatory instruments mentioned above.

"Radioactive installations" means plants and premises containing a source of ionising radiation or radioactive materials in the course of production, treatment or storage, as well as radiation-emitting equipment. These radioactive installations, which are divided into three categories according to decreasing order of danger, are subject to a prior licensing procedure whose conditions differ according to the category of the installation concerned.

The licensing procedure includes three distinct licences:

(a) a preliminary licence;

(b) a construction licence;

(c) an operating licence.

The application for a preliminary licence must provide the reasons justifying the purpose of the installation, list its general characteristics, provide a detailed description of the site selected and its environment and explain the financial aspects of the project. The application for a construction licence must include a series of documents, in particular: a general design of the installation; the procurement programme for components and materials; the analysis of the electricity market in the area affected, and the preliminary safety analysis report. The contents of this report are based on those reports which are developed in the country of origin of the main supplier and must include a reference plant against which the safety assessment is performed. Finally, the operating licence is divided into two parts. The applicant must first obtain a provisional operating licence, and then a final licence. The application must include a final safety study, the operating rules and the technical specifications of the nuclear testing programme.

As a general rule, the various types of licence required for nuclear and radioactive installations falling within the first category are issued by the Minister of Industry and Energy. Prior to issuing the preliminary licence for site approval, the Minister consults the local authorities concerned, the autonomous communities, pre-autonomy bodies or, failing this, the provinces concerned, whose opinions are forwarded to the Nuclear Safety Council. The latter draws up a report for the Minister of Industry and Energy who makes the decision. Construction and operating licences, whether provisional or final, are granted by the Minister in the light of a technical report prepared by the Council.

All the licences required for minor nuclear facilities (so-called "radioactive" installations) are granted by the Director-General for Energy, apart from those powers which are attributed to the autonomous communities [1980 Act, Section 3].

The Nuclear Safety Council has taken over responsibility for the safety of nuclear installations from the *Junta de Energía Nuclear*. Together with the competent authorities, it contributes to the

development of nuclear legislation on the subject and in particular, proposes criteria concerning emergency and physical protection plans for nuclear facilities. The inspectors of the Nuclear Safety Council monitor the safety and radiation protection of nuclear installations. The inspection work commences with the construction and assembling of the installation and continues throughout the normal operating period.

At the international level, Spain ratified the 1994 Convention on Nuclear Safety on 4 July 1995.

b) Protection of the environment against radiation effects

Environmental impact studies are becoming increasingly widespread in the industrialised countries, and Spain has, for many years, included various provisions concerning environmental protection in its legislation. Examples include the Order of the Ministry of Industry of 18 October 1976 concerning projects for new activities capable of contaminating the atmosphere and the extension of existing activities, together with the Act of 2 August 1985.

The relevant administrative procedure has been completed and strengthened by Royal Decree-Law No. 1302 of 28 June 1986 on environmental impact studies and Royal Decree No. 1131 of 30 September 1988, based on Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment. The Royal Decree-Law provides for the preparation of studies assessing the environmental impact of certain planned installations and activities [Section 1]. The installations and activities for which studies are now required are listed in the Annex to the Decree-Law: this list includes nuclear power plants and reactors (except for nuclear reactors the thermal capacity of which does not exceed 1 kW) as well as nuclear facilities for the storage and disposal of radioactive waste.

Environmental impact studies must include the following information [Decree-Law No. 1302/1986, Section 2]:

- a general description of the project and foreseeable requirements in relation to the use of the soil and other natural resources, an estimate of the type and quantities of waste and effluent produced in the course of operations or by the work concerned;

- an estimate of the foreseeable direct and indirect effects of the project on the population, fauna, flora, soil, air, water, climate, etc.;

- the measures envisaged for reducing or eliminating adverse effects on the environment;

- the environmental monitoring programme.

Studies are submitted to the competent authority within the context of the licensing procedure for the project in question, namely, the Ministry of Industry and Energy. In parallel with the procedure for informing the public [Section 3] and before adopting the administrative resolution for the construction of the installation or licensing of the activity concerned, the Ministry forwards the file to the Ministry of the Environment so that it can draw up the Environmental Impact Statement [Section 4] which is a public document. If there is a difference of opinion between this Ministry and the Ministry of Industry and Energy, the decision lies with the Council of Ministers.

c) Emergency response

An Order of 29 March 1989 approves of the Basic Nuclear Emergency Plan (PLABEN) together with the text of the Plan itself. This Basic Emergency Plan contains the instructions to be complied with when nuclear emergency plans are established at province level in accordance with the radiological criteria laid down by the Nuclear Safety Council in the event that an area is affected by an accident originating in a nuclear power plant. A State Decree of 1992 set out the characteristics of the emergency plan, entitled Basic Intervention Plan.

On the basis of a prior report by the Nuclear Safety Council and the National Civil Protection Commission, the Minister of the Interior makes any amendments required to the Basic Nuclear Emergency Plan.

A governmental representative of a province where a nuclear power plant is located is designated as the Director of the Province Plan. He is responsible for declaring emergency situations, deciding on the appropriate measures to be taken, informing the public and determining the protection measures required [Section 2.1]. At the same time, local groups are set up to deal with the emergency and co-ordinate operations.

The Basic Nuclear Emergency Plan is supplemented by Annexes which set out the different intervention levels, area limits, protection measures and transmission plans as well as a glossary of the terms contained in the Plan.

Spain ratified the 1986 Convention on Early Notification of a Nuclear Accident as well as the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency on 13 September 1989

5. Trade in Nuclear Materials and Equipment

a) General provisions

Spain is involved in nuclear trade essentially as an importer of nuclear materials.

Restrictions on the export of nuclear materials and equipment which are sensitive from the viewpoint of the non-proliferation of nuclear weapons, are not integrated into Spain's nuclear legislation. However, following Spain's membership of the European Union, the provisions concerning trade in nuclear items contained in both nuclear regulations and in general regulations are dealt with separately.

b) Patents

Provisions relating to patents, trademarks and inventions in the field of nuclear energy were included in the framework Nuclear Energy Act of 1964 as amended [Act No. 25/1964 amended by Act No. 25 of 20 June 1968].

Patent applications are filed in accordance with the normal procedure laid down by Spanish legislation on industrial property [Section 81].

Patents are issued by the Industrial Property Registration Office, following examination of a report by the CIEMAT.

On the basis of this report, the Ministry of Industry may grant exemption from the need to provide evidence of implementation and operation required by the law on industrial property, to any patent owner who has submitted a request to this effect to the Industrial Property Registration Office.

6. Radiation Protection

Radiation protection was mentioned for the first time in Spanish legislation in 1959. The Order of 22 December 1959 contains standards for protection against ionising radiation. Legislation on radiation protection has since been considerably expanded and the original Order has been amended and supplemented by Orders in 1962 and 1971 [Orders of 10 January 1962 and 9 March 1971]. General provisions concerning protection against ionising radiation have likewise been included in the Nuclear Energy Act of 29 April 1964 [Act No. 25/1964].

Royal Decree No. 2519 of 12 August 1982 approved the Regulations on protection against ionising radiation, adopted in pursuance of Nuclear Energy Act No. 25/1964. This Decree was amended in part by Royal Decree No. 1753 of 25 November 1987 in order to introduce European legal provisions on radiological protection, in particular Council Directives 80/836/Euratom of 15 July 1980 and 84/467/Euratom of 3 September 1984 laying down the basic standards for the protection of the public and workers against the dangers of ionising radiation.

In 1992, a Regulation on protection against ionising radiation [Royal Decree No. 53 of 24 January 1992] consolidated in a single instrument the regulations existing in this field, notably Decrees No. 2519/1982 and 1753/1987 mentioned above and now repealed.

These Regulations contain detailed administrative and technical provisions applicable to nuclear and radioactive installations and to the use of radiation-emitting equipment. These standards comply with the international radiation and nuclear safety regulations, in particular the recommendations of the International Atomic Energy Agency (IAEA), OECD Nuclear Energy Agency (NEA), International Labour Organisation (ILO) and World Health Organisation (WHO). They lay down the fundamental radiation protection measures applicable to persons exposed at work and to members of the public taken individually and collectively [Sections 5-14]; they contain provisions concerning medical supervision [Sections 40-46], radioactive waste [Sections 53-59], and the inspection of installations and activities representing a potential danger of exposure to radiation [Sections 60-63]. Various penalties are envisaged in the event of breach of the Regulations [Section 64]. The Regulations are supplemented by Annexes which contain definitions of radiological, biological and medical terms and by tables setting out radiation exposure limits.

The authorities responsible for ensuring implementation of the Regulations are the Minister of Industry and Energy, the Minister of Health and the Nuclear Safety Council, without prejudice to the special duties of other ministries or national agencies.

More recently, Royal Decree No. 413 of 21 March 1997 on the operational protection of workers employed by outside companies and exposed to the risk of ionising radiation during their activities in controlled areas, was adopted. This Decree was established to implement Council Directive 90/641/Euratom, and to ensure that this protective regime would apply to all workers carrying out activities in controlled areas. A Resolution of 16 July 1997, published on 4 October 1997,

was adopted by the Nuclear Safety Council in implementation of this Decree. This Resolution establishes a register of outside companies.

Radiation protection is a matter for the Nuclear Safety Council. In particular, the latter is responsible for radiation protection controls both within and around atomic facilities [Act No. 15 of 22 April 1980, Section 2]. In addition, the Directorate-General of Civil Protection, answerable to the Minister of the Interior, organises radioactivity warning networks which take the action required when any abnormal increase in radioactivity is recorded [Decree No. 53 of 10 January 1963].

The basic measures for the radiation protection of persons undergoing medical examination or treatment are contained in Royal Decree No. 1132 of 14 September 1990 which implements Council Directive 84/466/Euratom on this matter into Spanish legislation. The fundamental principle (the ALARA principle) is that all exposure to radiation for medical purposes must be kept As Low As Reasonably Achievable [Section 1]. Furthermore, all radiodiagnostic, radiotherapy and nuclear medicine facilities must be recorded in the national inventory which is kept by the Ministry for Health and Consumers to avoid unnecessary proliferation of such equipment [Section 6], in accordance with the provisions of the above Directive.

Royal Decree No. 1891 of 30 December 1991 relates to the use of X-ray equipment for the purposes of medical diagnosis. The Decree lays down the rules enabling government authorities to monitor the proper functioning of such appliances. It also takes account of Council Directive 80/836/Euratom, amended by Council Directives 84/467/Euratom, and 84/466/Euratom, referred to above. The Decree provides for a register of firms authorised to sell and maintain X-ray equipment for medical use and for a register of the equipment installed. It also sets out requirements relating to third party liability insurance, and to the qualifications and training of personnel operating the equipment.

Decree No. 2071/1995 of 22 December 1995 was enacted in order to establish procedures for implementing the two above-mentioned Decrees of 1990 and 1991, respectively. It sets out the criteria for quality control within the medical sector so as to avoid excessive exposures to both patients and workers. The verification of doses administered to patients is to be carried out according to the technical criteria set forth in Annex I to the Decree, while the levels of radiation at places of work and other places accessible to the public must comply with standards set out in Annex II.

7. Radioactive Waste Management

Under the Nuclear Energy Act of 29 April 1964, operators of nuclear and radioactive installations are required to ensure that they possess the equipment necessary to store, handle and transport radioactive waste resulting from the operation of such installations [Section 38]. Articles 2 and 57 of this Act were amended by the fourth additional provision of Act No. 54/97 in relation to the definition of radioactive waste. “Radioactive waste” means any material or product for which no future use is planned, and which contains or is contaminated by radionuclides whose concentration or level of activity exceeds the limits laid down by the Ministry of Industry and Energy.

The Radiation Protection Decree No. 2519 of 1982 also contains a number of provisions concerning radioactive waste.

In particular, it provides that installations whose activities are likely to produce significant quantities of radioactive waste must be equipped with adequate facilities for storage, treatment and

disposal of such waste. In addition, radioactive waste disposal requires an administrative permit and any operation of this type must be undertaken in compliance with the terms of the permit.

Royal Decree No. 1899 of 1 August 1984 amends Royal Decree No. 2967 of 7 December 1979 on the organisation of activities forming part of the nuclear fuel cycle, under which ENUSA was made responsible for the management of spent fuel, whereas the *Junta de Energía Nuclear* was entrusted with the permanent storage of radioactive waste. However, certain aspects, such as the storage of radioactive waste resulting from different fuel cycle processes and the dismantling of nuclear and radioactive installations, were not taken into account.

Decree No. 1899 thus authorises the National Enterprise for Radioactive Waste (ENRESA – created by Royal Decree No. 1522 of 4 July 1984, modified on 1 March 1996) to carry out the whole range of radioactive waste management activities. Moreover, companies producing nuclear energy and the operators of nuclear and radioactive installations may now call on the services of ENRESA to ensure the permanent storage, handling and transport of their radioactive waste.

The Minister of Industry and Energy approves the economic and contractual conditions of such services. It is moreover provided that the duration of the contract shall cover the operating life of the installations concerned, including dismantling.

Under Royal Decree No. 1522 of 4 July 1984, ENRESA is responsible in particular for selecting sites for the construction and operation of storage facilities for radioactive waste. But in as much as the resulting work inevitably affects the areas selected, an Order of 30 December 1988 adopted in pursuance of the above-mentioned Decree of 1984, and a supplementary Order of 1 December 1989 authorise ENRESA, within the context of its work, to provide financial assistance to the municipal councils of the communes on whose territory nuclear installations which store radioactive waste or spent fuel are located.

With respect to the financing of radioactive waste management operations, Decree No. 404 of 1 March 1996 establishes a Monitoring and Control Committee (*Comitato de Seguimiento y Control*) to take charge of the fund allocated to the management of such waste. In parallel, the Government Delegation which had been set up within ENRESA to manage the technical, economic and financial aspects of this fund has been disbanded. These functions are now, in effect, carried out for the most part by the new Committee, or alternatively, by the Ministry of Industry and Energy.

The Committee, which reports to the Ministry of Industry and Energy, is composed of a Commissioner of Accounts for State Administration, a Director-General of the Treasury and Financial Policy and a Director-General of Energy.

The management fund, which is constituted under the terms of the 1994 Law on the National Electricity System amended in 1997, will be utilised in the manner set forth in the General Plan on radioactive waste which must first receive the prior approval of the government, and then must be brought to the attention of the Parliament.

Spain ratified the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 11 May 1999. It is also a Party to the 1972 Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, ratified on 31 July 1974, and its 1996 Protocol.

8. Non-Proliferation and Physical Protection

The provisions on nuclear security contained in Nuclear Energy Act No. 25 of 29 April 1964 and in Decree No. 2869 of 21 July 1972 are quite brief.

The Ministry of Industry and Energy is kept informed of operations involving nuclear material, and keeps a register in which to record the movements of such material [Act No. 25/1964, Section 23].

Any loss, abandonment or theft of nuclear substances must be notified to the competent authorities as soon as possible [Section 40]. Offences are punishable by criminal or administrative penalties, depending on the seriousness of the offence, either by the competent department of the Ministry of Industry, the Minister himself or by the Council of Ministers when secret information relating to nuclear energy has been divulged [Sections 87 and 91].

At the international level, Spain ratified the following international instruments:

- the 1968 Treaty on the Non-Proliferation of Nuclear Weapons, on 5 November 1987;
- the 1996 Comprehensive Nuclear Test Ban Treaty, on 31 July 1998;
- the 1979 Convention on Physical Protection, on 6 September 1991.

9. Transport

The Act of 1964 on Nuclear Energy, in particular in Chapter VI, contains specific provisions on the transport of radioactive materials in general. Subsequent Decrees have completed the provisions of this Act [as amended by Act No. 25 of 20 June 1968], in respect of certain modes of transport, *e.g.* road, rail or air, to bring Spanish legislation into line with the international agreements ratified by Spain. The other transport modes – inland waterways and sea – are still governed by the original provisions of the 1964 Act.

As far as the transport of radioactive materials by **road** is concerned, Spain acceded, on 22 November 1972, to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Following this accession, several pieces of legislation were passed, including a 1973 Decree [Decree No. 2674 of 19 October 1973, as amended], implementing the ADR and determining the competent authorities. The purpose of the Order of 20 February 1985 on the international transport of dangerous goods by road was to bring up to date the text of the Decree of 1973 which provides the persons concerned by international transport with the necessary information on the procedures and formalities to be observed.

In order to meet the special needs of Spanish road transport, two Decrees were promulgated in 1976 [Decrees No. 1754 of 6 February 1976 and No. 2101 of 10 August 1976], implementing the national regulations for the transport by road of dangerous goods which contain the provisions laid down by the ADR. Decree No. 1754 was first amended by Decree No. 1999 of 29 June 1976 to take account of the amendments made in November 1977 to the ADR following the revised 1973 edition of the IAEA Regulations for the safe transport of radioactive materials, then by Decree No. 1723 of 20 June 1984.

A Regulation was adopted on 31 January 1997 in order to implement into national law the amendments made in 1993 to the Regulation on the international transport of dangerous goods by

road, which is an Annex to the 1980 Convention on international road transport. This Regulation was adopted pursuant to Royal Decree No. 879 of 2 June 1989 which enables the Minister of Public Works to amend the national regulations for the transport by road of dangerous goods to take account of modifications made at the international level which have been published in the Spanish Official Journal.

As regards **rail** transport, on 19 November 1974, Spain ratified the International Convention concerning the Carriage of Goods by Rail (CIM) and thus applies within its territory its Annex I: the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID).

As for **air** transport, Royal Decree No. 1749 of 1 August 1984 brought up to date by Ministerial Order of 28 December 1990, approved the national Regulations on the safe transport of dangerous goods by air. These Regulations, together with the detailed technical instructions accompanying them, are based on the 1981 revised version of the Dangerous Goods Annex of the Chicago Convention on International Civil Aviation. Radioactive substances are contained in class 7 of the classification of dangerous goods under the Regulations.

Responsibility for the transport of radioactive materials is shared by the Ministry of Industry and Energy and the Ministry of Transport, Tourism and Communications [Decree No. 1558 of 4 July 1977]. The Ministry of Industry is responsible for issuing licences for the transport of nuclear substances, in the light of a report submitted by the Nuclear Safety Council.

The Ministry of Industry is also responsible for issuing approval certificates and for licensing shipments of radioactive materials involving foreign undertakings [Act No. 25/1964, Section 22]. Further conditions may also be imposed by other government departments, including the Ministry of Trade. The carriers of radioactive substances or concentrates must report their activities to the Ministry of Industry, which keeps *ad hoc* records of all the information received [Section 23].

Regulations No. 2519/1982 on radiation protection provide in a supplementary section that any transport of radioactive material which is not governed by specific regulations shall be subject to the provisions of the 1982 Regulations, supplemented by the technical radiation protection standards contained in the latest edition of the IAEA Transport Regulations.

The Minister of Transport, Tourism and Communications has general responsibility for all transport [Decree No. 1558/1977, Section 11].

The Nuclear Safety Council is responsible for monitoring and enforcing safety and radiation protection requirements in the field of transport. To this effect, it helps the competent authorities to draw up criteria relating to emergency plans [Act No. 15 of 22 April 1980, Section 2].

10. Nuclear Third Party Liability

The framework Act of 29 April 1964 on Nuclear Energy laid the foundations for the rules governing nuclear third party liability [Act No. 25/1964, Chapters VII-X]. It was supplemented by an implementing Decree No. 2177 of 22 July 1967 approving the regulations on cover for nuclear damage risks, which was itself amended by Decree No. 742 of 28 March 1968 and then by Decree No. 2864 of 7 November 1968.

The basic general principle of Act No. 25/1964 is that the operator of a nuclear or radioactive installation is objectively liable for all nuclear damage up to the maximum amount of his liability

[Section 45]. However, persons using or storing radioactive materials or equipment which, according to the national standards in force, are incapable of emitting radiation representing a serious hazard, are excluded from the scope of the nuclear liability regime [Decree No. 2177/1967, Section 1].

As to the amount of liability, Section 57 of the Act of 29 April 1964 provides that the amount of the nuclear operator's liability should be reviewed if necessary to ensure that it is not lower than the amount established by the international conventions ratified by Spain and referred to below. Under this provision, the previous amount of ESP 850 million has been raised to ESP 25 billion as from 1994 [Act No. 40/1994 of 30 December 1994 on the Reorganisation of the National Electricity System]. Furthermore, a Regulation was adopted on 25 April 1997 to confirm that the two units of Almaraz NPP should be considered as one single nuclear installation. As a result of this, the two units are covered by the same insurance policy and the operator is liable for damage caused to third parties as if it were one single installation.

However, in respect of the transport of nuclear substances, for which the *Consejo de Seguridad Nuclear* judges the risk to be lesser to that in respect of nuclear installations, the Ministry of Industry and Energy may set a lower ceiling of liability, which may not in any case be less than ESP 1 billion. The legislation also provides that these liability amounts may be raised by the government, upon the proposal of the above-mentioned Ministry, either to implement Spain's international obligations or to take account of inflation, thereby effectively ensuring the same amount of financial cover.

At international level, Spain has ratified the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy on 31 October 1961 and the 1963 Brussels Supplementary Convention on 27 July 1966. It has also ratified the Brussels Convention Relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material on 21 May 1974.

II. INSTITUTIONAL FRAMEWORK

Nuclear activities are carried out in Spain under the control of various ministries, each being responsible for the area assigned to it under Spanish law. It should be noted, however, that the Ministry of Industry and Energy clearly plays a major role since it is generally responsible for enforcing existing nuclear legislation.

When the *Junta de Energía Nuclear* was set up in 1951 [Decree Law of 22 October 1951], it was the first specialised body with full powers over nuclear matters [Section 7]. Since then, as already explained, the *Junta* has been replaced by the Research Centre for Energy, the Environment and Technology (CIEMAT) [Act No. 13 of 14 April 1986]. The Nuclear Safety Council, the National Uranium Enterprise (ENUSA) and the National Enterprise for Radioactive Waste (ENRESA) also play an important role in the nuclear field.

1. Regulatory and Supervisory Authorities

a) Minister of Industry and Energy

The Minister of Industry and Energy controls the application of nuclear legislation, except for those responsibilities which are expressly assigned to other ministries [Act No. 25 of 29 April 1964, Section 3].

The Minister of Industry and Energy is the supervisory authority for CIEMAT and he appoints the members of CIEMAT either directly or on a proposal from the ministries concerned.

The National Enterprise for Radioactive Waste (ENRESA) is also under the direct supervision of the Minister of Industry and Energy, through the CIEMAT which holds the majority of the capital of ENRESA, the remainder being held by the State Company of Industrial Participation (SEPI), a public undertaking.

As far as the Nuclear Safety Council is concerned, the Minister of Industry and Energy submits proposals to the government regarding the appointment of the Council's Secretary-General. Appointments are then submitted to Parliament for approval [Act No. 15 of 22 April 1980, Section 5].

Together with the Minister of National Education or any other government department or body concerned, the Minister of Industry and Energy sets safety standards for the operation of nuclear research and training centres [Act No. 25/1964, Section 17]. To this end, the Minister of Industry and Energy has the power to carry out any inspection he deems necessary. In any case, he may limit the quantities of nuclear substances held by the said centres [Section 18].

As already stated, the Minister of Industry and Energy is responsible for classifying radioactive ore deposits [Section 21] on the basis of reports drawn up by ENUSA. On a proposal from the Minister, the Sub-Committee on Economic Affairs determines the characteristics of concentrates [Section 24].

The Minister of Industry and Energy is consulted when the terms under which ENUSA wishes to sell nuclear substances to third parties are to be fixed and approves the draft agreements drawn up for such transactions. The Minister is also responsible for determining the size of and management arrangements for the uranium reserve supplies maintained by ENUSA. Generally speaking, the Minister supervises implementation of the national plan for uranium exploration and prospecting [Decrees No. 3222 of 23 December 1971 and No. 2967 of 7 December 1979].

It is also recalled that the Minister of Industry and Energy has the power to grant licences for constructing and operating first-category nuclear installations and the Directorate-General for Energy of this Ministry is the competent body for all other licences such as those for the transport of radioactive substances and for manufacturing nuclear components, after consulting the competent authorities including the Nuclear Safety Council [Act No. 25/1980, Section 3].

Directorate-General for Energy

The Directorate-General for Energy is responsible for planning, co-ordinating and implementing Spanish electro-nuclear development, with the help of the competent bodies. It is also responsible for official procedures relating to administrative licences and, after receiving an opinion from the Nuclear

Safety Council, it issues the necessary licences other than those for first-category nuclear installations and radioactive installations, subject to those powers which are attributed to the Autonomous Communities [Section 3].

b) Minister of the Interior

The Minister of the Interior is the supervisory authority for the Directorate-General for Civil Protection.

The Directorate-General for Civil Protection is responsible for setting up an emergency warning network in the event of an increase in radioactivity on Spanish territory, especially in areas where nuclear facilities are located [Decree No. 53 of 10 January 1963].

The Minister of the Interior is responsible for drawing up and amending the basic nuclear emergency plan in consultation with the Nuclear Safety Council and the National Civil Protection Commission [Order of 29 March 1989].

c) Minister of Finance

The Minister of Finance takes decisions regarding the financing of expenditure to be met by the state under national nuclear legislation and international nuclear conventions [Act No. 25/1964, Section 68]. He approves the financial security to cover nuclear risks [Section 56].

Directorate-General of Insurance

The Directorate-General of Insurance is responsible for the Insurance Compensation Consortium, whose task is to share in covering nuclear risks should insurance companies be unable to meet the entire cost [Decree No. 2177 of 22 July 1967]. It undertakes reinsurance in accordance with directives of the Minister of Finance. The Consortium is a member of the Executive Committee of the Nuclear Insurance Pools.

A special Nuclear Risks Department has been set up under the Consortium for the purpose of insurance compensation. It is financially independent and is managed by a government committee chaired by the Director-General of Insurance. The committee meets either in plenary Session or in the form of a standing committee.

An appeal against the decisions of the Department lies to the Insurance Compensation Consortium, with the possibility of a further appeal to the Insurance Arbitration Court.

The plenary committee is responsible for applying the measures adopted for covering nuclear risks. It authorises reinsurance and pays damage in excess of ESP 1 million. The sale of assets of the Department and its expenditure must be approved by the Committee.

The Standing Committee is responsible for claims of less than ESP 1 million.

2. Public and Semi-Public Agencies

a) Nuclear Safety Council

In accordance with the guidelines of the National Energy Plan and the Resolution on Nuclear Energy adopted on 28 July 1979 by the Spanish Parliament, the Nuclear Safety Council was set up under Act No. 15 of 22 April 1980.

It is generally responsible for the regulation and supervision of nuclear installations. In this context, it therefore takes over the tasks previously carried out by the *Junta de Energía Nuclear* under the Nuclear Energy Act of 29 April 1964.

i) Legal status

Act No. 15/1980 provides that the Nuclear Safety Council is independent of government administration [Section 1]. A Royal Decree of 1982, adopted in pursuance of the Act of 1980, defines the Statute of the Council. It provides that the Council is a body governed by public law and that it enjoys legal personality and administrative and financial autonomy [Decree No. 1157 of 30 April 1982, Section 1].

The Statute of the Council was partly amended by Royal Decree No. 643 of 2 June 1989. This Decree provides for a reorganisation of the Council's work and amends Article 41 of its Statute concerning the Technical Directorate. It sets up several Sub-Directorates, under its responsibility: the Sub-Directorates for nuclear power plants, for radioactive and nuclear fuel cycle installations, for radiation protection, for analysis and evaluation and lastly, for siting and co-operation programmes at national and international level [Article 41.3(a)-(e)]. Royal Decree No. 2209/1995 of 28 December 1995 introduced a further amendment to the Statute of the Council. This Decree, published in the Official Journal on 12 January 1996 and which entered into force the day following its publication, in fact totally restructures the Technical Directorate into several general sub-divisions, each relating to a specific subject such as nuclear reactor control, the control of nuclear fuel cycle, radiation protection, etc. Furthermore, several existing sub-divisions were disbanded.

ii) Responsibilities

The Nuclear Safety Council is intended to be an independent body with exclusive jurisdiction in the field of safety and radiation protection [Act No. 15/1980, 3rd supplementary provision]. Nevertheless, it may delegate powers to the Autonomous Communities in accordance with procedures laid down by the Council itself [Royal Decree No. 1157/1982, Section 1].

The Council maintains contacts with similar bodies abroad [Act No. 15/1980 Section 2(i)] and advises the Spanish Government on the commitments it has entered into with other states or international organisations in the field of nuclear safety and protection against ionising radiation [Section 2(k)].

The Council has very extensive powers in its field of jurisdiction:

- In the field of research, the Council draws up plans concerning nuclear safety and radiation protection, and monitors their implementation [Section 2.1].

- In regulatory matters, the Council co-operates with the government to draw up or review rules concerning nuclear protection [Section 2(a)]. In collaboration with the competent authorities, it draws up and approves the criteria relating to emergency plans and those for the physical protection of nuclear and radioactive installations as well as those concerning the transport of nuclear substances and radioactive materials [Section 2(e)].

- By virtue of its administrative powers, the Council submits reports on the issuing of licences required for nuclear and radioactive installations, the transport of nuclear substances or radioactive materials and the manufacture of nuclear or radioactive components, to the Ministry of Industry and Energy before the latter takes any decisions in this respect [Section 2(b)]. In the case of site licences, the Nuclear Safety Council examines beforehand the reports prepared either by the autonomous communities or the pre-autonomous bodies, or failing this, by the provinces concerned [Section 3.3]. The opinions given by the Nuclear Safety Council must be followed when they are against the applications being granted. Any conditions contained in favourable opinions must also be complied with.

- In the field of radiation protection, the Council has the power to supervise nuclear or radioactive installations, transport and component manufacturing plants, to ensure that the safety requirements are complied with [Section 2(c)]. Where it notes that there is a safety risk, it has the right either to suspend the activities of the enterprises concerned or to propose to the Ministry of Industry and Energy that it should revoke the licence already granted. These measures may be accompanied by penalties [Section 2(d)]. Courts and government departments may consult the Council on matters concerning nuclear safety and radiation protection [Section 2(h)].

- The Council also checks on irradiation levels in the area surrounding nuclear and radioactive installations and in the areas through which nuclear or radioactive materials are transported. It monitors the cumulative doses received by persons exposed to radiation in the course of their work, and grants or renews the necessary licences [Sections 2(f) and (g)]. The Council is kept informed of incidents due to radiation and gives its opinion on the steps to be taken.

- The Council is also responsible for informing the public of its administrative activities and of matters relating to radiation protection [Section 2(j)]. Lastly, it reports each quarter to the Senate and the Chamber of Deputies on its activities [Section 11].

iii) Structure

The Nuclear Safety Council consists of a chairperson and a board composed of four members assisted by a General Secretariat.

The chairperson and the board members are appointed for a period of six years, renewable by the government, after consultation with the Minister of Industry and Energy and following a favourable opinion of at least three-fifths of the members of the competent committee of the chamber of deputies [Section 5.2].

The chairperson and members are selected in the light of their expertise in nuclear safety and radiation protection [Section 5.1]. One of the four members is appointed vice-chairperson by the board on a proposal from the chairperson, and replaces the latter in his absence.

The Secretary-General of the Nuclear Safety Council is appointed by the government on a proposal from the Minister of Industry and Energy [Section 5.3]. He takes part in the Council's meetings in an advisory capacity [Section 4.3].

The Council meets at least once a fortnight in regular session. Extraordinary sessions may be convened by the chairperson or at the request of a member of the board [Royal Decree No. 1157/1982, Section 45].

The Nuclear Safety Council recruits the necessary qualified staff and may, for the performance of specific tasks or for a set period of not more than one year, call upon persons outside the Council, both Spanish and foreign [Act No. 15/1980, Section 8].

iv) Financing

The Council's funds come from appropriations from the general state budget and from the Council's own resources. Other resources may also be allocated in some cases [Act No. 15/1980, Section 9; Royal Decree No. 1157/1982, Section 3].

The Nuclear Safety Council obtains its own funds through the levy of a special charge for services rendered, which has been established especially for this purpose [Act No. 15/1980, Section 10]. This charge is based on studies carried out by the Council in respect of the issue of licences, and on inspections relating to nuclear and radioactive installations, the transport of nuclear or radioactive substances, the manufacture of nuclear or radioactive components and type-approval of radioactive equipment [Section 10.3].

A charge is also levied on the issue or renewal of licences for operational staff in nuclear and radioactive facilities [Section 10.4]. The charge, usually paid to the competent collecting centre, is payable by persons who have applied for the said licences and permits. The entire proceeds are used to cover the cost of the services rendered by the Council on behalf of third parties.

b) Research Centre for Energy, the Environment and Technology (CIEMAT)

Under Act No. 13 of 14 April 1986 on the development and general co-ordination of scientific and technical research, the *Junta de Energía Nuclear* was replaced by the Research Centre for Energy, the Environment and Technology (CIEMAT).

The *Junta de Energía Nuclear* was set up in 1951 in the expectation of growing nuclear power applications in Spain. This body, which was to be given major technical, financial and staff resources, had been envisaged as an instrument for promoting nuclear industrial development and, to this end, had been given broad powers in this field.

Subsequently, because of the growth in nuclear activities connected with the need to meet energy requirements, and the corresponding increase in regulations to meet legitimate safety concerns, the government decided to split up the complex structures of the *Junta* into separate bodies in the nuclear field. As a result, the *Junta de Energía Nuclear* remained responsible for the tasks connected

with promotion and research relating to the peaceful uses of nuclear energy, whilst those connected with the industrial aspects of the nuclear fuel cycle were entrusted to ENUSA [Decree No. 2967 of 7 December 1979] and those relating to radioactive waste management and storage to ENRESA. Similarly, regulatory and supervisory duties for nuclear installations were transferred to the Nuclear Safety Council [Act No. 15 of 22 April 1980].

At the moment, CIEMAT, which has many activities outside the nuclear field, has taken over part of the tasks formerly carried out by the *Junta de Energía Nuclear*. Its responsibilities are set out in Royal Decree No. 221 of 14 February 1997. These principally include the promotion and development of fundamental and applied research activities, as well as the development of technology in the energy field.

i) Legal status

CIEMAT is a public body directly answerable to the Minister of Industry and Energy.

ii) Responsibilities

CIEMAT is a research centre, an advisory agency and a representative body at national and international level in the industrial sphere.

Nuclear research and development

CIEMAT has fundamental research laboratories and pilot plants in which – in agreement with the government departments concerned – it carries out fundamental and applied research. Possessing all the services required to perform its nuclear tasks, it gives technical assistance to ENUSA in the field of scientific research relating to the successive phases of the nuclear fuel cycle. It also gives advice and offers technical assistance in its sphere of competence to ENRESA, and to private industry. CIEMAT helps promote and develop nuclear energy by subsidising other Spanish research centres.

No nuclear invention may be patented without first having been the subject of a report by CIEMAT. On the basis of this report, the Ministry of Industry may grant a nuclear patent owner exemption from the need to provide evidence of implementation and operation, as required under the ordinary law of industrial property.

The general task of the CIEMAT is, in conjunction with the Directorate-General for Energy, to plan, co-ordinate and prepare the Spanish programme of action concerning nuclear energy.

CIEMAT is also one of the public research bodies responsible, under Act No. 13 of 14 April 1986 on the development and general co-ordination of scientific and technical research, for collaborating in the implementation of the national plan for scientific and technological development.

An advisory role

CIEMAT advises the government, through the Minister of Industry, on all civil nuclear problems within its jurisdiction.

In the event of a nuclear accident, CIEMAT is responsible for preparing a technical report on its circumstances. This report is used in the procedure for compensating any victims.

An expert body in the nuclear field, CIEMAT takes part in drafting nuclear legislation and submits projects concerning the development of nuclear energy applications to the Minister of Industry. Broadly speaking, when matters within its jurisdiction are being studied and put into practice, CIEMAT is always represented on joint advisory committees when these are not within the jurisdiction of the Minister of Industry and Energy.

A representative role

For matters within its remit which are not within the jurisdiction of the Ministry of Industry or other competent authorities, CIEMAT represents the government as regards implementation of nuclear provisions adopted. Within its jurisdiction, CIEMAT alone maintains official relations with corresponding foreign nuclear bodies with which it collaborates in the implementation of technical and scientific nuclear programmes. In this sphere of international relations, it acts in liaison with the Minister of Foreign Affairs.

Residual responsibilities in the industrial field

Following the reorganisation of the nuclear sector, the tasks of the former *Junta de Energía Nuclear*, notably in the fields of the nuclear fuel cycle, radioactive waste, nuclear installations and radiation protection, were transferred to ENUSA, ENRESA and the Nuclear Safety Council. CIEMAT may, however, offer technical assistance in fields within its jurisdiction.

iii) Structure

CIEMAT is administered by its chairperson [Act No.13/1986, Section 16]. A governing board is appointed in accordance with government directives.

The board is the supreme executive body of CIEMAT. It is responsible for drawing up the CIEMAT's general programme of action and the corresponding budgetary requirements. It gives its opinion on all matters referred to it.

CIEMAT is also empowered to set up all the services, divisions, sections or work centres required for its operation, such as the Auxiliary Commission for Plant Biology and Industrial Applications, responsible for centralising work on the applications of radioisotopes in agriculture. It recruits permanent staff and may also, if necessary, recruit temporary scientific or administrative staff.

iv) Financing

Contributions to the CIEMAT budget are made from both external and internal sources.

External income is received through regular and one-off grants from out of the general government budget, and from moneys from autonomous bodies, received through the government. Legal and natural persons, both Spanish and foreign, may contribute funds through gifts or subsidies. Lastly, other financial resources may be allocated to CIEMAT under contract or by judicial decision.

CIEMAT generates its own income through sales, payment for services rendered on behalf of third parties, and income from CIEMAT's shares in national and international enterprises.

In carrying out its tasks, CIEMAT may conduct all the financial transactions required for its operation. It is a shareholder in the National Uranium Enterprise and in the National Enterprise for Radioactive Waste.

c) Institute of Nuclear Studies

Following the Nuclear Energy Act of 29 April 1964 [Act No. 25/1964 amended by Act No. 25 of 20 June 1968], an Institute of Nuclear Studies was set up under the former *Junta de Energía Nuclear*, with a view to co-ordinating research and training in the nuclear field and with the objective of providing detailed instruction in nuclear sciences.

CIEMAT makes technical facilities and staff available to the Institute for the specialised training of future nuclear experts. Training at the Institute is intended merely to supplement the basic education received at universities and higher technical education establishments.

d) National Uranium Enterprise (ENUSA)

The National Uranium Enterprise (ENUSA) was set up by a Decree of 23 December 1971 [Decree No. 3322/1971] for the general purpose of assuming responsibility for the various stages of the nuclear fuel cycle, with the technical co-operation of CIEMAT.

Decree No. 2967 of 7 December 1979, amended by a Decree of 1 August 1984 implementing the guidelines of the national energy plan, widened ENUSA's scope in the nuclear fuel cycle by redefining its tasks to make them more independent of those of the former *Junta de Energía Nuclear* [Decree No. 2967/1979, Section 5.1]. The growth in the nuclear industry had made it necessary to transfer responsibilities from the *Junta de Energía Nuclear* to a unit which would efficiently secure uranium supplies for nuclear facilities.

i) Legal status

ENUSA is a state enterprise in the form of a limited liability company.

ii) Responsibilities

In general, ENUSA implements the national uranium exploration and prospecting plan [Decree No. 2967/1979, Section 5.1]. It has direct responsibility for the following tasks [Section 2]:

- prospecting and mining radioactive deposits with a view to processing ore into uranium and thorium concentrates;
- converting uranium concentrates into uranium hexafluoride;
- uranium enrichment;

- manufacturing nuclear fuel and reprocessing irradiated fuel.

The research and development activities relating to the various stages in the nuclear fuel cycle are undertaken with the technical assistance of CIEMAT.

Uranium supplies to nuclear power plants and uranium enrichment and the conversion of uranium concentrates into uranium hexofluoride are guaranteed by ENUSA.

iii) Financing

The State Company of Industrial Participation (SEPI) has a majority shareholding in ENUSA, with CIEMAT holding the remainder of the shares.

e) National Enterprise for Radioactive Waste (ENRESA)

Given the development of nuclear energy applications and the growing use of radioactive materials and the waste arising therefrom, Spain needed a body responsible for the overall management of radioactive waste, a task previously carried out in part by the former *Junta* and by ENUSA, as described above.

The National Enterprise for Radioactive Waste (ENRESA) was thus created on 22 November 1984 in pursuance of Royal Decree No. 1522 of 4 July 1984, supplemented by an Order of 30 December 1988, and has been given overall responsibility for the management of radioactive waste [Decree No. 1522/1984, Section 1].

i) Legal status

ENRESA is a state enterprise in the form of a limited liability company.

ii) Responsibilities

ENRESA is directly responsible for the following [Decree No. 1522/1984, Section 2]:

- the treatment and conditioning of radioactive waste;
- the siting, construction and operation of storage facilities (both temporary and permanent) for low, medium and high-level radioactive waste;
- the carrying out of all activities associated with the final shutdown of nuclear and radioactive installations;
- establishing procedures for the collecting, transfer and transport of radioactive residues;
- the final treatment of wastes resulting from the extraction and manufacture of ore concentrates;

- the carrying out of the technical, economic and financial studies necessary to determine the various costs associated with the management of radioactive waste, to help formulate an appropriate economic policy.

The Decree of 1984 was modified by Royal Decree No. 404 of 1 March 1996, revising the tasks to be carried out by ENRESA. This latter is, in effect, responsible for the management of radioactive waste in Spain.

ENRESA is also responsible for drawing up a permanent inventory of all radioactive waste storage facilities. This inventory will be maintained even after closure of the installation concerned [Section 6].

In case of nuclear emergency, ENRESA may be required to support the civil protection services [Section 2(e)].

Each year, ENRESA is to report to the Minister of Industry and Energy on its activities and also to submit a general plan for radioactive waste management including a review and cost analysis of technical solutions [Section 4].

ENRESA receives technical assistance and technological support from CIEMAT within its fields of competence.

iii) Financing

ENRESA's capital is constituted by CIEMAT and SEPI, an industrial public undertaking.

f) National Energy Commission

The Commission on the National Electric System, established by Law No. 40 of 30 December 1994, was replaced by a National Energy Commission pursuant to Act No. 34 adopted on 7 October 1998.

This new Commission exercises quite a wide range of powers, although its priority sectors remain the energy and fossil fuel markets. As an advisory body, the Commission is required to participate in the legislative procedure in the energy field, and in the licensing procedure for energy installations.

The Commission is a public body under the aegis of the Ministry for Industry and Energy. It is administered by a governing board made up of a chairperson and eight members. Its members are selected from amongst eminent figures, whose positions are confirmed by royal decree adopted on a proposal of the Minister of Industry and Energy.

SWEDEN

I. GENERAL REGULATORY REGIME

1. Introduction

The framework of Sweden's nuclear law is to be found in four Acts: the Nuclear Activities Act [SFS 1984:3], the Radiation Protection Act [SFS 1988:220], the Nuclear Liability Act [SFS 1968:45], and the Act on the Financing of Future Charges for Spent Nuclear Fuel [SFS 1992:1537]. The provisions of both the Nuclear Activities Act and the Radiation Protection Act lay down the general principles of the regulatory regime. These Acts are supplemented by a number of ordinances and other secondary legislation, and these contain more detailed provisions for particular aspects of the regime.

The Nuclear Activities Act replaced the Atomic Energy Act (which dated from the 1950s). It is concerned mainly with security and control considerations and with the overall safety of nuclear operations. The Radiation Protection Act, adopted in 1988, aims to protect people, animals and the environment from the harmful effects of radiation. The Nuclear Liability Act implements Sweden's obligations as a Party to the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy and the 1963 Brussels Convention Supplementary to the Paris Convention. These three Acts will be discussed in more detail under the various headings which follow. In 1998, the Act on Strategic Products [SFS 1998:397] entered into force. This Act is mainly concerned with the control of exports of nuclear material and equipment. Previously, such matters had been regulated by the Nuclear Activities Act.

In 1995, a number of amendments were made to the Swedish legislation on nuclear safety and radiation protection: two amendments stem from the entry of Sweden into the European Union, one concerns waste disposal and another concerns exports. To this extent the Nuclear Activities Act and the Radiation Protection Act were amended to conform to European Community legislation.

On 18 December 1997, the Swedish Parliament adopted the Act on the Phasing-Out of Nuclear Power [SFS 1997:13320], which entered into force on 1 January 1998. This Act formed part of the inter-party agreement on guidelines for energy policy, discussions upon which were initiated by the Swedish Government in 1995 in order to create conditions for the efficient use of energy and for a cost-effective supply of energy, thereby facilitating the creation of an "ecologically sustainable society". Further details on this Act are provided in Section 4 "Nuclear Installations" *infra*.

2. Mining Regime

The Mineral Act [SFS 1991:45], which replaced the 1974 Act on certain mineral deposits, provides that the investigation of ore deposits and working of certain minerals are subject to a special licence. This applies to numerous minerals, including those containing uranium and thorium.

3. Radioactive Substances, Nuclear Fuel and Equipment

Both the Nuclear Activities Act [SFS 1984:3] and the Radiation Protection Act [SFS 1988:220] are relevant to this topic. The Nuclear Activities Act applies to all "nuclear activities", and these include the acquisition, possession, transfer, handling, processing, transport and other dealings with nuclear material and waste [Section 1]. Generally speaking, none of these activities may be carried on without a licence issued under the Act [Section 5], although there is also provision in the Act for exemptions to its requirements [Section 2(a)]. In the event of serious breaches of the Act, criminal sanctions apply [Sections 25-29].

In addition, the Radiation Protection Act imposes obligations on people engaged in activities involving ionising radiation. Any dealings with radioactive substances or with equipment capable of generating or emitting ionising radiation can be carried on only in accordance with a licence issued under the Act [Section 20]. However, if the activity in question is also covered by the Nuclear Activities Act, the requirement for a licence under the Radiation Protection Act is automatically waived unless stated otherwise in the licence issued under the Nuclear Activities Act [Section 23].

The Act also provides that manufacturers and importers are required to provide radiation protection information about their products (by means of labelling, etc.) and to ensure that the products are fitted with appropriate radiation protection equipment [Sections 9, 10 and 11]. Those who are responsible for the handling of waste resulting from radiation activities must store and dispose of radioactive waste and discarded sources of radiation in a way that is "satisfactory from the viewpoint of radiation protection" [Sections 13 and 14].

In the event of serious breaches of the Radiation Protection Act, criminal sanctions apply [Sections 34-37] and radioactive substances or equipment used in such a breach may be forfeited [Section 40].

The Pharmaceuticals Act [SFS 1992:859] contains provisions imposing licence obligations for the manufacture, importation and sale of radioactive pharmaceuticals.

4. Nuclear Installations

Most aspects of Sweden's nuclear facilities are regulated by the Nuclear Activities Act [SFS 1984:3] (containing general provisions) and the Nuclear Activities Ordinance [SFS 1984:14] (containing more detailed rules).

The fundamental provisions of the Act state that nuclear activities are to be conducted in such a manner as to fulfil both safety requirements and Sweden's international nuclear non-proliferation obligations [Section 3]. Nuclear activities can only be conducted in accordance with a licence issued under the Act [Section 5].

a) Licensing and inspection, including nuclear safety

The Act defines "nuclear activities" to include the construction, possession and operation of a nuclear plant and the recovery, production, handling, processing, storing and final disposal of nuclear substances [Section 1]. The licensing procedure established by the Act for a new nuclear installation can be divided into the following main stages:

- the filing of the application;

- consultation of parties concerned;
- the granting of the licence;
- the granting of the construction licence;
- the granting of the operating licence.

However, it should be noted that the Act was amended in 1987 to prohibit the issue of a licence for the construction of a nuclear power reactor [Section 5(a)]. It is also relevant that licences for nuclear installations are decided upon and issued by the government. This 1987 amendment reflected Parliament's decision after a referendum held in 1980, following which the Swedish Parliament decided that no new nuclear power facilities would be constructed in Sweden, and that existing facilities should gradually cease operations. At the time this policy was announced, it was envisaged that the last power reactor would cease to operate in 2010. Therefore, the only new installations to be subject to the Act's licensing procedure will be those constructed for the handling, storage and final disposal of nuclear waste, including spent nuclear fuel. The licensing provisions also continue to apply in relation to the operation of those nuclear power facilities which had already been constructed at the time of the 1987 amendments.

As a result of the referendum held in 1980, the Act on the Phasing-out of Nuclear Power [SFS 1997:13320] was adopted in 1997 and entered into force on 1 January 1998. The Phasing-out Act gives the Swedish Government the right to revoke a permit to operate a nuclear power reactor on a date to be decided by the government. It provides that the order and timing of the closures will depend on Parliament's decision on the transformation of the energy system, and that in deciding when a reactor should be taken out of operation, due regard should be taken of its location, age, design, and its importance for the national energy supply system. The Act confirms that the licensee is entitled to compensation from the state for losses incurred due to an enforced close-down. On the basis of this Act, the Swedish Government decided on 5 February 1998 that the nuclear power reactor Barsebäck No. 1 was to close down by 1 July 1998. This decision was confirmed by the Swedish Supreme Administrative Court on 16 June 1999. The Court decided, however, that the right to operate the nuclear power reactor was not to cease before 30 November 1999.

The Act on the Phasing-out of Nuclear Power contains a mechanism for environmental impact assessments to be carried out in prescribed cases to assess the impact of a proposed plant, activity or measure on the environment or on public health [Section 5(b)]. Further details on these measures are provided in the following Sub-Section (b) "Protection of the environment against radiation effects".

The authority with major responsibility for the administration and supervision of the licensing procedure is the Swedish Nuclear Power Inspectorate (*Statens Kärnkraftinspektion* – SKI*)*. The Inspectorate is able to attach conditions relating to safety to any licence it issues under the Act [Section 8]. The Act lays responsibility for the safety of every aspect of a nuclear activity squarely with the person who is the licence-holder in respect of that activity. As well as having a general responsibility to maintain safety, the licensee is responsible for ensuring the safe handling and final storage of nuclear waste arising from the activity and the safe shut-down and decommissioning of plants in which nuclear activities are no longer conducted [Section 10].

The Act also obliges the licensee to conduct research and development work in relation to nuclear waste and the decommissioning of nuclear plants [Section 11]. The programme of research and development is to be worked out in consultation with other nuclear operators, and must be approved by the government [Section 12].

If the licensee fails to comply with conditions attached to the licence or with safety obligations arising in any other manner under the Act, the government or the Swedish Nuclear Power Inspectorate has the authority to revoke the licence altogether [Section 15]. The decision lies with the authority that has issued the licence. The Inspectorate has the power to require access to the plant or site where nuclear activities are carried out, and to obtain any information or documentation needed by the Inspectorate to carry out its function of ensuring compliance with the Act [Section 17]. The Inspectorate may give directions to a licensee in a particular situation to ensure compliance, and if the licensee fails to take the necessary action, the Inspectorate may proceed to carry out the action at the licensee's expense [Section 18]. Certain clauses in the Nuclear Activities Act concerning sanctions in the event of non-observance of its provisions were amended in 1995 to conform to those of the Euratom Treaty [Sections 18 and 27, as amended by SFS 1995:875]. Finally, the Act also contains criminal sanctions for non-compliance with its requirements [Sections 22, 25 and 25a].

Although the Swedish Nuclear Power Inspectorate carries the main responsibility and authority in relation to the operation of nuclear installations, the Swedish Radiation Protection Institute (*Statens Strålskyddinstitut* – SSI*)* also participates in inspections of installations in order to ensure compliance with the Radiation Protection Act [SFS 1988:220].

At the international level, Sweden ratified the 1994 Convention on Nuclear Safety on 11 September 1995. It is also of relevance that Sweden ratified both the 1986 Convention on Early Notification of a Nuclear Accident, on 27 February 1987, and the 1986 Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency, on 24 June 1992.

b) Protection of the environment against radiation effects

Both the Nuclear Activities Act [SFS 1984:3] and the Radiation Protection Act [SFS 1988:220] contain procedures for the carrying out of environmental impact assessments. These Acts were amended in 1998 to incorporate references to the Environmental Code [SFS 1998:808], which amalgamates 15 of the principal environmental statues into a consolidated version. The Environmental Code and its subsequent amendments entered into force on 1 January 1999. These amendments provide that certain provisions in the Environmental Code shall apply when considering matters under the Acts on Nuclear Activities and on Radiation Protection. Such provisions include the general rules of consideration, which contain common requirements for all activities that involve a general risk to human health or the environment, and the Environmental Quality Norms, which specify the levels of pollution or disturbance in respect of land, water, air or the environment in general that humans may be exposed to without any significant risk. Permits, approvals or exemptions may not be issued for a new operation that would contravene an Environmental Quality Norm, unless precautionary measures to alleviate the negative effects are taken.

Furthermore, it is mandatory to submit an Environmental Impact Statement (EIS) together with an application for a permit to construct, possess or operate a nuclear power plant. In the case of applications for permits for other matters than those mentioned, the government or the appointed authority may issue regulations calling for an EIS to be included in the application for a permit. Similarly, according to the amendment of Article 27 of the Act on Radiation Protection, the government or the appointed authority may issue regulations calling for an EIS in matters concerning conditions on radiation protection for a nuclear operation. The EIS aims to facilitate an overall assessment of the planned operation's effects on the environment, health and management of natural resources, thus providing a better basis for the decision.

5. Trade in Nuclear Materials and Equipment

Sweden's trade activities in nuclear materials and equipment are governed mainly by the Strategic Products Act [SFS 1998:397] and the Nuclear Activities Act [SFS 1984:3], as well as instruments made under these Acts. The Nuclear Activities Act's definition of nuclear activities includes, *inter alia*, the import of nuclear material and waste [Section 1] and export of nuclear materials and equipment is included in the Strategic Products Act. These activities are therefore subject to the regimes of both Acts concerning licensing, supervision and compliance. They are also subject to one of the fundamental principles of the Acts, that nuclear activities be conducted in compliance with Sweden's international obligations. Sweden ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 9 January 1970. It has also concluded bilateral agreements with its major suppliers, agreeing not to re-export material or equipment except with the approval of the original supplier. Thus, these international commitments will be taken into account in decisions about the issue of export licences.

The Nuclear Activities Act specifically forbids Sweden to receive spent nuclear fuel or other nuclear waste from another country for final disposal in Sweden [Section 5(a)]. This ban is subject to very limited exceptions. The ban is also applicable with respect to intermediate storage awaiting final disposal [Section 5(a) of the Nuclear Activities Act, as amended by SFS 1995:875].

The Ordinance on Nuclear Activities [SFS 1984:14] deals with the import of nuclear material and equipment at a more detailed level. The Ordinance provides for a hierarchy of licensing and notification, depending on the category of material or equipment to be imported.

The licensing procedure requires an application to be made to the Swedish Nuclear Power Inspectorate, which makes the decision whether to issue the necessary licence. This procedure applies to the importation into Sweden of defined quantities of uranium, plutonium and thorium [Section 16].

Finally, the Nuclear Activities Ordinance specifies various categories of importation, acquisition and use of materials and equipment which are licensed as long as advance notification is given to the Swedish Nuclear Power Inspectorate. Universities and research institutes, for example, may import natural or depleted uranium and thorium and their compounds [Section 5]; these substances may also be imported for use as counterweights in aircraft or in the production of radiation-protection screens, ceramic or glass production etc. [Sections 8 and 9]. Deuterium, tritium, lithium and their compounds may be imported if they are to be used for medical purposes [Section 6].

The export of nuclear material and equipment is governed by the Swedish legislation on strategic products, as well as by Council Regulation (EC) No. 3381/94 of 19 December 1994 and Council Decision 94/942/CFSP also of 19 December 1994, which lists in its Annex 1 export controlled dual-use goods. According to the Swedish legislation, SKI has jurisdiction to decide certain cases on the export of such nuclear material and equipment listed in Annex 1 to the above-mentioned Council Decision. In certain cases, however, permission for export is granted by the government. The ministry in charge is in this case the Ministry for Foreign Affairs.

The legislation on strategic products lists the nuclear-related products and technology which can be exported only after the Swedish Nuclear Power Inspectorate has made a recommendation to the Ministry of the Environment, which has in turn consulted with the Ministry of Foreign Affairs. The matter is then put before the Cabinet, which makes the decision whether to grant the export licence. The items come under the following headings: nuclear reactors and associated equipment; non-nuclear material for reactors (*e.g.* deuterium, heavy water); installations for processing of irradiated fuel elements and associated equipment; installations for the production of nuclear fuel cells; installations

for separating uranium isotopes and associated equipment. It also includes certain dual-use products, that is, equipment not initially designed or prepared for use in the nuclear field but which could be used for the manufacture of nuclear devices.

In the event of trade in nuclear materials or equipment in breach of the regime established under the Nuclear Activities Act, the sanctions contained in the Act (including criminal prosecution) apply. In certain circumstances the Act on Penalties for the Smuggling of Goods [SFS 1960:418] would be applicable instead.

6. Radiation Protection

On 1 July 1988, a Radiation Protection Act came into force, replacing the previous Act of the same name which dated from 1958. The 1988 Act states that its purpose is: "to protect people, animals and the environment against the harmful effects of radiation" [Section 1]. The Act establishes a system of licences and applies to both ionising radiation (radiation from gamma rays, X-rays and the like) and non-ionising radiation (optical radiation, radio-frequency radiation, ultrasound radiation, etc.) [Section 2]. However, more stringent regulation and supervision is applied to activities involving ionising radiation.

The Act's main obligations are imposed on the people who conduct activities involving ionising radiation. These activities include the manufacture, importation, transport, sale, acquisition, possession, use or dealing with a radioactive substance, and also the use of, or any dealing with, a technical device capable of generating ionising radiation [Section 5]. Generally speaking, a licence must be obtained from the Swedish Radiation Protection Institute before any of these activities can be commenced [Section 20]. The licence may be issued for a limited period, may be subject to conditions, and may be revoked if the licensee fails to comply with the Act, regulations or conditions in any significant respect [Sections 24, 26 and 28]. In 1995 the Radiation Protection Act was amended to conform to European Community legislation (the "Shipment Directive", in particular) concerning radiation protection and licensing in connection with the production, possession, use of, trade in, etc., radioactive materials [Section 20(a), as amended by SFS 1995:874].

The obligations placed by the Act on a person conducting activities involving radiation are expressed in very broad terms: to take the measures that are necessary to prevent or counteract injury to people and animals and damage to the environment; to supervise and maintain radiation protection at the site where radiation occurs; and to properly maintain all the equipment used in the radiation activities, including measuring and radiation protection equipment [Section 6]. However, there are also more specific duties owed to employees: employers must ensure that people working in radiation activities are fully informed of the risks associated with their work, and of all the regulations and conditions to be observed in carrying out the work [Section 7]. The employer must also make sure that workers are adequately trained, particularly in relation to the functioning of radiation protection systems [Section 7]. A complementary duty is placed on the employee to use the safety systems provided by the employer [Section 8].

The Act provides certain conditions for radiation protection of employees. No one under the age of 16 may do work involving ionising radiation, and special rules apply to workers aged between 16 and 18 [Section 16]. Compulsory medical examinations are stipulated for those engaged in ionising radiation work [Section 18]. The Institute is given the power to intervene to impose particular procedures for a particular kind of work, or to prohibit it altogether [Section 17].

Criminal sanctions apply in the case of serious breaches of the Act [Sections 34-37], and radioactive substances or equipment used in such a breach may be forfeited [Section 40].

Although the main supervisory responsibility in relation to radiation protection lies with the Swedish Radiation Protection Institute, this body may delegate in part to local authorities which have public health and environment protection responsibilities [Sections 29 and 30]. Where this happens, the local authorities are endowed with certain information-gathering powers, rights of access and power to give directions, so that they can enforce the Act and regulations effectively [Sections 31–33].

While the Act imposes duties and responsibilities on various groups of people in general terms, most of the details of specific aspects of the radiation protection regime are set out in two ordinances, the Radiation Protection Ordinance [SFS 1988:293], and the Ordinance with Instructions for the Swedish Radiation Protection Institute [SFS 1988:295]. The Radiation Protection Ordinance designates the Swedish Radiation Protection Institute as the government's central agency for the purposes of the Act, lists certain substances and equipment that are exempt from the requirements of the Act, and sets out topics on which the Institute may issue regulations. The Ordinance with Instructions for the Swedish Radiation Protection Institute deals with some other functions of the Institute, giving it responsibility for research and development in the field of radiation protection, dissemination of information on the subject, establishment of international radiation protection standards in the national context, and provision of advice to public authorities in the event of a nuclear accident affecting Sweden. In accordance with the Radiation Protection Ordinance, the Swedish Radiation Protection Institute has issued four regulations implementing Council Directive 96/29/Euratom of 13 May 1996. This Directive lays down basis safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. It is based on the recommendations of the International Commission on Radiological Protection (ICRP). The regulations are the following: Swedish Radiation Protection Institute's Regulations on Monitoring and Reporting of Individual Radiation Doses [SSI FS 1998:5]; Swedish Radiation Protection Institute's Regulations concerning Categorisation of Workers and Workplaces at Work with Ionising Radiation [SSI FS 1998:3]; Swedish Radiation Protection Institute's Regulations concerning Dose Limits at Work with Ionising Radiation [SSI FS 1998:4]; Swedish Radiation Protection Institute's Regulations concerning Medical Surveillance of Exposed Workers [SSI FS 1998:6].

7. Radioactive Waste Management

Management and disposal of radioactive waste is regulated principally by provisions of the Nuclear Activities Act [SFS 1984:3] and Ordinance [SFS 1984:14] and the Radiation Protection Act [SFS 1988:220] and Ordinance [SFS 1988:293].

Responsibility for the management of radioactive waste lies with the licensee carrying out the activities which produce the waste. The Nuclear Activities Act states that the licensee must ensure the safe handling and final storage of nuclear waste and the safe decommissioning and dismantling of nuclear plants which are no longer in use [Section 10]. In practice this means that the producer of nuclear waste is responsible for its collection, transport, treatment and interim storage. In addition, each person who holds a licence to operate a nuclear power reactor is specifically required to conduct research and development into the safe handling and final storage of nuclear waste, in consultation with other reactor operators. The research and development programme must cover a period of six years, is subject to government approval, and is reviewed every three years by government authorities. The government may require changes to the programme and may impose certain conditions [Sections 11 and 12].

If the operator of a nuclear facility does not comply with these obligations relating to research and development, and this non-compliance has serious implications as far as the safety of the facility is concerned, the operator's licence may be revoked [Section 15].

All activities relating to radioactive waste created in the course of nuclear power production come within the definition of "nuclear activities" under the Nuclear Activities Act [Sections 1 and 2], and therefore can only be carried on under the licensing system established by the Act. Any proposal to construct a new facility for the handling, processing, storage or final disposal of nuclear waste would be subjected to the licensing procedure (as outlined in Section 4 "Nuclear Installations" *supra*) and to the supervision and control of the Swedish Nuclear Power Inspectorate (SKI) and the Swedish Radiation Protection Institute (SSI). A final repository for low and intermediate level reactor waste – SFR facility – has been constructed at the Forsmark nuclear power plant and now operates under the terms and conditions of an operating licence which is issued by the government, but is supervised by both the Swedish Nuclear Power Inspectorate and the Swedish Radiation Protection Institute. Since 1985, the Central Interim Storage Facility for Spent Nuclear Fuel (CLAB) is in use, serving as an intermediate storage facility prior to the final disposal of the fuel. The research and development programme concerning a final repository for spent fuel is revised every three years and reported to the government through SKI. The implementation of this programme is developed in stages over a period of many years and involves SKI, SSI, and numerous other government agencies and includes consultations with the public. Plans for a final repository for spent nuclear fuel are being discussed and it is expected that important decisions will be taken within the next few years in this respect.

A separate Act deals with the question of financing the final disposal of nuclear spent fuel and waste as well as the decommissioning of nuclear reactors. The Act on the Financing of Future Costs of Nuclear Waste Management [SFS 1992:1537] requires the producers of nuclear power to pay an annual levy to the state. The amount of the levy is calculated according to the energy output of each nuclear facility and according to information provided by the producers as to the estimated costs of carrying out their legal obligations in relation to radioactive waste (*i.e.* its safe handling, storage, and research and development). The levies are paid into a fund whose assets are to be used to cover the future costs of spent fuel disposal, decommissioning of reactors and research in the field of nuclear waste. The fund is also used to cover the ongoing costs of the safe handling and storage of radioactive waste, and of the research and development programmes carried out by the producers in fulfilment of their obligations under the Nuclear Activities Act. The SKI has the responsibility for reviewing the calculations of the fees and for proposing the fee to be paid every year by operators of nuclear reactors. Until recently, the fund was managed by the National Board for Spent Nuclear Fuel but in 1992 the Board was abolished and its functions were transferred to the Swedish Nuclear Power Inspectorate.

The handling and disposal of radioactive waste that comes from activities other than nuclear power production is dealt with in the Radiation Protection Act [SFS 1988:220] and is, generally speaking, under the supervision of the Swedish Radiation Protection Institute. The Act states that people who have conducted activities involving either radiation or devices capable of emitting radiation are responsible for ensuring that any radioactive waste (or discarded radioactive source) is handled and, if necessary, stored "in a manner that is satisfactory from the viewpoint of radiation protection" [Sections 13 and 14]. The Swedish Radiation Protection Institute also issues regulations applicable to radioactive emissions from nuclear power plants, for example, the Regulations on the Limitation of Releases of Radioactive Substances from Nuclear Power Plants [SSI SF 1991:5]. The Regulations provide that releases of radioactive substances from nuclear power plants follow the ALARA (as low as reasonably achievable) principle, that releases into the water or the air be monitored, analysed and reported to the Institute, and that the Institute has various supervisory and inspection functions in relation to the waste management practices of nuclear power plants.

The importation into Sweden of nuclear waste from another country is included as a "nuclear activity" to which the Nuclear Activities Act applies. However, Sweden's policy is that every country should assume full responsibility for the nuclear waste it produces and should deal with it, and dispose of it finally, within its own borders. The Nuclear Activities Act was amended in 1995 so as to ban (with very limited exceptions) the importation of foreign spent fuel into Sweden for final disposal [Section 5(a)]. According to this amendment, the ban is also applicable with respect to intermediate storage of waste awaiting final disposal [Section 5(a)].

Through the Environmental Code [SFS 1998:808], the dumping at sea of any kind of waste, including radioactive waste, is prohibited. The rules in the Code replace the Marine Dumping Prohibition Act of 1971 [SFS 1971:1154].

It is also of note that, at the international level, Sweden ratified the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter on 21 February 1974. It furthermore ratified the 1997 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on 29 July 1999.

8. Non-Proliferation and Physical Protection

Sweden has ratified both the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (on 9 January 1970) and the 1979 Convention on the Physical Protection of Nuclear Material (on 1 August 1980). It also ratified the 1996 Comprehensive Test Ban Treaty on 2 December 1998. Sweden's obligations under these Treaties are given effect by means of several general provisions in the Nuclear Activities Act [SFS 1984:3] and wide regulation-making powers conferred on the Swedish Nuclear Power Inspectorate under the Nuclear Activities Ordinance [SFS 1984:14]. The Act states the fundamental requirements for the conduct of all Swedish nuclear activities: they are to be carried out in a manner that meets safety requirements and that honours Sweden's obligations relating to the non-proliferation of nuclear weapons and the unauthorised dealings with nuclear material [Section 3]. The Act also expressly states that one of the main methods of achieving safety in nuclear activities is to prevent unlawful dealings with nuclear material [Section 4].

At a more specific level, the Act places obligations on people who have been licensed to conduct nuclear activities to ensure that international inspectors have access to the nuclear installations and have sufficient information at their disposal in order to facilitate their task of supervising Sweden's non-proliferation obligations [Section 17].

The Nuclear Activities Ordinance gives the Swedish Nuclear Power Inspectorate the responsibility for issuing regulations dealing with the following matters:

- measures to maintain safety in nuclear activities, as required by Section 4 of the Nuclear Activities Act;

- measures to ensure fulfilment of Sweden's obligations regarding non-proliferation of nuclear weapons and unauthorised dealings with nuclear material;

- the powers to be exercised by the international observers referred to in Section 17 of the Nuclear Activities Act [Section 20(a)].

The Ordinance also gives the Swedish Nuclear Power Inspectorate the task of drafting regulations relating to the supervision and inspection of all aspects of nuclear activities (for example,

handling, processing, transport) so as to ensure that the safety requirements referred to in Sections 3 and 4 of the Act are met [Section 21].

9. Transport

The transport of nuclear material and waste is a "nuclear activity" and as such is subject to the licensing system of the Nuclear Activities Act. A licence must be obtained, and it may be subject to time limits and other conditions. The Ordinance on Nuclear Activities [SFS 1984:14] specifies that in the case of transport of nuclear material or highly radioactive waste, the Swedish Nuclear Power Inspectorate determines the question of licences after consultation with the Swedish Radiation Protection Institute about conditions that will need to be imposed in the interests of radiation protection [Section 18].

The transport of radioactive substances comes within the scope of the Radiation Protection Act [SFS 1988:220] since it is included in the list of "activities involving radiation" [Section 5]. People involved in the transport of radioactive substances are therefore subject to the general obligations of the Act (to take measures necessary to protect people, animals and the environment from radiation damage and to provide proper safety systems, training and information to the employees). They are also required to obtain a licence for transport activities [Section 20], unless the activity is subject to the licensing requirements of the Nuclear Activities Act [Section 23]. The Swedish Radiation Protection Institute is empowered to impose conditions on the licence [Section 27] and to issue regulations relating to transport licences [Section 21]. Licensees are subject to the provisions of the Act that require information and access to be given to the supervisory authority (the Institute) [Section 31], and they are of course also subject to the penalty provisions of the Act [Sections 35 to 40].

Other relevant legislation is the Transport of Dangerous Goods Act [SFS 1982:821]. However, its provisions apply to radioactive substances only to the extent that they do not conflict with the framework of rules, regulations and conditions established by the Nuclear Activities Act and the Radiation Protection Act. The Act and the Ordinance [SFS 1982:923] on the Transport of Dangerous Goods transpose the Conventions and other international agreements on the subject – International Regulations concerning the Carriage of Dangerous Goods by Rail (RID), International Convention concerning the Carriage of Goods by Rail (CIM), European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), SOLAS, the International Maritime Dangerous Goods Code (IMDG), ICAO agreements etc. – into Swedish national law.

The 1982 Ordinance designates the Swedish Nuclear Power Inspectorate as the competent authority for nuclear materials and the Swedish Radiation Protection Institute for other radioactive materials as concerns the issuing of certificates, approvals, licences etc. The regulatory authority for transport by road is the National Rescue Services Agency, for transport by sea, the Swedish Administration of Shipping and Navigation and for transport by air, the Swedish Civil Aviation Administration.

10. Nuclear Third Party Liability

Sweden is a party to the following instruments on nuclear third party liability:

- the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy and the 1963 Brussels Convention Supplementary to the Paris Convention, as amended by the two

1982 Protocols; Sweden ratified these two Conventions on 1 April 1968 and 3 April 1968 respectively;

- the 1971 Brussels Convention on Civil Liability in the Field of Maritime Carriage of Nuclear Material, which it ratified on 22 November 1974;

- the 1988 Joint Protocol relating to the Application of the Paris Convention and the Vienna Convention, which it ratified on 27 January 1992.

The national legislation which implements Sweden's obligations under these treaties is the Nuclear Liability Act [SFS 1968:45]. The Act has been amended several times to keep it in line with developments at the international level, and to make increases from time to time to the amounts of the operator's liability.

Following the Chernobyl accident in 1986, Sweden passed legislation in that year dealing specifically with compensation for those who had suffered economic loss in Sweden as a result of the accident.

The Nuclear Liability Act

This Act provides that the operator of a nuclear installation which is the source of a nuclear incident is liable to provide compensation to those who have suffered personal injury or damage to property as a result. The operator's liability is strict and exclusive. The amount of the operator's liability has been raised progressively since the Act was first passed in 1968. Originally the limit (which is specified in Section 17 of the Act) was Swedish kronor (SEK) 50 million per incident; this was increased progressively To attain the current limit (which came into effect on 1 July 1995) of Special Drawing Rights (SDR) 175 million corresponding to approximately SEK 1 925 million [SFS 1968:45, as amended by SFS 1995:420].

The liability limit for incidents occurring at installations that produce, treat or store only unirradiated uranium, and for incidents occurring in the course of transport of such uranium has remained at the amount of SEK 100 million per incident [Section 17].

Except in the case where a nuclear installation is operated by the state, every Swedish nuclear operator must have insurance, approved by the government, to cover his liability as set out by the legislation.

The Act provides for compensation over and above that available under the terms of the Paris Convention and the Brussels Supplementary Convention. If there is a nuclear incident for which the operator of a nuclear installation located in Sweden is liable, and the amounts available under the two Conventions are insufficient to allow compensation in full, the state will compensate the victims from a maximum sum of SEK 3 000 million per incident. This extra tier of compensation is available only in relation to nuclear damage suffered in Sweden, Denmark, Finland, Norway or in the territory of any other Party to the Brussels Supplementary Convention (and only to the extent that that Party provides similar additional compensation for damage suffered in Sweden).

A person wishing to claim compensation under the Nuclear Liability Act must do so within three years of becoming aware of his or her entitlement to compensation, or, in any case, within 10 years of the nuclear incident which caused the damage complained of [Section 21]. The Act also

contains provisions establishing which Swedish courts have jurisdiction to hear a particular claim for compensation [Sections 36 and 37].

Two Decisions relating to the Paris Convention were adopted on 27 December 1977 by the OECD Steering Committee for Nuclear Energy and subsequently implemented by Sweden in an Ordinance in 1981 [SFS 1981:327, Section 1]. The first Decision concerns the exclusion of certain kinds of nuclear substance from the application of the Paris Convention; the second Decision concerns the similar exclusion of small quantities of nuclear substances while in transport.

Chernobyl legislation

In the wake of the Chernobyl accident, the Swedish Parliament passed legislation to provide for compensation to be paid by the state to those who had suffered economic loss because of the accident. This legislation established various measures regarding emergency systems and allocated the sum of SEK 250 million as compensation to claimants who had been obliged to discard animal carcasses, vegetable products and milk, rehabilitate horticultural areas, abandon commercial hunting activities, etc. In addition, a number of ordinances were made dealing with specific economic activities which were adversely affected by the accident (for example, the Ordinance on compensation to agricultural, garden and reindeer-raising enterprises for costs and losses resulting from radioactive fallout, SFS 1986:621); the latest Ordinance on this matter was passed in 1994 [SFS 1994:246].

II. INSTITUTIONAL FRAMEWORK

Under the Swedish Constitution, ministers are responsible for making proposals on matters within their portfolios. However, decisions are made collectively by the whole government rather than by one minister.

Various national bodies exist with regulatory or supervisory responsibilities in the nuclear field. As a general rule these bodies enjoy considerable independence within the broad policy framework laid down by the government.

Regulatory and Supervisory Authorities

a) Ministry of the Environment

The Ministry of the Environment is responsible for drawing up and implementing legislation and state financing for both nuclear safety and radiation protection.

b) Ministry of Industry and Trade

The Ministry of Industry and Trade is responsible for energy policy in general, including nuclear energy policy.

c) Ministry of Justice

The Ministry of Justice is responsible for drawing up and implementing legislation on nuclear liability as well as other fields of civil and criminal law.

d) Ministry of Foreign Affairs

The Ministry of Foreign Affairs is responsible for drawing up and implementing legislation concerning strategic products.

e) Swedish Nuclear Power Inspectorate (SKI)

i) Legal status

On 1 July 1974, the Swedish Atomic Energy Board was renamed the Swedish Nuclear Power Inspectorate (*Statens Kärnkraftinspektion* – SKI). Its functions are set out in the Ordinance on Instructions for the Swedish Nuclear Power Inspectorate [SFS 1988:523]. It comes under the authority of the Ministry of the Environment and is the "authority appointed by the government" under the Nuclear Activities Act to be the main regulatory body for the Swedish nuclear power industry.

ii) Responsibilities

SKI's principal duties, conferred by the Nuclear Activities Act and secondary legislation made under it, are as follows:

- to follow developments in the field of nuclear energy, in particular regarding safety issues;
- to investigate issues and initiate measures to increase the level of safety of nuclear facilities;
- to follow developments with regard to methods for handling and final disposal of spent nuclear fuel and radioactive waste, and to the shutdown and decommissioning of nuclear facilities;
- to initiate research and development work on the safety of nuclear power plants and other nuclear installations, the safe transport of nuclear material and waste, and, finally, safe methods for handling and storage of spent nuclear fuel and nuclear waste. Also to initiate research and development on methods for the shutdown and decommissioning of reactor facilities, to the extent that no other authority has jurisdiction over such tasks, and otherwise to initiate any other research necessary for the Inspectorate to carry out its assignments;

- to actively contribute towards providing members of the general public with information about work carried out in the fields of nuclear safety and radioactive waste;

- to ensure control of nuclear materials pursuant to Sweden's international obligations or as otherwise required;

- to provide technical advice to authorities responsible for the protection of the public in the event of a nuclear accident in Sweden or elsewhere;

- to account for funds that SKI administers in accordance with the Act on the Financing of Future Expenditure on Spent Nuclear Fuel [1992:1537] and the Ordinance on the Financing of Future Expenditures on Spent Nuclear Fuel, etc. [1981:671];

- to recommend to the government on a yearly basis the amount of the fee which is to be paid by producers of nuclear power to the Inspectorate, and accumulated in a fund managed by SKI; and

- to issue regulations concerning safety aspects of nuclear activities, and these constitute SKI's own Code of Statutes (identified by the reference SKI FS).

iii) Structure

A board appointed by the government governs SKI, and the chairperson of the board is the Director-General of SKI. Among the members of the board are representatives from bodies such as the Swedish Radiation Protection Institute, universities and representatives from the *Riksdag* (the Swedish Parliament). The SKI is divided into several departments: Reactor Safety, Nuclear Materials Control, Nuclear Waste Safety, Research, Information Technology, Information, Administration and Personnel. In addition, SKI is supported by three Advisory Committees (Reactor Safety, Safeguards and Research).

iv) Financing

Funding for SKI's activities comes from statutory licensing fees under a special ordinance on fees, revised annually [SFS 1991:739, as amended by SFS 1996:1509].

f) Swedish Radiation Protection Institute (SSI)

i) Legal Status

The Swedish Radiation Protection Institute (*Statens Strålskyddsinstitut* – SSI) is the central national authority under the responsibility of the Ministry of the Environment, appointed for the purposes of the Radiation Protection Act of 1988.

ii) Responsibilities

SSI is the principal authority responsible for protection against ionising and non-ionising radiation. Its functions are set out in the Ordinance on Instructions to the Swedish Radiation Protection Institute [SFS 1988:295]. SSI is involved in regulating and supervising aspects of both the inner and outer environments of nuclear power plants, the use of radioactive substances in industry, medicine and research, dental and veterinary X-ray diagnostics, and the use of non-ionising radiation (for example, in sun lamps and lasers).

SSI's functions also include:

- acting as the central co-ordinating body for radiation protection research, as well as conducting research in this field;
- taking account of international standards in the formulation of national radiation protection requirements; and
- disseminating information to the public on radiation hazards and radiation protection.

The Radiation Protection Act empowers the Institute to issue regulations on numerous aspects of radiation protection, and these constitute the Institute's own Code of Statutes (identified by the reference SSI FS).

iii) Structure

A board appointed by the government governs SSI, the chairperson of which is the Director-General of the Institute. The members of the board represent bodies such as the National Board of Health and Welfare, the National Environment Protection Board, the National Board of Occupational Health and Safety, the Swedish Nuclear Power Inspectorate, the *Riksdag* (the Swedish Parliament) and the trade unions.

The Institute's operations are carried out by four departments as follows:

- Occupational and Medical Exposures;
- Waste Management and Environmental Protection;
- Emergency Preparedness and Biomedicine; and
- Environmental Monitoring and Dosimetry.

The Institute is supported by an Advisory Scientific Board. Its task is to decide upon grants for basic radiation protection research and to give advice on other scientific matters.

iv) Financing

A proportion of SSI's activities is funded by licence fees. The remainder of its funding is provided by the government.

SWITZERLAND

I. GENERAL REGULATORY REGIME

1. Introduction

It was in 1946 that the peaceful use of nuclear energy was first regulated by the Swiss Confederation in the form of a Federal Order, dated 18 December 1946, encouraging research in the field of nuclear energy.

Given the complexity of the issues raised by the use of nuclear technology and the fact that large sums of money are required to put it into effect, the Federal Parliament in June 1957 authorised an amendment to the Constitution (Article 24 quinquies) so that nuclear legislation should fall within the sole jurisdiction of the Confederation, and this was approved in a referendum and by all the cantons in November 1957. Cantons, therefore, are not responsible for nuclear safety questions and have a residual jurisdiction only with regard to the licensing of nuclear installations (building permits, mining legislation, fire permits, water samples and use, etc.). This division of jurisdiction between federal and cantonal authorities was sanctioned at Federal Tribunal level in decisions of 18 August 1973 and 23 March 1977.

In Switzerland, the development and use of nuclear energy is not a state monopoly, and a large place is left to private industry. The first commercial nuclear power plant was brought into service in 1969. Many local authorities, however, have a direct or indirect interest in the operation of nuclear installations.

Nuclear legislation in Switzerland is based essentially on a Federal Act, the Act of 23 December 1959 on the peaceful use of atomic energy and protection against radiation. Several Ordinances have been adopted to regulate problems of implementation in the field of nuclear energy.

Legislation was initially limited and concerned mainly the field of radiation protection. More recently, given public reaction to the use of atomic energy, the legislature has had to intervene in the economic sphere. Thus the Federal Order of 6 October 1978, adopted temporarily pending a comprehensive review of the Atomic Energy Act of 23 December 1959, introduced a so-called need requirement : the general licence to construct a nuclear power plant will be refused if it seems that the setting up of the installation is not essential to meet the energy needs of the country. The validity of this Order, already in 1983 extended by Parliament until 1990, was again, in that year, extended until 31 December 2000.

The Swiss authorities have long felt the need to revise the present Federal Act of 23 December 1959, a revision which has been discussed for several years. In August 1982, the Federal Council decided to separate the field of radiation protection from that of the use of nuclear energy, and to ask the Federal Department of the Interior and the Federal Department of the Environment, Transport, Energy and Communications to prepare two separate sets of proposals for legislation.

It should also be noted that referenda on nuclear energy were held on 22 and 23 September 1990. The Swiss population and the cantons had to take a decision on three questions of major importance for the country's energy policy:

- public motion, as set out in the Constitution, calling for the progressive and final abandonment of nuclear energy;

- public motion, as set out in the Constitution, calling for a ten-year moratorium on the construction of all new nuclear power plants;

- a government proposal to amend the Constitution in order to give the Confederation authority to promote energy savings.

The proposal for abandonment was rejected by a 52.9% majority, that for a moratorium was accepted by a 54.6% majority and the constitutional article on energy was accepted by a 71% majority. The cantons unanimously accepted the constitutional article on energy, while a majority of cantons decided in favour of the moratorium and against abandonment. In concrete terms, this means that the Swiss Government has been given the necessary constitutional basis, namely the constitutional article on energy, for implementing legal provisions to promote energy savings and the use of renewable forms of energy. Furthermore, Switzerland, which currently has five reactors located on four sites, will not build any new nuclear power plants before the year 2000.

2. Mining Regime

There are no special mining regulations in Switzerland relating to nuclear ores.

Nuclear ores (uranium and thorium) are not considered as nuclear fuels within the meaning of the Ordinance of 18 January 1984 on definitions and licences in the field of atomic energy [Section 1].

Source materials may be acquired by the Confederation to ensure that nuclear installations receive supplies and for scientific research [Act of 23 December 1959, Section 3].

3. Radioactive Substances, Nuclear Fuel and Equipment

Given the special properties and possible uses of nuclear fuels, Swiss nuclear legislation contains more detailed rules with regard to them than to other radioactive substances.

a) Nuclear fuels

The Federal Act of 23 December 1959 on Atomic Energy contains the basic provisions as to the possession and use of nuclear fuels. Import and export of nuclear fuels (and residues) is governed by the Federal Council Ordinance of 18 January 1984 on definitions and licences in the atomic energy field. However, these provisions do not apply to source materials which are not used to produce energy, to special fissile materials whose level of radioactivity does not exceed 1 000 kilobecquerels (1 kilobecquerel = 0.027 microcuries) or to uranium-bearing ores, these being governed by the Act of 22 March 1991 and the Ordinance of 22 June 1994, on radiation protection.

The possession, transport, import and export of nuclear fuels are subject to licensing by the Confederation [Act of 23 December 1959, Section 4]. The Federal Energy Office is the body

competent to deal with licensing applications [Ordinance of 18 January 1984, Section 9]. It grants licences on the advice of thePrincipal Division for the Safety of Nuclear Installations (*Direction principale de la sécurité des installations nucléaires* – DSN). It is also the DSN which certifies that the international regulations on the transport of dangerous goods have been complied with. In accordance with the Ordinance of 18 January 1984, any proposed export of sensitive nuclear equipment or products is considered in the light of the Nuclear Suppliers Group ("London Club") guidelines on nuclear transfers, subject to the provisions relating to the transfer of nuclear technology, and is submitted to the Federal Energy Office and the Secretariat of State for the Economy (*Secrétariat d'État à l'économie* – SECO).

The revocation of a licence to possess nuclear fuels results in a transfer of the nuclear materials either to another licence-holder or to the Confederation [Act of 23 December 1959, Section 9]. If necessary, the Confederation may arrange for such materials to be seized at the expense of the person whose licence has been revoked [Act of 23 December 1959, Section 39].

The possession of nuclear fuels is subject to supervision by the Confederation, to which end the Federal Council or any bodies designated by it may take all necessary steps to protect persons, property and important rights. In practice, supervision is mainly carried out by the principal Nuclear Safety Division of the Federal Energy Office. The Federal Council has the general task, in the context of the possession and use of nuclear fuels, of laying down implementation standards and setting up any necessary bodies [Act of 22 May 1991 on Radiation Protection, Sections 37.1.a.1 and 38].

b) Radioactive substances and equipment generating ionising radiation

The Radiation Protection Ordinance of 22 June 1994 contains provisions regulating substances, objects and waste with a level of activity, concentration, contamination, dose rate or mass in excess of the values listed in the Annex. The licensing authorities are the Federal Office of Public Health (*Office fédéral de la santé publique* – OFSP) and, for activities performed in nuclear installations and for tests using radioactive substances in the framework of preparatory measures as defined in the Federal Order of 6 October 1978 concerning the Atomic Energy Act, the Federal Energy Office (*Office fédéral de l'énergie* – OFEN).

The OFEN grants licences for : activities performed in nuclear installations; activities performed in the Paul-Scherrer Institute (IPS) in Villigen which do not involve the application of radiation or radioactive substances to the human body; the import and export of radioactive waste from nuclear power plants.

The OFSP is the competent licensing authority in all other cases.

A licence is required for the handling of radioactive substances or of equipment or objects containing such substances, for the manufacture, marketing, construction, or use of installations or equipment capable of emitting ionising radiation and for the application of radiation or radioactive substances to the human body [Radiation Protection Act, Section 28].

A licence must also be obtained by anyone who, in an enterprise subject to licensing, employs persons who are exposed to radiation in the course of their duties in accordance with the Radiation Protection Act or the Atomic Energy Act. Licences are not required for: work with radioactive substances the activity of which does not exceed a given threshold per day; the use of radioactive substances authorised under Section 128 of the Ordinance; the sale, use, storage, transportation, disposal, import, export or transit of ready-made watches containing radioactive substances if they satisfy the requirements of ISO 3157 and 4168 and watch components containing luminescent

radioactive paint. Equipment and radioactive sources may be authorised for general use by the Federal Office of Public Health if the following conditions are satisfied:

- design features ensure that persons are not exposed to radiation or contaminated in an inadmissible fashion;

- provision is made for the disposal, in the same manner as radioactive waste, of any radioactive source as necessary after its use; and

- the ambient dose rate at a distance of ten centimetres from the surface does not exceed one microsievert per hour.

Licensing applications must be submitted, along with the necessary documentation, to the competent licensing authority. The authority issuing the licence (for a maximum period of ten years) communicates its decision to the canton concerned, to the supervisory authority and, in the case of enterprises subject to labour legislation, to the competent Federal Labour Inspectorate.

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

The regulations currently in force were adopted pursuant to the Federal Act of 1959 on Atomic Energy which provides for a system of licensing for the construction and operation of nuclear installations [Section 4]. However, the Federal Order of 6 October 1978 concerning the Act on Atomic Energy amended the licensing procedure by requiring nuclear operators first of all to obtain a so-called "general licence" determining the site and outline of the project [Section 1]. A "need requirement" has been attached to this licence which will not be granted unless it is shown that construction of the planned nuclear installation meets a real need in the country, and unless plans have been made for the decommissioning of the installation and disposal of the radioactive waste arising from it [Section 3].

Apart from this formal additional obligation imposed by the Order [Section 12.1.a.2], the construction and operating licences required by the Federal Act of 23 December 1959 were not in principle granted until after a procedure approving the site proposed for the installation. That is why Swiss legislation has, on a temporary basis, introduced a simplified procedure for the granting of the general licence in the case of operators who have already been authorised to locate their installations on a given site. The details of this simplified procedure are contained in a Federal Council Ordinance of 11 July 1979 specifying the procedure applicable to general licences for nuclear installations with regard to holders of a site licence. There is no longer any need for this transitional legislation.

It is relevant to note that, at the international level, Switzerland ratified the 1994 Convention on Nuclear Safety on 12 September 1996.

Granting of general licences

The Federal Council is the body which decides upon applications for general licences [Act of 23 December 1959, Section 8]. Its decision is then submitted to the Federal Assembly for approval [Federal Order of 6 October 1978, Sections 1 and 8]. General licences are granted after an inquiry procedure organised by the Federal Council during which, in particular, the opinion of the cantons and communes concerned, together with that of the Federal Services specialised in this field, are sought.

The general licence determines the site to be selected for the installation and the general outline of the project [Federal Order of 6 October 1978, Section 1].

Granting of technical licences

These licences are now granted by the Federal Council [Ordinance of 18 January 1984, Section 6].

The applications considered by the Federal Energy Office are sent to the cantons concerned for their opinion [Act of 23 December 1959, Section 7]; the Office also consults national expert bodies [Order of 6 October 1978, Section 6]. By virtue of the Federal Work Act, nuclear industrial enterprises are required over and above the specific nuclear licences, to obtain approval of plans and a special licence. In all cases, the cantonal authorities remain competent to grant licences in respect of building, fire (fire prevention measures) and water (using water as a coolant) regulations, in accordance with Section 4.3 of the Act of 23 December 1959.

Technical advisory and supervisory bodies

The principal Nuclear Safety Division (*Division principale de la sécurité des installations nucléaires* – DSN) of the Federal Energy Office (which is part of the Federal Department of the Environment, Transport, Energy and Communications – DETEC) gives an expert opinion on safety reports relating to the various nuclear installations. The Federal Commission for the Safety of Nuclear Installations (*Commission fédérale de la sécurité des installations nucléaires* – CSN) draws up an opinion at the same time on certain particular aspects of the project. This CSN report completes the opinion of the DSN [Ordinance of 14 March 1983]. On the basis of these documents, the Federal Council takes a decision as to the licences. The Federal Energy Office is responsible for implementing licensing procedures for nuclear installations.

Nuclear installations are supervised by the Confederation [Act of 23 December 1959, Sections 8 and 39]. To this end, the Federal Council and the bodies designated by it may establish measures, and monitor the implementation of such measures, in order to protect persons, property and important rights, to assure Switzerland's external security and to guarantee that its international commitments will be fulfilled. In practice, it is the principal Nuclear Safety Division (DSN) which carries out most technical inspections of installations although the DSN may call on experts from outside the Federal Administration.

The Federal Commission for the Safety of Nuclear Installations and the DSN advise the Federal Energy Office on measures that are necessary for the technical safety of installations [Ordinance of 14 March 1983, Section 2].

Collection of fees

Under Section 37.3 of the Atomic Energy Act of 23 December 1959, the Federal Council decides on the fees payable for the granting of licences and the carrying out of controls. Since 1971, the operators of nuclear power plants reimburse every year the federal supervisory authorities for the expenses they incur as a result of the construction and operation of such installations.

However, an Ordinance on fees in the nuclear energy field, adopted by the Council on 30 September 1985, now defines in detail the activities subject to the payment of fees and lays down the criteria for calculating the amount of such fees.

Decommissioning of nuclear installations

To meet the expenses of the decommissioning and dismantling of nuclear installations which are no longer in operation and of the disposal of the resulting waste, a fund for the decommissioning of nuclear installations was set up on 5 December 1983 under the responsibility of the Federal Council [Ordinance of 5 December 1983, Section 1, supplemented by the Regulations of the Federal Department of the Environment, Transport, Energy and Communications of 21 February 1985], to collect the necessary payments from the operators of nuclear installations. Operators pay annual contributions, the amount of which is fixed in accordance with the anticipated cost of decommissioning and dismantling the installation [Ordinance of 5 December 1983, Sections 3 and 4]. The necessary capital may be advanced to the Fund by the Federal Council which also lays down detailed rules governing the operation of the Fund and, in general, the implementing provisions relating to nuclear installations.

b) Protection of the environment against radiation effects

The Federal Office of Public Health (*Office fédéral de la santé publique* – OFSP) is responsible for the constant monitoring of radioactivity in the air, in precipitation, water and the soil. The Federal Commission for the Monitoring of Radioactivity is the competent technical advisory body. In the event of an increase in radioactivity, it proposes measures to be taken to ensure the protection of the population. The Federal Council is regularly informed of the monitoring results.

c) Emergency response

On 15 April 1987, the Federal Council adopted an Ordinance organising the measures to be taken in the event of increased radioactivity (OROIR), which replaced the previous Ordinance of 9 September 1966 on alert in the event of increased radioactivity. This new Ordinance establishes the organisation responsible for such emergency response and describes the tasks to be performed in the event of a hazard being caused by a nuclear installation [Section 1]. The situation in Europe resulting from the Chernobyl accident highlighted the need to set up such an organisation in Switzerland to co-ordinate the measures to be taken by the different public services concerned, so as to achieve optimum results. Accordingly, the Ordinance lists a number of bodies in which these services are represented, lays down the conditions for their involvement, and provides for a co-ordinated network to enable an appropriate response to be made to an increase in radioactivity [Sections 5-16].

The Ordinance of 28 November 1983 on emergency measures for protection of the population in the neighbourhood of nuclear installations is also applicable [Ordinance of 15 April 1987, Section 1.3]. It lays down the measures to be taken, the tasks of nuclear operators [Ordinance of 28 November 1983, Section 4], of the federal services [Section 5] and of the cantons and communes [Section 6]. It also establishes the apportionment of the costs incurred from the organisation of emergency measures and the alarm system [Section 9].

In the event of an alarming increase in radioactivity, the emergency organisation monitors developments and proposes or recommends the measures required. At the head of this organisation is the Radioactivity Steering Committee (*Comité directeur de la radioactivité* – CODRA), which body is

answerable to the Federal Department of the Interior. Among other resources at the disposal of the organisation is the National Alarm Centre which is responsible for alerting the authorities and the population [Ordinance of 3 December 1990].

For this purpose, the Federal Department of the Environment, Transport, Energy and Communications must, in consultation with the Federal Department of the Interior and the cantons concerned, define two zones around each nuclear installation. Zone I covers the area in which a serious incident occurring in the installation could give rise to a hazard for the population requiring rapid protection measures. Zone II, immediately beyond Zone I, covers an area with a 20 kilometre radius (with the nuclear installation at its centre) divided into sectors [Ordinance of 28 November 1983, Section 2]. Depending on the circumstances, a simple warning, a general alarm or a radioactivity alarm may be triggered [Sections 3-7]. The nuclear operator is responsible for providing for the appropriate emergency measures for his installation, for installing the necessary equipment and co-operating with the emergency organisation.

The distribution of iodine tablets to the population is provided for in an Ordinance of 1 July 1992. These tablets are to be used in the event of an accident leading to the emission of radioactive particles representing a potential danger to the public [Section 1]. The Federal Office of Public Health is responsible for organising the supply so as to enable the appropriate bodies to distribute the tablets according to defined geographical criteria within three Zones, and to build up sufficient reserves [Section 2]. In Zone I, tablets are given as a preventive measure and in sufficient quantities to all persons regularly in the Zone [Section 3]. Moreover, the Ordinance imposes on cantons and communes an obligation to build up sufficient stocks, and prescribes storage conditions which are identical to those for medicines [Sections 6 and 7]. Operators of nuclear installations participate with the Swiss Confederation in financing the costs generated by these operations [Section 13].

At the international level, Switzerland ratified both the 1986 Convention on Early Notification of a Nuclear Accident and the 1986 Convention on Assistance in the case of a Nuclear Accident or Radiological Emergency on 31 May 1988.

5. Trade in Nuclear Materials and Equipment

The Swiss Confederation has committed itself internationally to co-operate in the campaign against the proliferation of nuclear weapons. It ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons (NPT) on 9 March 1977, and in the same year became a member of the “London Club”, a group of the main states involved in the export of nuclear items. Since the adoption of an Ordinance in 1978 on definitions and licences in the atomic energy field, replaced in 1984 by a new Ordinance, nuclear items have been subject to an export licence in accordance with the London Club Guidelines [IAEA Document INFCIRC/254]. There was, however, no legal basis upon which control could be exercised, as provided for in the London Club Guidelines, over exports of “technology” (unpublished technical information on installations for enriching and reprocessing nuclear fuels and for producing heavy water). With the amendments of 2 March 1987 and 15 November 1995 to the 1984 Ordinance, the Swiss Government has been able to make exports of technology subject to the granting of a licence [Section 11].

The granting of licences for the export of sensitive nuclear equipment and materials is assessed by the competent federal authorities in the light of the London Club Guidelines and of internal legislation. The “non-proliferation of nuclear weapons” is one of the licensing criteria laid down by the Act [partial revision of 9 October 1986 of the Act of 23 December 1959, Section 5.1].

The export of nuclear energy is forbidden when it is contrary to the public interest [Act of 23 December 1959, Section 4.5]. The export of fissile materials and nuclear equipment must be authorised twice over : first by the import and export branch of the Trade Division of the Federal Department of Economy (*Département fédéral de l'économie* – DFE), and secondly, a joint authorisation from the Federal Energy Office, the Federal Foreign Affairs Department (*Département fédéral des affaires étrangères* – DFAE) and the Secretariat of State for Economy [Ordinance of 28 October 1987, amending the Ordinance of 18 January 1984, Sections 11 and 15].

Swiss nuclear legislation does not include any regulations dealing specifically with nuclear industrial property. Accordingly, the ordinary law on patents applies in the nuclear field.

6. Radiation Protection

In general, radiation protection measures taken by the Confederation are based on the recommendations of the International Commission on Radiological Protection (ICRP), and on the joint standards of international bodies (IAEA, NEA, ILO, WHO).

Aware for many years of the need to carry out a total revision of the Federal Act of 23 December 1959 on the Peaceful Uses of Atomic Energy and Protection against Radiation, the Federal Council decided in August 1982 to separate the field of radiation protection from that of the use of nuclear energy and asked the Department of the Interior to prepare a draft Bill on Radiation Protection [Message relating to a Bill on Radiation Protection of 17 February 1988]. The proposed Bill was based on Article 24 quinquies, sub-section 2 of the Constitution and covers the whole field of radiation protection (the objective being to protect man and his environment against the hazards caused by ionising radiation), but the Chapter on "Licences and Supervision" does not cover activities (nuclear installations) subject to licensing under the Atomic Energy Act.

The Radiation Protection Act of 22 March 1991 is a framework Act designed to protect man and the environment against the dangers arising from ionising radiation. It applies to all activities, installations, events and situations which could present a radiation hazard, and in particular to the use of radioactive substances and equipment, installations and objects containing such substances or capable of emitting ionising radiation. The Act lays down the broad principles of protection against radiation and gives the Federal Council power to promulgate detailed implementing regulations which can thus be adapted rapidly to keep pace with scientific and technological progress. The comprehensive revision of the Radiation Protection Ordinance is an example of such adaptation.

The new Radiation Protection Ordinance of 22 June 1994 is based largely on the most recent recommendations of the ICRP. Increased protection is afforded to persons exposed to radiation in the course of their work and to the public, especially to unborn children. Dose limits and derived guideline levels have been reduced and brought into line with the new ICRP recommendations.

The Ordinance introduces new rules concerning the upkeep, modernisation and control of medical X-ray equipment. Routine controls are now to be carried out by private firms, which means that controls will be more frequent than before.

Limits and guideline levels have been introduced for concentrations of radon in housing, temporary accommodation and the workplace. The cantons are the competent executive authorities in this connection. Measures to decrease levels will be imposed having regard to the seriousness of each case and the financial implications involved.

Another new provision is that limits and tolerance levels for radioactive substances in foodstuffs are established in accordance with the Radiation Protection Act. These levels will be adopted also in the Ordinance on foreign bodies in, and the contents of, foodstuffs.

Lastly, the transport of radioactive substances has for the first time been made subject to licensing. In order to obtain a licence, firms transporting radioactive substances, whether on their own account or on behalf of others, must now prove that they have the technical know-how required and a suitable quality assurance programme.

Both the Act and the Ordinance on Radiation Protection entered into force on 1 October 1994.

The Federal Department of the Interior (*Département fédéral de l'intérieur* – DFI) and the Federal Department of the Environment, Transport, Energy and Communications (DETEC) are responsible for implementing regulations in the field of radiation protection. They concentrate particularly on the protection of persons, and thus are concerned with health risks which may affect certain groups of people – workers or patients – or the population as a whole, when exposed to ionising radiation. Those who, in their work, handle radioactive substances or use radiation-producing equipment, are required to have received adequate radiation protection training.

The Federal Commission for Protection against Radiation (*Commission fédérale de la protection contre les radiations* – CPR) gives advice on matters concerning radiation protection to the Federal Council, the DFI the DETEC, interested services and the Swiss National Accident Insurance Office (*Caisse nationale suisse d'assurance en cas d'accidents* – CNA).

It gives its opinion, *inter alia*, on:

- the interpretation and evaluation of international recommendations concerning radiation protection with a view to their application in Switzerland;

- the preparation and development of standard principles for applying radiation protection requirements.

The competent authorities for granting licences to use ionising radiation are the Federal Office of Public Health (*Office fédéral de la santé publique* – OFSP) and, for activities carried on in nuclear installations and tests involving radioactive substances in the framework of preparatory measures within the meaning of Section 10.2 of the Federal Order of 6 October 1978 concerning the Atomic Energy Act, the Federal Energy Office.

The OFSP, the CNA and the principal Nuclear Safety Division (*Division principale de la sécurité des installations nucléaires* – DSN) are responsible for supervising the protection of persons and the neighbourhood.

The OFSP exercises control over firms in which the primary concern is to protect the public, in particular, medical companies and research and training institutes in higher education establishments.

The CNA exercises control over firms in which the primary concern is protection of workers, in particular, industrial firms and small businesses.

The DSN supervises:

- nuclear installations;
- preparatory measures within the meaning of Section 10.2 of the Federal Order of 6 October 1978 concerning the Atomic Energy Act;
- the Paul-Scherrer Institute, except for applications of ionising radiation or radioactive substances to the human body;
- the radioactive waste collection centre.

7. Radioactive Waste Management

It should be pointed out in this context that in Swiss regulations, the term "residues" (*résidus*) is used for a particular category of materials. The 1984 Ordinance on definitions and licences in the atomic energy field stipulates that residues are the radioactive materials (including activation products) whose activity does not exceed 100 gigabecquerels and which are formed from nuclear fuels after the nuclear transmutation process [Ordinance of 18 January 1984, Section 2, as amended on 18 October 1987]. The Federal Council may also include in this category, by assimilation, integral parts of nuclear installations which have become radioactive during atomic energy production [Act of 23 December 1959, Section 1]. The term "radioactive waste" applies to nuclear materials and articles contaminated by such materials which are not to be used again [Ordinance of 18 January 1984, Section 3]. In practice, radioactive waste (*déchets*) is mainly material resulting from the use of radioisotopes. Such radioactive waste results from the handling of radioactive sources of all kinds; it broadly includes waste produced as a result of industrial, medical, research and educational uses.

In fact, Swiss regulations do not always make this distinction and, for convenience, the term "waste" has been used in this section. When residues are concerned, this is indicated in brackets.

a) Waste from nuclear installations

Licensing system

The Federal Atomic Energy Act of 1959 dealt with the question of radioactive waste (residues) only from the viewpoint of a licence, or the revocation of a licence, for its possession and transport [Act of 23 December 1959, Sections 4 and 9].

Provisions dealing with the question of waste are now included in the Federal Order of 6 October 1978, supplementing the Atomic Energy Act [Sections 1 and 10]. A Federal Council Ordinance of 27 November 1989 contains details as to the implementation of the licensing procedure, and lays down the preparatory steps to be taken in constructing a repository for radioactive waste provided for in Section 10 of the Federal Order of 1978.

The Federal Council lays down implementing provisions and designates the relevant administrative bodies and the commissions responsible for studying nuclear energy questions. The possession, transport, import and export of radioactive waste (residues) require a licence from the Confederation [Act of 23 December 1959, Section 4].

The licensing regime applicable to radioactive waste repositories follows the same procedure and involves the same authorities as those involved in the licensing of nuclear installations (general licences) [Ordinance of 18 January 1984, Section 6 and amendment of 2 March 1987]. The general licence, which fixes the site and the general outline of the project, also determines the storage capacity and the categories of waste as well as the structure of the underground or surface installations. Before granting a licence, the Federal Council consults the local communities concerned and the services of the Confederation specialised in the field.

The Federal Energy Office is responsible for implementing the procedure for licences for installations for the disposal of nuclear waste after consultation with the Federal Commission for the Safety of Nuclear Installations. The latter gives its opinion after having seen the first safety assessment reports by the principal Nuclear Safety Division of the Federal Energy Office [Ordinance of 14 March 1983, Section 2].

Should a licence to possess radioactive waste (residues) be revoked, the waste is transferred either to another licence-holder or to the Confederation [Act of 23 December 1959, Section 9.4].

The Confederation is responsible, as it is for nuclear installations, for supervising the possession of radioactive waste (residues) [Section 8], and this task is carried out by the principal Nuclear Safety Division of the Federal Energy Office. The supervisory bodies are empowered to have any radioactive waste which constitutes a radiation protection hazard seized or disposed of, at the producer's expense [Act of 23 December 1959, Sections 9 and 39; Federal Order of 6 October 1978, Section 10].

A licence is also required for the transport or possession of wastes (residues) [Section 4.1]. The granting of such licences is the responsibility of the Federal Energy Office [Ordinance of 18 January 1984, Section 9]. The task of supervising these activities is carried out by the principal Nuclear Safety Division.

Storage and disposal of waste

As provided for by the Federal Order of 6 October 1978 supplementing the Atomic Energy Act, different principles apply to the management and disposal of radioactive waste, such as the responsibility of producers of waste to organise its safe disposal [Section 10.1]; the introduction by the Federal Council of a special procedure authorising preparatory measures for the construction of a radioactive waste repository [Section 10.2]; the obligation for waste producers to become members of a public body and to pay equitable contributions to cover the costs of waste disposal [Section 10.3]; the guarantee of the safe disposal of radioactive waste (transitional provisions having been made for installations in operation or being built] being made a condition for the granting of general licences for nuclear power plants [Section 3.2].

Repositories must conform to the safety conditions and technical criteria laid down by the Federal Commission for the Safety of Nuclear Installations and the Federal Energy Office in Directives R-21 of October 1980.

A Confederation Working Group on Radioactive Waste Management (*Groupe de travail de la Confédération pour la gestion des déchets nucléaires* – AGNEB) was set up by the Federal Council on 15 February 1978. This Group is responsible for following the work carried out in this sector by other bodies, and for preparing the technical elements necessary for making an evaluation and which will serve as an aid to the Federal Council and the Federal Department of the Environment, Transport, Energy and Communications when taking decisions in this field. It ensures that the Confederation respects the time limits prescribed for licensing procedures and reports once a year to the Department.

In 1972, the producers of radioactive waste, including the Confederation, formed a private company – the National Corporation for the Disposal of Radioactive Waste (*la Société coopérative nationale pour l'entreposage des déchets radioactifs* – NAGRA) – which has the task of managing the radioactive waste for which waste producers are responsible.

With respect to operating licences for nuclear power plants not covered by the provisions of the Federal Order of 6 October 1978 as they were already in operation or under construction, the Federal Department of the Environment, Transport, Energy and Communications made prolongation of their validity beyond 1985 subject to the guarantee of a satisfactory method of disposing of the waste from the installation. The electricity companies concerned were thus obliged to submit proposals offering such a guarantee to the Federal Council before 31 December 1985.

Since then, NAGRA, commissioned by the Swiss nuclear power plants, has been at work to demonstrate the feasibility of waste disposal. In January 1985, NAGRA submitted a "1985 Guarantee Project" (*"projet Garantie 1985"*) to the Swiss safety authorities (namely the principal Nuclear Safety Division and the Federal Commission for the Safety of Nuclear Installations. The Confederation Inter-Agency Working Group entrusted with supervising work on nuclear waste management (AGNEB) was made responsible for submitting a prior opinion on the NAGRA project to the Federal Council. Swiss and foreign experts were called upon to assist in preparing this opinion.

Since the assessment of such a project is time-consuming, the Federal Council, so as not to compromise its exhaustive and scientific nature, decided to extend the time limit for establishing the "Guarantee" until such time as it was able to judge the contents of the said report. Until then, operating licences for nuclear power plants were to remain valid.

In June 1988, following a detailed examination by the safety authorities, the Federal Government decided that a sufficient guarantee of safety had been established for all categories of waste, although a site still had to be found for high and medium-level waste.

On 27 November 1989, the Federal Council adopted an Ordinance on preparatory measures for the construction of radioactive waste repositories, thus repealing the Ordinance of the same name of 24 October 1974. The Federal Order of 6 October 1978 concerning the Atomic Energy Act provides that the Federal Council must grant a licence before preparatory measures can be undertaken for constructing a radioactive waste repository (in practice, the research carried out by NAGRA, the licensing procedure being determined by ordinance [Section 1]. Under the 1989 Ordinance, the federal licensing procedure, which has been simplified, is restricted mainly to nuclear safety. Some work, such as seismic research and surface drilling, must be notified to the supervisory authorities, but they no longer require a licence from the Federal Council [Ordinance of 27 November 1989, Section 2.2]. This new Ordinance should enable NAGRA to accelerate its work.

Over and above the licences required for nuclear installations, a special licence is necessary in the case of waste repositories in order to proceed with preparatory steps to set up such a repository [Ordinance of 27 November 1989, Section 2]. The Federal Council is the competent authority to grant such licences [Section 14] by virtue of an instruction issued to the Federal Department of the Environment, Transport, Energy and Communications; the cantons concerned and the specialised services of the Confederation are invited to make observations [Sections 10-12]. Supervision of the preparatory and follow-up measures and work is carried out jointly by the specialised services of the Confederation designated by the Federal Council, and by the cantons concerned [Section 15]. The Federal Order of 6 October 1978 gave the Federal Council the power of compulsory purchase in order to establish repositories, and this power may be transferred to the beneficiary of the compulsory purchase [Section 16].

b) Waste from industrial, research, medical and educational uses

These types of waste are governed by the Radiation Protection Ordinance of 22 June 1994 [Sections 79-93] as amended on 3 June 1996 by the Federal Council. The Ordinance of 8 July 1996 on the transport of radioactive waste (RS 814.557), regulates the method of treating radioactive waste in the workplace, its transport and the declaration to be made to the Paul-Scherrer Institute (IPS). It co-ordinates the collection activity organised by the Federal Office of Public Health together with the IPS. The Ordinance entered into force on 1 August 1996 and repeals the Ordinance of the Federal Department of the Interior of 18 March 1977. Annexes 1 to 4 specify the types and classes of radioactive waste, the type of packaging required, including technical details, and the proper accompanying documentation for each delivery.

In accordance with the Radiation Protection Ordinance, all radioactive waste producers must make provision for the temporary storage of waste at the site of production, and submit details of their proposal for approval either to the Swiss National Accident Insurance Office in the case of enterprises subject to the Federal Accident Insurance Act, or to the Federal Office of Public Health in all other cases. This procedure is necessary before the Insurance Office or the Office of Public Health can take a decision as to the licences for the possession and use of radioactive substances, and equipment containing such substances [Ordinance of 22 June 1994, Sections 84-86; Act of 22 March 1991].

It is the Confederation's responsibility to collect all the radioactive waste produced by the institutes and enterprises within its territory. The collection of this waste is organised jointly by the Federal Office of Public Health and the Paul-Scherrer Institute (IPS). The waste is sent to collection centres designated by the public authority, either to be stored in a depot set up under the responsibility of the Federal Department of the Interior, or else to be disposed of [Ordinance of 22 June 1994, Sections 82-86]. The modification of the Ordinance of 8 July 1996 now requires that radioactive waste not derived from the use of nuclear energy must be delivered to the IPS at Villigen (Canton of Argovie) after having been properly treated in the workplace.

The Federal Department of the Interior is the regulatory authority responsible for making any implementing provisions required for radioactive waste management [Ordinance of 22 June 1994, Section 87.3].

8. Non-Proliferation and Physical Protection

There is no legislation dealing specifically with nuclear security in Switzerland. However, special provisions have been included in nuclear instruments adopted by the Confederation.

The general licence required for the operation of a nuclear power plant is granted only to Swiss citizens resident in Switzerland. Section 5.3 of the Federal Act of 23 December 1959 on Atomic Energy provides that "the Federal Council may make licences to construct or operate nuclear installations subject to the condition that the applicant be a Swiss citizen residing in Switzerland. For licences requested by corporations, the Federal Council may require that at least two-thirds of the Board of Management be Swiss citizens residing in Switzerland and that the registered office be located in Switzerland". Similarly, Section 3.3 of the Federal Order of 6 October 1978 amending the said Federal Act, provides that "general licences are granted only to Swiss citizens resident in Switzerland and to corporations regulated by Swiss law which have their registered office in Switzerland and are under Swiss control". In addition, licences for nuclear installations may be refused or made subject to particular conditions when this is necessary to ensure Switzerland's external security, the fulfilment of its international commitments or the protection of persons, property or important rights.

In supervising nuclear installations and the possession of nuclear fuels, the Federal Council, or the body appointed by it, takes all steps which may be necessary for the external security of the country and for the fulfilment of its international commitments [Act of 23 December 1959, Section 8]. Generally, those responsible for inspections in the nuclear field have wide powers of investigation and are bound by professional secrecy [Sections 39 and 40]. When the national defence is at stake, the supervisory authorities in the radiation protection field have the power to waive health requirements.

The Atomic Energy Act of 23 December 1959 provides for criminal sanctions which, generally speaking, are applicable to persons who intentionally infringe provisions laid down in the field of nuclear energy [Section 29 *et seq.*]. In the present context, the betrayal of secrets concerning the peaceful use of atomic energy is judged more or less severely depending on whether the secrets were or were not passed on to a foreign body or undertaking [Section 34].

It should be noted that, at the international level, Switzerland ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons, on 9 March 1977, and the 1996 Comprehensive Test Ban Treaty, on 1 October 1999. It also ratified the 1979 Convention on the Physical Protection of Nuclear Materials.

9. Transport

The transport of radioactive or fissile materials in Switzerland is governed by a number of different regulations, each dealing with a particular form of transport. In general, these instruments implement in Switzerland the international regulations in this field.

Thus, for road transport, the basic text is the Federal Council Ordinance of 24 May 1972 (as updated on 1 January 1979), relating to the transport of dangerous goods by road (SDR). The Ordinance provides that foreign vehicles which do not fully satisfy the technical norms which it prescribes shall nevertheless be allowed into Switzerland provided that the transport operation meets the standards laid down in the European Agreement of 30 September 1957 (as revised on 1 October 1978), concerning the International Carriage of Dangerous Goods by Road (ADR) [Ordinance of 24 May 1972, Section 1.4].

For transport by rail, the legislation in force is contained in the Regulations concerning transport by rail and by water, known as the Transport Regulations, of 2 October 1967 (updated on 1 January 1990) whose Annex I incorporates the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID). This Annex is itself entitled “Swiss International Regulations concerning the Carriage of Dangerous Goods by Rail (RID/RSD)”.

The transport of radioactive or fissile materials by inland waterway is governed by the above-mentioned Transport Regulations (RID/RSD), and if on the Rhine, is subject to the Regulations for the Transport of Dangerous Goods on the River Rhine (ADNR) of 29 April 1970.

The Air Transport Regulations of 3 October 1952 apply to the transport by air of radioactive or fissile materials authorised by the Federal Civil Aviation Office, on condition that the transport is carried out in accordance with the regulations laid down by the International Air Transport Association (IATA) concerning the transport of restricted articles by air [Regulations of 3 October 1952, Sections 13 and 14, approved by the Federal Order of 16 December 1952. Decision of 1 July 1963].

The sending by post of radioactive or fissile materials whose specific activity does not exceed 0.002 microcurie per gram is governed by the Federal Council Ordinance of 1 September 1967 as

amended on 21 November 1979, which amends the Ordinance implementing the Post Office Act. In cases where the specific activity of the materials exceeds this figure, it is the Transport Regulations (RID/RSD) which apply.

The Federal Department of the Environment, Transport, Energy and Communications is responsible for transport operations by road, rail and inland waterway. This Department has the task, along with the other bodies concerned, of drawing up regulations in the field of the transport of radioactive or fissile materials. In the case of air transport, the Federal Civil Aviation Office may impose additional requirements to be observed during transport operations, as long as these do not contradict the regulations laid down in this field by IATA [Air Transport Regulations of 3 October 1952, Section 14]. As for sea transport, the relevant international regulations are applied directly [Decision of 1 July 1963, Section 1].

10. Nuclear Third Party Liability

Switzerland has signed the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy, and the 1963 Brussels Supplementary Convention, but has not ratified them. On 14 December 1992, the Federal Council decided not to ratify the Paris Convention and the Brussels Supplementary Convention in the near future, on the grounds that Switzerland had adopted relatively recently an Act on Nuclear Third Party Liability dated 18 March 1983, and that certain provisions adopted differed from those of the Paris Convention. Moreover, a comprehensive review of Swiss nuclear energy legislation is being undertaken. Ratification of the two Conventions has thus been postponed until a later date. Switzerland, however, continues to follow with great interest international developments in the law of nuclear third party liability, and participates in work carried out in this field.

Provisions relating to nuclear third party liability were originally contained in the Federal Act of 23 December 1959. These provisions were completed on 13 June and 19 December 1960 respectively by a Federal Council Ordinance and Order. This legislation, whose purpose was to regulate the operation of the Fund for Delayed Atomic Damage provided for under Section 19 of the 1959 Federal Act, has since been repealed.

The Federal Council decided to exempt operators of nuclear installations, whose nuclear fuel and waste has an activity of less than 1 curie, from the legal provisions on third party liability and mandatory insurance.

Meanwhile, questions of third party liability were regulated in a general fashion by the Act of 18 March 1983 on Nuclear Third Party Liability (*Loi sur la responsabilité civile en matière nucléaire* – LRCN), which was followed by an implementing Ordinance of 5 December 1983. This Act abides by two basic principles, namely that of strict liability and that of the channelling of liability to the operator of a nuclear installation. On the other hand, the LRCN rejects the principle of the limitation of third party liability in amount and provides that the person liable must commit himself for an unlimited amount. The Federal Council is obliged under this Act to increase the minimum amount covered by private insurance once the insurance market offers higher cover on acceptable terms. Accordingly, on 19 November 1997, the government further amended the Ordinance of 5 December 1983 on Nuclear Third Party Liability (*Ordonnance sur la responsabilité civile en matière nucléaire* – ORCN), which had already been amended in December 1985, in October 1990 and in December 1996.

Liability is covered as follows:

- by private insurance up to Swiss francs (CHF) 700 million for each nuclear installation (CHF 50 million for each operation involving the transport of nuclear goods across Switzerland) [LRCN of 18 March 1983, Section 11; ORCN of 5 December 1983, Section 3, as amended on 2 December 1996];

- by the Confederation up to CHF 1 billion when the damage exceeds the amount covered by private insurance [LRCN of 18 March 1983, Section 12];

- by all the assets of the person liable;

- according to a special procedure with regard to "catastrophes".

The adoption of an Ordinance of 19 November 1997, which entered into force on 1 January 1998, modified the method of calculating federal nuclear third party liability insurance premiums to be paid by potentially liable persons. As of 1 January 1998, these amounts are fixed in Swiss francs rather than as a percentage of the premiums collected by private insurers for third party liability coverage.

The Fund for Delayed Atomic Damage has been transformed into a Fund for Nuclear Damage. Fees are levied from nuclear operators and holders of transport licences so as to cover the contributions made by the Confederation [Sections 14 and 15].

The ORCN of 5 December 1983 specifies the scope, insurance conditions, coverage of costs by the Confederation and the management of the Fund for Nuclear Damage set up by the LRCN. The Fund is not a separate legal entity but is financially independent. The ORCN also provides for the assignment of the costs of preventive measures taken by the appropriate authorities.

II. INSTITUTIONAL FRAMEWORK

Since 24 November 1957, when Article 24 quinquies was inserted into the Swiss Constitution, nuclear energy has been declared to be the responsibility of the federal legislature. Thus the Confederation supervises all nuclear activities and is very active in their organisation and development. The Confederation also plays an important role in the field of research and the training of nuclear specialists [Act of 23 December 1959, Section 2]. Lastly, it may acquire the nuclear materials necessary or forbid the export of such materials (although it is normally the operators of nuclear power plants who acquire and possess nuclear fuels, with the authorisation of the Confederation) [Sections 3 and 5].

The Federal Council has the necessary regulatory and administrative powers to adopt the regulations required for the development of the use of nuclear energy and for radiation protection. The Federal Department of the Environment, Transport, Energy and Communications, and the Federal Department of the Interior are responsible for implementing the provisions adopted by the Federal Council in the field of the use of atomic energy and the field of protection against ionising radiation,

respectively. Various commissions study questions relating to the use of atomic energy, each in its specific field of competence.

Apart from the federal departments and the specialised services of the Confederation, the public sector is also represented by a public scientific research centre, the Paul-Scherrer Institute.

1. Regulatory and Supervisory Authorities

a) Federal Council

The Federal Council, which represents the executive branch of government in Switzerland at federal level, plays an important role in the organisation and running of nuclear activities.

In the first place, the Federal Council assists in the development of regulations in the atomic energy field, and ensures their implementation [Act of 23 December 1959, Sections 11 and 37]. More particularly, the Federal Council has the power to broaden the category of activities for which a preliminary licence is required [Section 4.2]. On the other hand, it may also waive the rules on licences, third party liability and insurance, in the case of activities which give rise to only a very low risk of radiotoxicity [Section 1.4].

On an administrative level, the Federal Council has been made responsible for examining and deciding upon applications for preliminary general licences for nuclear installations, prior to construction and operating licences [Federal Order of 6 October 1978, Sections 1, 5-8; Ordinance of the Federal Council of 11 July 1979, Sections 3 and 4]. The Federal Council also grants licences for taking preparatory steps for the setting up of a radioactive waste repository [Federal Order of 6 October 1978, Section 10; Ordinance of the Federal Council of 27 April 1989, Section 2].

In general, the Federal Council licenses and supervises nuclear installations and materials, and may take measures necessary for the protection of persons, property and important rights, as well as for Switzerland's external security and fulfilment of its international commitments [Act of 23 December 1959, Section 8; Ordinance of 18 January 1984, Section 6].

In general, the Federal Council sets up the necessary administrative bodies, and the commissions responsible for studying questions relating to the use of nuclear energy and to radiation protection [Act of 23 December 1959, Sections 37 and 38].

For the purposes of promoting nuclear research, the Federal Council is authorised to give financial assistance to research agencies. In particular, subsidies are granted to the Swiss National Scientific Research Fund, a body which manages part of the funds intended for research and the training of specialists in the field of nuclear science in Switzerland.

b) Federal Assembly

The Federal Assembly, Switzerland's parliament, is involved in the nuclear field in approving the Federal Council's decisions as to general licences for nuclear installations [Federal Order of 6 October 1978, Sections 1 and 8; Ordinance of the Federal Council of 11 July 1979, Section 4].

The Assembly is also competent in respect of third party liability and insurance [Act of 18 March 1983, Section 29]. Thus, in the case of catastrophes, the Federal Assembly is empowered to

draw up indemnification rules determining the general principles of compensation for victims. A special independent body may be set up by the Federal Assembly to ensure that these principles are applied.

c) Federal Department of the Environment, Transport, Energy and Communications (DETEC)

The general task of the Federal Department of the Environment, Transport, Energy and Communications (*Département fédéral de l'Environnement, des Transports, de l'Énergie et de la Communications* – DETEC) is to prepare legislation on the use of nuclear energy [Ordinance of the Federal Council of 9 May 1979]. In conjunction with the Federal Department of the Interior, and after having consulted the competent supervisory bodies, it lays down guidelines on the supervisory measures which should be taken to protect the population, and on co-ordinating the work of the bodies responsible for supervision [Ordinance of the Federal Council of 30 June 1976, Section 20].

The DETEC has the task of following the licensing procedure in the case of applications for licences to take preparatory steps for studying sites with a view to setting up radioactive waste repositories [Ordinance of 27 November 1989, Sections 4, 10 *et seq.*].

Lastly, the Federal Commission for the Safety of Nuclear Installations reports to the DETEC [Ordinance of 9 May 1979].

d) Federal Energy Office (OFEN)

Under the Order of the Federal Council of 23 December 1968 on the reorganisation of Swiss administrative authorities, the Federal Energy Office, which forms part of the Federal Department of the Environment, Transport, Energy and Communications, was given the powers which previously belonged to the Delegate for Atomic Energy Questions, except for those which were expressly conferred on the Science and Research Division [Order of the Federal Council of 23 December 1968, Section 5; Federal Act of 19 September 1978 on the organisation of the Administration; Ordinance of 9 May 1979].

The Federal Energy Office therefore is competent to prepare and apply legislation in the field of nuclear energy, and also to prepare, in conjunction with the Federal Department of Foreign Affairs, international nuclear treaties and to ensure that they are properly implemented. The Office also has the task of examining and co-ordinating studies carried out in the field of nuclear energy. The Federal Energy Office is responsible for examining applications for the construction, operation or modification of nuclear installations [Ordinance of the Federal Council of 18 January 1984], and in the case of nuclear installations which do not produce electricity, it also grants the licences.

Furthermore, the Office is the competent authority for licensing the transport, import and export of nuclear materials and equipment, and for the storage of nuclear fuels and radioactive waste [Section 9].

The Federal Energy Office includes a principal Nuclear Safety Division (*Division principale de la sécurité des installations nucléaires* – DSN). This Division is called upon to give an expert opinion on the technical safety reports relating to the various licences required under Swiss nuclear law: general licences and licences for the construction and operation of nuclear installations, licences for the transport and marketing of nuclear materials and equipment, and licences in the field of radioactive waste management. The Division also ensures that technical checks are carried out on

nuclear installations and on the Paul-Scherrer Institute, and concentrates on measures to be taken to prevent nuclear catastrophes.

e) Federal Department of the Interior

As regards nuclear matters, the Federal Department of the Interior (*Département fédéral de l'intérieur*) has been given regulatory and administrative powers in the area of radiation protection. It is also competent with regard to nuclear research questions and co-ordinates activities with the universities and federal *Écoles Polytechniques* [see Section 3, a) "Paul-Scherrer Institute" *infra*].

With regard to its regulatory powers, the Federal Department of the Interior has a general responsibility for radiation protection questions. It has the task of laying down the necessary rules for applying measures enacted by the Federal Council for protection against ionising radiation. In particular, the Federal Department of the Interior, with the assistance of the Federal Department of the Environment, Transport, Energy and Communications, and after consulting the competent supervisory bodies, lays down guidelines for supervisory activities to be carried out in the radiation protection field.

In addition, the Federal Department of the Interior, in agreement with the Federal Commission for Protection against Radiation, lays down guidelines on measures to be adopted for the protection of persons exposed to radiation for medical purposes. With regard to foodstuffs, the Federal Department of the Interior determines the maximum concentrations of radionuclides which may be incorporated in food products.

Moreover, the Federal Department of the Interior determines the training programme, the method of examination, and rights in relation to the training and refresher courses offered by the Confederation in the field of radiation protection. Courses given by private institutions must first be approved by the Federal Department, or the competent supervisory body, if they are to benefit from subsidies which are fixed by the Federal Department of the Interior. In any event, in order to use radioactive materials or equipment generating ionising radiation in a professional context, it is necessary to have completed training recognised by the Federal Department of the Interior or the competent supervisory body. By reason of its administrative powers, the Federal Department of the Interior, with the assistance of the Federal Department of the Environment, Transport, Energy and Communications, co-ordinates the activities of nuclear bodies involved in radiation protection monitoring.

The Federal Department of the Interior also has the power to impose any necessary measures with regard to the medical supervision of persons exposed to ionising radiation at work.

In the radioactive waste management field, the Federal Department of the Interior ensures the disposal by the Paul Scherrer Institute (IPS) of radioactive waste other than that coming from electricity-producing nuclear installations and facilities for the reprocessing of spent fuel.

Lastly, the Federal Office of Public Health and the Federal Office of Education and Science both report to the Federal Department of the Interior [Order of the Federal Council of 23 December 1968, Section 1]. It may hear appeals from decisions made by the Federal Office of Public Health.

f) Federal Office of Public Health (OFSP)

Through the agency of its Radiation Protection Division, the Federal Office of Public Health (*Office fédéral de la santé publique* – OFSP) enjoys wide administrative and supervisory powers in the field of protection against radiation.

Administrative powers

The Office is the competent authority for the granting or revocation of licences for the production, use, possession, disposal, import and export of radioactive substances and for nuclear equipment, whether used for industrial, scientific, medical or agricultural purposes, with the exception of nuclear installations, nuclear fuel and radioactive waste (residues). If, however, a negative response is given by the Swiss National Accident Insurance Office (*Caisse nationale suisse d'assurance en cas d'accidents* – CNA), which considers applications from enterprises bodies subject to the Federal Act on Accident Insurance, then the Federal Office is bound by this opinion. Persons possessing radioactive substances or equipment emitting ionising radiation for which no licence is required because the quantity or activity of the nuclear material concerned is below a given threshold, must make a declaration to the Federal Office. Producers trading in such substances or equipment which are not freely available or are for restricted use, must submit an annual report to the Federal Office on their activities. The Office may allow certain types of radioactive substances and equipment emitting ionising radiation or containing radioactive substances to be used generally or for specific purposes. The Federal Office of Public Health grants the necessary licence for the restricted use of substances and equipment, and receives the declarations of persons possessing substances or equipment available for general use, unless it waives such formalities.

The Federal Office of Public Health, in consultation with a panel of experts representing various interests, is also the competent authority for approving radioactive substances intended to be used for medical purposes. It must authorise any work involving unsealed radioactive sources which a company wishes to carry out outside its own premises.

Supervisory powers

An expert designated by the Federal Office of Public Health checks those parts of equipment used for radiotherapy which determine the radiation dose given, every time the equipment is modified in such a way that this dose could be affected and in any event at least once a year [Section 58]. The licence-holder keeps a record of the results of these verifications. The Federal Office may require that equipment used for diagnosis be checked annually over a period of four weeks in normal working conditions. A record is kept of the number and location of radiographic and radioscopic examinations carried out during this period, as well as of the conditions under which they took place.

In general, the Office advises the Federal Department of the Interior and that of Transport, Communications and Energy on the guidelines to be adopted with regard to the carrying out of inspections.

The Federal Office of Public Health supervises enterprises in which the primary concern is protection of the public, while the Swiss National Accident Insurance Office, in the event of an accident, supervises those in which the primary concern is protection of workers.

The principal Nuclear Safety Division on the other hand is responsible for inspecting the safety of nuclear installations. The Federal Office of Public Health and the Federal Energy Office, each in its

own sphere, control the import and export of radioactive substances as well as equipment and objects containing such substances.

Other powers

The Radiation Protection Section of the Federal Office of Public Health is responsible for the collection and dispatch of radioactive waste from industrial, research, and medical activities. It sends a circular to listed waste producers to inform them that waste will be collected from the centre which has been assigned to them. The Office works in co-operation with the Paul-Scherrer Institute with respect to the collection and conditioning of this waste. The Office represents the central administration responsible for collecting radioactive waste other than that from nuclear installations, within the National Corporation for the Disposal of Radioactive Waste (NAGRA).

The Office also organises, along with other federal services and non-governmental organisations, training and refresher courses in radiation protection. It is responsible for the payment of subsidies allocated by the Confederation to private institutions organising such courses.

g) Federal Office of Education and Science (OFES)

The Federal Office of Education and Science (*Office fédérale de l'éducation et de la science* – OFES), set up in 1968, replaced the Delegate for Atomic Energy Questions. It is part of the Federal Department of the Interior where, together with the Federal Council of *Ecoles polytechniques*, it forms part of the Science and Research Group, whose activities are administered by a directing body *(état-major)*.

The OFES co-ordinates research activities carried out in university circles, the private sector, and by government authorities. It represents the government in bodies carrying out fundamental and applied research. It also deals with research into thermal nuclear fusion, and high and medium-energy nuclear physics.

h) Other authorities

Other Federal Departments are called on to regulate questions falling within the nuclear energy field, and in particular : the Federal Department of Justice and Police, for the transport by road of dangerous goods, and in relation to public protection measures; the Federal Department of Foreign Affairs and the Federal Economics Department for the export of nuclear materials of particular significance; the Department of Public Protection and Sport for radiation protection on behalf of the army; and the Federal Finance Department with respect to legislation on nuclear measurement units.

2. Advisory Bodies

a) Federal Commission for the Safety of Nuclear Installations

i) Legal status

The Federal Commission for the Safety of Nuclear Installations (*Commission fédérale de la sécurité des installations nucléaires*) was set up by Ordinance of the Federal Council dated 13 June 1960. The Commission, which is administratively attached to the Federal Energy Office, acts as an advisory body to the Federal Council and the Federal Department of the Environment, Transport, Energy and Communications [Ordinance of the Federal Council of 13 June 1980, Section 1].

ii) Responsibilities

The Commission's functions were redefined by a Federal Council Ordinance of 14 March 1983 which repealed the 1960 Ordinance. The Commission is henceforth less involved with operational aspects.

The Commission gives its opinion with regard to applications for general licences as well as for licences for the construction, start-up, operation and modification of nuclear installations [Ordinance of 14 March 1983, Section 2].

In particular, it stipulates whether, in view of experience gained and the state of the art of science and technology, all necessary measures of a reasonable nature have been taken to protect man and the environment from ionising radiation. The Commission may restrict itself to dealing with basic nuclear safety questions, or with points on which a project diverges from solutions which have proved satisfactory in other cases.

With regard to the protection of installations against attacks by third parties, it gives its opinion on the technical aspects of design and operation inasmuch as they are connected with nuclear safety. It comments on the expert reports prepared on this topic by the principal Nuclear Safety Division and by other federal services.

The Commission monitors the operation of nuclear installations in Switzerland and abroad in relation to nuclear safety and its basic aspects. It suggests measures it considers necessary and which may reasonably be required in the light of experience and the current state of science and technology [Section 3].

The Commission provides an opinion when nuclear safety legislation is being drawn up or amended. It follows the development of regulatory requirements concerning nuclear safety. It may recommend the adoption or amendment of requirements applying to nuclear power plants, and may participate in any work of this kind carried out by other bodies.

The Commission analyses basic nuclear safety questions concerning installations themselves, and studies the general difficulties involved in assessing their degree of safety. It may recommend measures to increase the safety of installations, and improvements to the licensing procedure and the supervision of the operation of installations.

It follows nuclear safety research at home and abroad, and proposes relevant research that could be carried out in Switzerland, or suggests that Swiss bodies be involved on a bilateral or multilateral basis in the implementation of projects.

The Federal Department of the Environment, Transport, Energy and Communications, and the Federal Energy Office may submit other nuclear safety questions to the Commission for consideration.

iii) Structure

The Federal Commission for the Safety of Nuclear Installations comprises a maximum of thirteen nuclear experts, proposed by the Federal Department of the Environment, Transport, Energy and Communications, and nominated by the Federal Council. The Chairperson of the Federal Commission is appointed by the Federal Council on the proposal of the said Department. Members of the Commission carry out their duties in a private capacity, and not as part of their main professional activities. They are not bound by any instructions and may not nominate a substitute to take their place.

In order to carry out its duties properly, the Federal Commission may set up internal permanent sub-commissions and specialised groups of experts. If necessary, it may, with permission of the Federal Energy Office, invite external experts to assist with its work.

Representatives of the principal Nuclear Safety Division (DSN) may attend meetings and inspections of the Federal Commission.

The quorum for discussions within the Federal Commission is fixed at two-thirds of its members, and its decisions are taken on a simple majority basis. Should there be an equal number of votes on each side, the Chairperson of the Federal Commission has the casting vote.

The Federal Commission's work is confidential and an obligation of professional secrecy is imposed on experts. The Chairperson of the Federal Commission may nevertheless, with the permission of the Federal Department of the Environment, Transport, Energy and Communications, send inspection results to the competent cantonal or local authorities, and to the insurer of the installation involved. The Federal Commission for the Safety of Nuclear Installations is served by a secretariat attached to the principal Nuclear Safety Division.

b) Federal Commission for Protection against Radiation

The Federal Commission for Protection against Radiation (*Commission fédérale de la protection contre les radiations)* is attached to the Federal Department of the Interior.

i) Responsibilities

The Commission is responsible for giving general advice to the Federal Department of the Interior on questions relating to the protection of the population against hazards from ionising radiation. Thus, the Commission is consulted in particular on the changes or additions to be made to maximum permissible dose definitions for persons exposed to radiation, and on guideline activity levels and surface contamination in the environment.

If there are medical grounds for removing, whether temporarily or permanently, a person occupationally exposed to ionising radiation from his workplace, the Federal Department of the Interior must ask for the Federal Commission's opinion on the matter.

Guidelines relating to requirements for the protection of patients exposed to radiation for medical examination purposes are adopted by the Federal Department of the Interior.

ii) Structure

Members of the Federal Commission come from university and medical circles and from the administration.

c) Federal Commission for the Monitoring of Radioactivity

The Federal Commission for the Monitoring of Radioactivity (*Commission fédérale de surveillance de la radioactivité)*, which is under the authority of the Federal Department of the Interior, keeps a permanent check on radioactivity in the environment. It regularly informs the Federal Council of the results of its monitoring activities, and prepares information to be given to the public in the event of an increase in the level of ambient radioactivity. If necessary, the Federal Commission may propose to the Federal Council the measures that should be taken to ensure the protection of the population. Work carried out involving unsealed radioactive sources and taking place outside a firm's premises, must be notified to the Federal Commission by the Federal Office of Public Health when there is a risk of contamination of the environment.

Members of the Federal Commission for the Monitoring of Radioactivity include experts from university circles and from the Federal *École polytechnique*. They are appointed by the Federal Council on the proposal of the Federal Department of the Interior.

d) Organisation for giving warning of any increase in radioactivity

In the event of a dangerous increase in radioactivity, an Organisation for giving warning of any increase in radioactivity (*Organisation d'intervention en cas d'augmentation de la radioactivité*) is called upon to follow developments in the situation and to propose or recommend appropriate protection measures. The Organisation is headed by a Radioactive Steering Committee (*Comité directeur de la radioactivité* – CODRA) which is under the aegis of the Federal Department of the Interior. The Warning Committee has at its disposal an alarm post, a monitoring centre and other resources such as the National Alarm Centre.

Members of CODRA include representatives from federal departments, government services, the cantons and directors of the different federal offices and other bodies. CODRA also has at its disposal various federal commissions.

e) Technical Commission for the Practical Application of Ionising Radiation

The Technical Commission for the Practical Application of Ionising Radiation (*Commission technique pour l'application pratique des radiations ionisantes)* reports to the Federal Department of the Environment, Transport, Energy and Communications. It is responsible for giving advice to the

Confederation and interested firms on the subject of Swiss participation in national or international projects concerning the use of ionising radiation.

3. Public and Semi-Public Agencies

a) Paul-Scherrer Institute (IPS)

On 30 November 1987, the Federal Council decided on the merger, on 1 January 1988, of the Federal Institute for Reactor Research (IFR) and the Swiss Institute for Nuclear Research (ISN), into a research establishment, the Paul-Scherrer Institute (*Institut Paul-Scherrer* – IPS), located in Villigen. While the ISN and the IFR worked on fundamental research and applied research covering industrial applications, respectively, the Paul-Scherrer Institute is more of a multi-disciplinary research establishment for natural sciences and engineering [Ordinance of 13 January 1993, Section 2].

i) Legal status

The IPS is a Confederation research establishment governed by public law. This independent legal entity is answerable to the Federal *Écoles polytechniques* Council.

ii) Responsibilities

The Paul-Scherrer Institute is entrusted with research activities in the following fields:

- nuclear physics and particle physics;
- radiation medicine, radiobiology and radiological hygiene;
- research on solids and material sciences;
- nuclear energy techniques (especially relating to nuclear safety and radioactive waste disposal);
- non-nuclear energy techniques and environmental sciences related to energy.

It is thus responsible for the development of large facilities for complex research.

The Paul-Scherrer Institute is also competent as regards education and training in colleges *(hautes écoles)*, with which it has close ties. The IPS may make its research facilities available to such colleges which may also manage laboratories jointly with the IPS.

The Institute also provides various services to the government and to other public bodies and the economy, in particular in the fields of nuclear safety, radioactive waste disposal and environmental protection in relation to energy use. The IPS may advise federal bodies and carry out research on their behalf. It also provides support to the supervisory authorities responsible for nuclear safety.

Lastly, the Institute collaborates with the international scientific community in preparing joint research and development programmes.

iii) Structure

The Paul-Scherrer Institute is divided into different research and administrative sectors. The Federal *Écoles polytechniques* Council is responsible for organising the administration of the Institute. Management is entrusted to the following bodies:

- the Federal *Écoles polytechniques* Council;
- the Advisory Committee; and
- the Management of the Institute.

The Federal *Écoles polytechniques* Council directs and generally supervises the IPS and its installations. For this purpose, it draws up internal rules and drafts guidelines for the efficient functioning of the Federal Institute.

After consulting the Committee, the Council approves the annual programme of work prepared by the Management of the Institute.

The Advisory Committee, composed of between five and nine members, assists the Federal *Écoles polytechniques* Council with important questions for IPS activities. The Council appoints the chairperson and the members for a period of four years.

The Management of the Institute includes the director and other members who are answerable to him and who are responsible for specific sectors as determined by the *Écoles polytechniques* Council. The director administers the IPS and has overall responsibility for the establishment's management and safety. He is answerable in this to the *Écoles polytechniques* Council, which lays down the tasks and responsibilities of the Management and of each of its members.

iv) Financing

Fees are payable for the Institute's services and must cover the cost thereof. The *Ecoles polytechniques* Council decides on what fees should be charged, after hearing the opinion of the Federal Finance Department.

b) Fund for the Decommissioning of Nuclear Installations

i) Legal status

Provision was made in the Federal Order of 6 October 1978 concerning the Atomic Energy Act for the setting up of a fund for financing the decommissioning and dismantling of nuclear installations no longer in service (*Fonds pour le financement de la désaffectation et le démantèlement des installations nucléaires mises hors service)*. This Fund was set up on 1 January 1984 and is managed under the supervision of the Federal Council. It has been given its own legal personality, and has its headquarters in Bern.

ii) Responsibilities

The Fund was set up to cover costs arising from the decommissioning and dismantling of nuclear installations no longer in use and from the management of the waste produced.

iii) Structure

The Fund is administered by an administrative Commission with a maximum of eleven members appointed by the Federal Council and including representatives of operators, the Confederation, and various economic circles.

iv) Financing

The Fund's resources are constituted by the contributions paid by the owners of nuclear installations subject to the Ordinance of 5 December 1983 concerning the Fund for the Decommissioning of Nuclear Installations. Every three years, the Commission of the Fund fixes the annual amount due by each owner.

c) National Corporation for the Disposal of Radioactive Waste (NAGRA)

i) Legal status

The National Corporation for the Disposal of Radioactive Waste – NAGRA (*Société co-opérative nationale pour l'entreposage des déchets radioactifs*) is a private co-operative company set up in 1972 by the waste producers (the Confederation and six electricity companies), to undertake, at national level, the study and final disposal of the various categories of radioactive waste.

ii) Responsibilities

NAGRA is responsible for locating sites suitable for the storage of radioactive waste.

In conjunction with the competent federal authorities and the Paul-Scherrer Institute, NAGRA undertakes research programmes with a view to establishing new permanent repositories for waste storage. This research concerns in particular the physical and chemical properties of the geologic formations envisaged as potential storage sites, the safety of solidified waste, packaging material, proposed repositories, the organisation of storage sites and the identification of new ideas for the safe disposal of waste.

To ensure the exchange of information and to promote co-operation in the field of waste management, NAGRA maintains contact with similar organisations in foreign countries.

iii) Structure

All Swiss producers of waste of nuclear origin, including the Confederation, are members of NAGRA. The Confederation participates on two counts, first as a producer of waste from research

reactors and from the processing of radioactive materials, and secondly as the collector of waste produced in the fields of industry, research, medicine and education.

The Board of Directors of NAGRA is composed of persons from Ministerial Departments and from industry circles concerned with the disposal of radioactive waste. Particular responsibility for studying the technical and safety aspects of waste processing has been given to a Technical Commission made up of specialists in the nuclear energy field. To accomplish its task, the Commission may call upon external experts.

iv) Financing

NAGRA is a non-profit making co-operative organisation. Expenses are paid out of capital and members' subscriptions. The cost of radioactive waste disposal is borne entirely by the producers of the waste concerned.

TURKEY

I. GENERAL REGULATORY REGIME

1. Introduction

Turkey has no general Nuclear Energy Act and apart from legislation relating to the Turkish Atomic Energy Authority (*Türkiye Atom Enerjisi Kurumu* – TAEK) [Act No. 2690 of 9 July 1982, published in *Resmi Gazete (*RG) No. 17753 of 13 July 1982], the applicable law mainly covers protection against ionising radiation and the licensing of nuclear installations. At present, there are no nuclear power plants in Turkey.

2. Mining Regime

Turkish legislation regulating mining activities specifies that in principle, the prospecting and mining of radioactive ores, even where deposits are located on private land, is a state monopoly; however, the state may grant prospecting and mining licences to applicants for such licences [Act No. 6309 of 3 March 1954 – RG No. 8655 of 11 March 1954, amended by Act No. 271 of 11 July 1963 – RG No. 11459 of 20 July 1963].

Exploration for and handling of radioactive ores are undertaken by the government in accordance with Act No. 2840 of 13 June 1983 and Act No. 3971 of 16 February 1994. Under the Turkish mining regime, the General Directorate of Mineral Research and Exploration (*Maden Tetkik Enstitüsü* – MTA) is responsible for exploring for radioactive minerals and related technological research. The General Directorate of ETIBANK Mining is responsible for mining and milling of radioactive minerals (see Part II "Institutional Framework" *infra* for further details).

3. Radioactive Substances, Nuclear Fuel and Equipment

Regulations governing the use in general of radioactive substances, fissile materials and equipment emitting ionising radiation are laid down in the Radiation Safety Decree of 1985 [RG No. 18861 of 7 September 1985], which superseded Decree No. 7/9038 of 1974 on that subject. In accordance with the 1985 Decree, a regulation was issued in 1991 [RG No. 2098 of 6 September 1991] which contains provisions on the system for registering and licensing such materials. This Regulation supersedes similar regulations issued in 1968 and 1975.

4. Nuclear Installations

Turkish regulations for the licensing of nuclear installations are laid down in Decree No. 83/7405 of 11 November 1983 [RG No. 18256 of 19 December 1983]. This Decree, which entered into force on 19 December 1983, supersedes Decree No. 7/9141 of 5 December 1974 on the

same subject, while maintaining, in essence, the same licensing procedure.[1] Various other technical regulations adapted from the Codes of Practice of the International Atomic Energy Agency (IAEA) applicable to the overall design and safety criteria to be met in the design and construction of reactors have also been published.[2] A new Code of Practice concerning the issuing of licences for the operating staff of research reactors and defining their duties and responsibilities was issued in 1989 [RG. No. 20255 of 17 August 1989].

In accordance with Decree No. 83/7405, the licensing procedure is divided into three main stages:

- site licence;
- construction licence;
- operating licence.

Any application for a licence for a reactor or other category of nuclear installation must be submitted to the Turkish Atomic Energy Authority (TAEK). In the case of a power reactor, the applicant is usually the Turkish Electricity Generation and Transmission Company, Inc. (*Türkiye Elektrik Üretim ve Iletim A.S. Genel Müdürlügü* – TEAS).

The licensing procedure for nuclear installations is carried out in accordance with Decree No. 83/7405. The following nuclear reactor and nuclear fuel cycle facilities require a licence from TAEK.

"Nuclear reactor facilities" mean:

- training reactors;
- research reactors;
- materials testing reactors;
- test reactors;
- prototype reactors;
- reactors for electric power production.

1. Other regulations which govern the licensing of nuclear installations are the Regulations on General Project and Safety Criteria for Design and Construction of Nuclear Power Plants [RG of 3 September 1975] (currently under revision); the Decree on Radiation Safety [RG No. 18861 of 7 September 1985]; the Regulations on Radiation Safety [RG No. 20983 of 6 September 1991]; the Guide on Earthquake-Related Subjects Requested in the Issuance of Limited Work Permit and Site Licenses [1989]; the Guide on Seismic Design and Qualification of Nuclear Plant Facilities, approved by the AEC on 29 May 1996; and the Regulations on Quality Assurance and Inspection of Nuclear Installations [RG No. 22932 of 13 March 1997].

2. Regulation Nos. 3, 4, 5 and 6 issued by TAEK in 1978 and Regulation No. 7, published in RG No. 16675 of 23 June 1979.

"Nuclear fuel cycle facilities" mean:

- mining, milling and refining facilities;
- conversion facilities;
- enrichment facilities;
- nuclear fuel element fabrication facilities;
- reprocessing facilities for used fuel elements; and
- radioactive waste management facilities (including final storage).

An application for a licence to operate a nuclear installation must be submitted in writing to TAEK accompanied by all the necessary supporting documents describing the nature of the installation to be constructed. After having studied the relevant documents, the results of inspections and/or tests performed at the proposed site or installation, the Department of Nuclear Safety prepares an evaluation report which also includes the observations of the Advisory Committee on Nuclear Safety (ACNS). The Vice President for Nuclear Power and Safety submits a report indicating the results of the evaluation report to the President of the Authority, who then takes both reports to the first meeting of the Atomic Energy Commission (AEC). The Authority delivers the permit or licence together with the applicable conditions as established in an appendix thereto.

Turkey ratified the 1994 Convention on Nuclear Safety on 8 March 1995. It is also a Party to the 1986 Convention on Early Notification of a Nuclear Accident and the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, both ratified on 3 January 1991.

5. Trade in Nuclear Materials and Equipment

TAEK is responsible for establishing the general principles which govern all kinds of prospecting, exploitation, purification, distribution, import, export, trade, transportation, use, transfer and storage of nuclear raw materials, special fissionable materials and other strategic materials used in the nuclear field. This Authority also makes recommendations on these subjects and encourages co-operation in the field. A draft Regulation on Permission for the Export of Material and Equipment used in the Nuclear Field and Related Technology is under consideration at the time of writing of this study (1999).

6. Radiation Protection

In addition to the Radiation Safety Decree of 1985 [RG No. 18861 of 7 September 1985], a number of regulations provide for radiation protection in various activities:

- Regulations for the Safety and Licensing of Gamma and Electron Beam Irradiation Facilities [RG No. 21964 of 18 June 1994] lay down general safety provisions for the design, construction, installation, operation, maintenance and decommissioning of such facilities with a view to protecting the public and the environment;

- Regulations for the Licensing of Radiotherapy Equipment [RG No. 21997 of 21 July 1994] contain provisions for the radiation protection of workers, patients, the public and the environment against equipment emitting ionising radiation and sealed sources used in radiotherapy;

- Regulations for the Licensing of X-ray Equipment Used in Dentistry [RG No. 21666 of 12 August 1993] aim to protect dentists, patients, other persons and the environment against the ionising radiation produced by X-ray equipment used in dentistry.

In 1973, the Ministry of Labour issued a Decree on Dangerous Activities [Decree No. 7/6174 of 29 March 1973 – RG No. 14502 of 9 April 1973], a list of which includes activities involving the use of X-rays, radioactive substances and radiation-emitting equipment. The Decree lays down the safety rules to be complied with when handling such substances and equipment.

Another Decree issued in 1973 by the above Ministry [Decree No. 7/6229 of 5 April 1973 – RG No. 14511 of 18 April 1973 amended by Decree No. 7/8761 of 15 July 1974], relates to the protection of workers in radiology and nuclear medicine. The Turkish Atomic Energy Authority and, in particular, its Nuclear Safety and Radiation Health and Safety Departments are responsible for drawing up and enforcing the implementing regulations.

A Regulation on Radiopharmaceuticals entered into force in 1993 [RG No. 21797 of 23 December 1993]. It provides that the Drug Regulatory Authority of the Ministry of Health is responsible for licensing and inspecting radiopharmaceutical manufacturers and for registering and controlling such products. This work is carried out in co-operation with TAEK.

7. Radioactive Waste Management

Radioactive waste processing installations are classified as nuclear installations and as such, are covered by Decree No. 83/7405, which governs the licensing of nuclear installations.

Measures for protecting workers and the public against hazards arising from radioactive waste are laid down in the Radiation Safety Decree [RG No. 18861 of 7 September 1985].

8. Non-Proliferation and Physical Protection

Nuclear installations in Turkey are covered by IAEA safeguards. Turkey ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 17 April 1980 and signed the relevant Safeguards Agreement with the IAEA, which entered into force on 1 August 1984.

Turkey is also a Party to the 1979 Convention on the Physical Protection of Nuclear Material (ratified on 27 February 1985). It had already issued a Code of Practice in 1979 on physical protection requirements for special nuclear materials [Regulation No. 8 published in RG No. 16702 of 20 July 1979], based on the relevant IAEA Recommendations [INFCIRC/225/Rev.1].

A Regulation on Nuclear Material Accounting and Control was adopted in 1997 [RG No. 2106 of 10 September 1997].

9. Transport

A Regulation on the Safe Transport of Radioactive Materials entered into force in 1997 [RG No. 23106 of 10 September 1997].

The Turkish Atomic Energy Authority is generally responsible for licensing and supervising the transport of radioactive substances.

As regards international agreements relating to the safe transport of dangerous goods, including radioactive substances, Turkey applies the International Regulations concerning the Carriage of Dangerous Goods by Rail (RID) [Regulation published in RG No. 15742 of 22 October 1976]; the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) [Decree No. 8/522 of 6 March 1980 – RG No. 16998 of 25 May 1980], and the relevant international regulations issued by the International Air Transport Association (IATA) and the International Maritime Organisation (IMO).

10. Nuclear Third Party Liability

Although Turkey has been a Contracting Party to the 1960 Paris Convention on Third Party Liability in the Field of Nuclear Energy since its entry into force in 1968 (ratified by Turkey on 10 October 1961), it has not yet adopted any special legislation in this field. However, a Law on Nuclear Liability in the Nuclear Energy Field is being prepared at the time of writing of this study (1999). There already exists a requirement that any operator of a nuclear installation within the meaning of the Convention must have insurance or other suitable form of financial security, approved by the Turkish Atomic Energy Authority, to cover its liability [Act No. 299 of 8 May 1961 – RG No. 10806 of 13 May 1961; Act No. 878 of 1 June 1967 – RG No. 12620 of 13 June 1967].

II. INSTITUTIONAL FRAMEWORK

1. Regulatory and Supervisory Authorities

a) Prime Minister

At the outset, nuclear activities in Turkey were placed under the authority of the Prime Minister. More specifically, the Atomic Energy Commission (now the Turkish Atomic Energy Authority) was established under his authority and it is still administratively attached to the Prime Minister's Office [Act No. 6821 of 27 August 1956 setting up the Commission, now superseded by Act No. 2690 of 13 July 1982].

b) Ministry of Energy and Natural Resources

This Ministry sets national goals and policies concerning the use of energy and natural resources to improve and strengthen the national defence, welfare and economy.

c) Ministry of Health

This Ministry is responsible for public health. It is also the supervisory authority over the General Directorate for Drugs and Pharmacy which was established in 1946 and reorganised in 1984 to become the Drug Regulatory Authority under the Ministry.

d) Ministry of the Environment

This Ministry, established by Act No. KHK/443 in 1991, establishes principles of national policy and related plans and programmes for protection and improvement of the environment, and the prevention of environmental pollution. In concrete terms, the Ministry's responsibilities include ensuring the most proper and effective use and protection of land, the protection and improvement of the natural plant and animal habitat and the prevention of environmental pollution. In order to carry out these responsibilities, the Ministry issued a Decree on assessment of installations in terms of their environmental impact on 23 June 1997 [RG No. 23028]. According to this Decree on Environmental Impact Assessment, the operator of a facility has to prepare an Environmental Impact Assessment Report (EIAR) at the planning stage, which should be submitted to the Ministry. The Ministry evaluates the report for the feasibility and environmental aspects of the proposed installation, and grants permission to the operator to carry out his project if the report is found satisfactory. Nuclear installations fall within the definition of facilities which require this authorisation from the Ministry.

2. Public and Semi-Public Agencies

a) Turkish Atomic Energy Authority (TAEK)

The former Atomic Energy Commission was reorganised to give it greater operational independence and to broaden its fields of responsibility, and was renamed the Turkish Atomic Energy Authority (*Türkiye Atom Enerjisi Kurumu* – TAEK) by Act No. 2690 of 13 July 1982.

i) Legal status

To enable it to carry out the programme assigned to it by the 1982 Act, TAEK, although remaining under the authority of the Prime Minister, now has its own legal status [Section 3].

ii) Responsibilities

TAEK's general objective is to promote the peaceful uses of nuclear energy under the energy development plans approved by the Turkish Government and the application of nuclear techniques. Its task is to provide a framework within which the basic principles and policies related to nuclear energy may be established and scientific, technical and administrative research in this field may be carried out and supervised [Section 1]. TAEK is also responsible for defining safety measures for all nuclear

activities and for drawing up regulations concerning radiation protection and the licensing and safety of nuclear installations.

More specifically, TAEK is responsible for the following [Section 4]:

- formulating general policy and relevant programmes on the peaceful use of nuclear energy and submitting them to the Prime Minister for approval;
- carrying out and/or co-ordinating research on nuclear energy applications in the context of Turkey's scientific, technical and economic development;
- establishing research and training centres, laboratories and pilot plants without energy-producing purposes;
- conducting research to provide industrial access to nuclear technology and know-how;
- establishing and operating installations for the production of radioisotopes and quality control;
- issuing licences to both private and state enterprises conducting various activities involving radioactive materials, supervising the radiological safety of such enterprises, and ensuring compliance with licence conditions;
- issuing authorisations, permits and licenses related to the siting, construction, operation and environmental safety of nuclear installations;
- performing the necessary reviews, assessments and inspections of these installations;
- limiting the operating authorisation in the event of non-compliance with the permit or licence;
- revoking licences and/or permits issued previously either temporarily or permanently, and submitting recommendations to the Prime Minister on the closure of installations covered by such authorisations;
- preparing the necessary rules and regulations governing the above operations;
- taking the necessary steps to arrange for transportation, processing, storage and disposal of radioactive waste produced by nuclear installations and radioisotope laboratories;
- establishing relations with the national institutions and bodies concerned with the peaceful uses of atomic energy;
- training the staff required in the nuclear field;
- supplying all necessary information in this field.

iii) Structure

TAEK is headed by a president appointed by the Prime Minister. The president is TAEK's official representative and is responsible for implementing its programme [Section 5]. He is assisted by three vice-presidents.

TAEK is comprised of an Atomic Energy Commission (AEC), an Advisory Council and several specialised departments, centres and institutes [Section 3].

The members of the Commission, which is also headed by the president, include the vice-presidents, three representatives of various ministries and four representatives of universities. The representatives of the ministries and universities are appointed for four-year terms by the Prime Minister. The Commission determines the work principles and programmes of TAEK, approves its draft budget and submits it to the Prime Minister. The Commission is responsible for the preparation of decrees and regulations in its field of competence [Section 6].

The members of the Advisory Council are appointed for three-year terms from among university representatives and experts within various governmental bodies. The Council studies and makes recommendations on matters submitted to it by the Commission [Section 7].

Under the three vice-presidents are five specialised departments empowered to carry out the responsibilities of TAEK pursuant to legislation [Section 8]:

- the Nuclear Safety Department;
- the Radiation Health and Safety Department;
- the Research, Development and Co-ordination Department;
- the Technology Department; and
- the Administration and Financial Affairs Department.

iv) Financing

As a result of a structural reorganisation, TAEK now has its own budget. Its financial resources are derived from:

- appropriations from the general budget of the government;
- local and foreign aid, donations, etc.;
- income for services provided, production of goods and sale of publications.

Çekmece Nuclear Research and Training Centre (ÇNAEM)

The Çekmece Centre (*Çekmece Nükleer Araştirma ve Eğitim Merkezi* – ÇNAEM) was founded in 1962 near Istanbul and is affiliated to the Turkish Atomic Energy Authority. It is a government

research centre and, as such, may co-operate with universities and other scientific and research institutes in the development and application of nuclear science and technology.

The programme of work of the ÇNAEM is co-ordinated with TAEK's nuclear programme in support of the national economy, and focuses on nuclear technology, applications and training.

The ÇNAEM constructed a 1 megawatt thermal power reactor (TR-1) in 1959 for both research and production of isotopes for industrial and medical purposes. It was operational from 1962 to 1977, and has now been dismantled. A 5-megawatt TR-2 reactor was later built and has been operating since 1982 for irradiation purposes.

The Centre is managed by a Director, who is assisted by a Technical and Administrative Committee and by a Nuclear and Radiological Safety Committee. Three Deputy Directors responsible for technical, research and training, and administrative matters respectively, direct the different departments involved.

Ankara Nuclear Research and Training Centre (ANAEM)

This Centre (*Ankara Nükleer Araştirma ve Eğitim Merkezi – Beşevler –* ANAEM) was established in Ankara in 1966. It has four research departments, namely Nuclear Physics, Nuclear Chemistry, Materials Research and Nuclear Electronics. Activities carried out in the research centre include applications of nuclear analytical techniques such as instrumental NAA (Nuclear Activation Analysis), XRF (X-ray Fluorescence), gamma ray spectrometers, pesticide research using nuclear technologies, basic research in the field of neutron physics, radiation detection and measurement in various samples as well as AFM (Atomic Force Microscopy) for surface analysis of various samples, ESR (Electron Spin Resonance) spectrometer for investigation of irradiated samples.

The Centre is planning to build a 0.5 MeV accelerator for research and applications in biomaterial science and a 30-40 MeV high flux cyclotron, mainly for the production of medically important radionuclides such as thallium 201 and iodine 131 etc. which are used for PET (Positron Emission Tomography) and SPECT (Single Photon Emission Computed Tomography).

The equipment in the laboratories of the Centre is used for material research, dose measurements, environmental monitoring and development of nuclear analytical techniques.

Lalahan Nuclear Research Institute in Animal Health

The Institute was established in 1981 by the Turkish Atomic Energy Authority and its research programme is directed towards the use of nuclear related techniques in animal reproduction, nutrition, parasitic and infectious diseases and food irradiation.

The Institute collaborates closely with other research institutes of the Ministry of Agriculture and Rural Affairs, universities and other national and international institutions. The Institute is managed by a director, who is assisted by two deputy directors responsible for research and administration respectively.

b) General Directorate for Mineral Research and Exploration (MTA)

The General Directorate for Mineral Research and Exploration (*Maden Tetkik Arama Enstitüsü* – MTA) was established on 22 June 1935 to explore ore deposits in Turkey. MTA is a government organisation under the supervision of the Ministry of Energy and Natural Resources [Act No. 2804 of 14 June 1935 – RG No. 3035 of 22 June 1935] and is headed by a director-general appointed by the government. MTA undertakes explorations of mineral and raw material deposits and carries out scientific and geologic investigations as well as chemical analyses and technological tests [Act No. 2804 and Act No. 3213 of 4 June 1985].

c) General Directorate of ETIBANK Mining

ETIBANK was established by Act No. 2805 of 14 June 1935 [RG No. 303 of 25 June 1935] to carry out activities in the fields of mining, metallurgy and chemicals. In 1997 ETIBANK was divided into two companies, ETIBANK and the ETIBANK Mining Company, the latter of which does not carry out any bank-related functions. Both ETIBANK and the ETIBANK Mining Company are state economic enterprises under the supervision of the Ministry of Energy and Natural Resources, and their tasks include the mining of radioactive ores explored by MTA and the production of uranium concentrate.

d) Turkish Electric Generation and Transmission Company, Inc. (TEAS) and Turkish Electric Distribution Company, Inc. (TEDAS)

The Turkish Electricity Authority (TEK) was established in 1970 [Act No. 1312 of 15 July 1970, RG No. 13559 of 25 July 1970] and defined by Act No. 1312 as a state economic enterprise. Almost 92%of electrical energy is generated, transmitted and distributed by TEK.

By Act No. 93/4789 of 12 August 1993 [RG No. 21699 of 15 September 1993], TEK was divided into two new public companies: the Turkish Electricity Generation and Transmission Company, Inc. (*Türkiye Elektrik Üretim ve Iletim A.S. Genel Müdürlügü* – TEAS) which manages power generation and transmission, and the Turkish Electricity Distribution Company, Inc. (*Türkiye Elektrik Dagitim A.S. Genel Müdürlügü* – TEDAS), which is responsible for electricity distribution.

i) Legal status

Both TEAS and TEDAS are state economic enterprises under the supervision of the Ministry of Energy and Natural Resources. They are separate legal entities and each possesses its own Statute.

ii) Responsibilities

In addition to general duties concerning electricity generation and transmission, TEAS is responsible for planning, surveying, constructing, commissioning and operating nuclear power plants in Turkey.

iii) Structure

TEAS has a board of directors, a general manager and four assistant general managers. The duties related to nuclear energy are carried out by the Nuclear Power Plants Department.

iv) Financing

The capital stock of TEAS is assigned by the government. Additionally, the financial requirements of TEAS can be met from the following sources:

- appropriations from the general budget of the government;
- annual profits from energy sales;
- various local and foreign credits.

UNITED KINGDOM

I. GENERAL REGULATORY REGIME

1. Introduction

In the United Kingdom, the legislation dealing specifically with nuclear energy dates from 1946, in step with the development of the uses of this type of energy for peaceful purposes [Atomic Energy Act 1946]. In discussing nuclear legislation, a division is sometimes made between laws and regulations primarily directed at the protection of people, such as the Radioactive Substances Act 1993, the Factories Act 1961, the Health and Safety at Work etc. Act 1974, the Ionising Radiation Regulations 1985, and legislation dealing with nuclear installations, primarily concerned with licensing and controlling the safe operation of nuclear plants and also dealing with third party liability for nuclear damage, such as the Nuclear Installations Act 1965 as amended.

The purpose of this part is to provide an overall picture of the law governing all civil nuclear activities in the United Kingdom. The following part will deal in greater detail with the institutional framework for such activities.

2. Mining Regime

There are no mining activities connected with uranium extraction in the United Kingdom. However, the Secretary of State (in practice the Secretary of State for Trade and Industry) is empowered to search for and work minerals and may authorise other persons to do the same on his behalf [Atomic Energy Act 1946, Section 6]. He is also empowered to provide for the compulsory vesting of the right to work minerals either in himself or in the United Kingdom Atomic Energy Authority (UKAEA) [Section 7], and may compulsorily acquire certain minerals, and plants designed or adapted for the production or use of atomic energy or research [Section 8].

3. Radioactive Substances

The keeping and use of radioactive material and accumulation and disposal of radioactive waste are controlled mainly by the Radioactive Substances Act 1993 ("RSA 1993"). As a result of the Environment Act 1995, enforcement of RSA 1993 is the responsibility of the Environment Agency in England and Wales and the Scottish Environment Protection Agency in Scotland. In Northern Ireland enforcement is carried out by the Environment and Heritage Service through its Industrial Pollution and Radiochemical Inspectorate, an agency within the Department of the Environment for Northern Ireland.

RSA 1993 regulates, by way of compulsory registration with the relevant Environment Agency, the keeping and use of radioactive material on any premises, and similar control is exercised on mobile radioactive apparatus [Sections 6-12]. It lays down general provisions for registration of users

of radioactive material for the purposes of an undertaking carried on by them. It states certain exemptions from registration including premises covered by a nuclear site licence, and states that the Secretary of State may grant further exemptions from registration through specific orders. These cover such things as gaseous tritium light devices [S.I. 1985, No. 1047], radioluminous articles [S.I. 1985, No. 1048], testing instruments [S.I. 1985, No. 1049] and certain substances of low activity [S.I. 1986, No. 1002].

The relevant Environment Agency is:

- for England and Wales, the Environment Agency;
- for Scotland, the Scottish Environment Protection Agency; and
- for Northern Ireland, the Industrial Pollution and Radiochemical Inspectorate.

Accumulation of radioactive waste on non-nuclear sites is regulated under the Act. Accumulation of radioactive waste on nuclear licensed sites is regulated by means of the nuclear licensing regime provided by the Nuclear Installations Act 1965.

The Act also requires the authorisation by the relevant Environment Agency of disposals of radioactive waste from both nuclear and non-nuclear sites [Section 7].

In the public sector of education, radioactive substances with an activity in excess of 100 becquerels per gram may not be used in the course of instruction without the approval of the Secretary of State for Education in England and Wales, and Scottish ministers in Scotland. There is a similar restriction on the use of an apparatus (other than a television set or similar apparatus) in which electrons are accelerated by a potential difference of 5 kilovolts or more. [In England and Wales: Education Reform Act 1988, Section 218(1)(e); The Education (Schools and Further and Higher Education) Regulations 1989, S.I. 1989, No. 351, Regulation 7; Education Act 1993, Sections 172(6), 189(2) and 301(6); The Education (Special Needs) (Approval of Independent Schools) Regulations 1994, Schedule 1, Section 7, S.I. 1994, No. 651. In relation to Scotland: the Dangerous Materials and Apparatus (Educational Establishments) (Scotland) Regulations 1984, S.I. 1984, No. 668, made under Section 19(a) of the Education (Scotland) Act 1980. In relation to Northern Ireland: the Ionising Radiation Regulations 1985].

4. Nuclear Installations

a) Licensing and inspection, including nuclear safety

The Nuclear Installations Act 1965 and the Nuclear Installations Regulations 1971 made under the Act [S.I. 1971, No. 381] govern the construction and operation of nuclear installations in the United Kingdom, and health protection at such installations is regulated by the Health and Safety at Work etc. Act 1974.

The competent authority for the licensing of nuclear installations is the Health and Safety Executive (HSE) which is responsible through the Health and Safety Commission (HSC) to the Secretary of State for Trade and Industry for civil nuclear safety questions [Nuclear Installations Act 1965, Section 1, as amended by S.I. 1974, No. 2056, and Regulations made thereunder, and Sections 10 to 12 of the Health and Safety at Work etc. Act 1974].

The Nuclear Installations Inspectorate, part of the Nuclear Safety Directorate of the HSE, ensures that all statutory safety requirements relevant to nuclear installations are complied with. Its nuclear installations inspectors are appointed by the HSE and have the necessary powers to enforce the relevant legislation. The purpose of inspections is to verify that the requirements of the nuclear site licence are met throughout the construction, commissioning and operating period of the nuclear installation and its decommissioning. They also provide checks on the effectiveness of the safety measures taken by the licensee.

The Nuclear Installations Act 1965 makes provision for the licensing of nuclear installations by means of a nuclear site licence which sanctions the use of a particular site for a specific reactor type or plant. Previously, nuclear installations operated by the UKAEA were not subject to the licensing system of the 1965 Act. By Ministerial directive, the UKAEA was required to maintain equivalent standards to those imposed on other nuclear operators. However, the Nuclear Installations Act 1965 (Repeal and Modification) Regulations 1990 removed the UKAEA's exemption from licensing [S.I. 1990, No. 1918].

The 1971 Regulations prescribe as licensable various classes of installation in the nuclear field where nuclear hazards could arise. Sections 1, 3 to 6, 22 and 24A of, and Schedule 2 to, the 1965 Act are listed in Schedule 1 of the Health and Safety at Work etc. Act 1974 and are thus relevant statutory provisions within the meaning of Part 1 of that Act.

The 1965 Act [Section 1] provides that no nuclear reactor (other than one comprised in a means of transport) or nuclear installation of a kind prescribed by regulations (currently the 1971 Regulations) may be installed or operated on a site unless a nuclear site licence has been granted by the HSE in respect of that site.

The installations prescribed by the 1971 Regulations [Regulation 3] are:

- an installation manufacturing fuel elements for the production of atomic energy from enriched uranium, plutonium or any alloy or chemical compound containing them;

- an installation used for producing alloys or chemical compounds from enriched uranium or plutonium or for producing enriched uranium or plutonium from any alloy or chemical compound containing them;

- an installation for the incorporation of enriched uranium or plutonium, or any alloy or chemical compound containing them, in devices designed for subsequent irradiation in a reactor or to form part of a nuclear assembly;

- an installation comprising a nuclear assembly for the production of neutrons, which contains enriched uranium, plutonium or any alloy or chemical compound of them and in which a controlled chain reaction can be maintained with an additional source of neutrons;

- an installation for processing irradiated nuclear fuel;

- an installation for the storage of fuel elements, irradiated nuclear fuel or bulk quantities of other radioactive matter produced or irradiated in the course of producing or using nuclear fuel;

- an installation involved in the extraction of plutonium or uranium by the treatment of irradiated material, or in the enrichment of uranium;

- an installation for the production of radioisotopes from nuclear material.

A licence may be granted only to a corporate body [Nuclear Installations Act 1965, Section 3(1)]. It is not transferable and is granted in respect of a specific site. [Sections 3(1) and 1(1)]. The licence enables the corporate body (the licensee) to install and operate a nuclear installation of a kind prescribed by regulations, or a nuclear reactor, on the site specified in the licence. Conditions attached to the licence provide the necessary checks and controls to be exercised during the design, construction, commissioning and operational stages of the installation as well as the decommissioning stages; these conditions may include, *inter alia*, provisions for [Section 4(1)]:

- securing the maintenance of an efficient system for detecting and recording the presence and intensity of ionising radiations emitted from anything on the site or from anything discharged on or from the site;

- regulating the design, siting, construction, installation, operation, modification, maintenance and decommissioning of any plant or installation on the site.

In addition to licensing requirements under the 1965 Act, the applicant for a nuclear site licence for a nuclear power plant requires the consent of the Secretary of State (in practice, the Secretary of State for Trade and Industry) under Section 36 of the Electricity Act 1989.

Under the Electricity Act 1989, the Secretary of State may, with the approval of the Treasury, make grants or loans for the decommissioning of nuclear installations licensed under the Nuclear Installations Act 1965 [Schedule 12].

The Secretary of State for Trade and Industry may exempt from the licensing requirements of Section 1 of the 1965 Act any installation described in Regulation 3 of the 1971 Regulations which he is satisfied is not a relevant installation [1971 Regulations, Regulation 4].

Finally, the 1965 Act provides that a permit granted by the UKAEA or a government department is required in addition to a nuclear site licence (where that is required) for the use of any site by any person other than the UKAEA or a government department, for any treatment of irradiated material involving the extraction of plutonium or uranium or for the enrichment of uranium. Permits granted by the UKAEA are limited to work for the purpose of research and development [Section 2(1A) as inserted by Section 17 of the Atomic Energy Authority Act 1971].

It is relevant to note that at the international level the United Kingdom ratified the 1994 Convention on Nuclear Safety on 17 January 1996.

b) Protection of the environment against radiation effects

In the United Kingdom, environmental protection provisions with respect to the harmful effects of radiation are not embodied in a single piece of legislation but are set out in several different texts dealing with health and safety, nuclear site licensing, pollution from radioactive waste and dumping at sea (environmental protection in the context of radioactive waste and dumping are dealt with under Section 7 “Radioactive Waste Management”, *infra*).

The Environment Act 1995 created the Environment Agency in England and Wales and the Scottish Environment Protection Agency in Scotland. These Agencies enforce environmental protection legislation and specifically, with respect to radioactivity, are the enforcement organisations

for the Radioactive Substances Act 1993 (RSA 1993). In Northern Ireland the Industrial Pollution and Radiochemical Inspectorate is the enforcement organisation for the Radioactive Substances Act 1993.

The RSA 1993 deals primarily with the control of radioactive waste. All authorisations under the RSA 1993 for nuclear licensed sites include a clause to apply the best practicable means with respect to minimising quantities and volumes of waste disposed of. The Environment Agencies have a duty to apply the provisions of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora when exercising their powers under the RSA.

The Health and Safety at Work etc. Act 1974 provides [Section 5] that it is the duty of persons having control of premises of a kind prescribed by regulations to use the best practicable means to prevent the emission of noxious substances into the atmosphere and for rendering harmless substances so emitted. The premises prescribed include these in which any ore or material containing uranium is treated for the production of uranium, or in which any specific compounds of uranium are manufactured or used, or in which uranium or its compounds are manufactured or fashioned by methods giving rise to dust or fume, other than licensed nuclear sites of nuclear reactors (or facilities for the processing of irradiated fuel therefrom) for the purposes of removing fission products. [The Health and Safety (Emissions into the Atmosphere) Regulations 1983, S.I. 1983, No. 943]. Section 1(1)(d) of the 1974 Act was, however, repealed, with effect from 1 April 1996 in relation to England and Wales. In Northern Ireland, Industrial Pollution Control (Northern Ireland) Order 1997 applies.

For nuclear installations, the Nuclear Installations Inspectorate attaches standard conditions to the nuclear site licence covering radioactive waste disposal, provisions relating to leaking and escape of radioactive material and radioactive waste.

c) Emergency response

Until the Radiation (Emergency Preparedness and Public Information) Regulations, currently under preparation, are adopted, provisions regarding emergency responses to a nuclear incident or accident exist in the framework of a nuclear site licence granted in accordance with the Nuclear Installations Act 1965 and also under the Ionising Radiation Regulations 1985. The conditions attached to a nuclear site licence include provision for the making, implementation and testing of adequate arrangements to deal with nuclear emergencies. These emergency arrangements are individual to each site, and a licensee will develop such arrangements as best suit its business whilst demonstrating that safety is being properly managed.

The Secretary of State for Trade and Industry is responsible for co-ordinating the framework for nuclear emergency plans in Great Britain. The Secretary of State for Northern Ireland is responsible for co-ordination of nuclear emergency planning in Northern Ireland. Under an agreement with the Secretary of State for Trade and Industry, the Scottish Executive undertakes those functions relating to civil nuclear emergencies in Scotland.

On 9 February 1990, the United Kingdom ratified the 1986 Convention on Early Notification of a Nuclear Accident and the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

5. Trade in Nuclear Materials and Equipment

The keeping or use of radioactive substances is controlled under the Radioactive Substances Act 1993, and the Medicines Act 1968. Certain provisions of these Acts do not apply, however, to nuclear installations licensed under the Nuclear Installations Act 1965, namely, reactors, fuel fabrication and reprocessing plants and fuel enrichment plants, including those which hold plutonium extraction permits under Section 2 of the 1965 Act and are bodies corporate within the meaning of Schedule 1 to the Act, and those which are designated companies under Section 19 of the Atomic Energy Authority Act 1971. Those are companies established in connection with the Agreement on the gas centrifuge process, Urenco Ltd. and CENTEC which are subject to security provisions [see below under Section 8 "Non-Proliferation and Physical Protection"].

The Medicines Act 1968 is mainly the concern of the Secretary of State for Health and deals, *inter alia*, with the keeping and use of radioactive apparatus and substances for medicinal and therapeutic purposes. The Radioactive Substances Act 1993 is mainly the concern of the Secretary of State for the Environment, Transport and the Regions in England and Wales, the Secretary of State for Scotland in Scotland and the Department of the Environment for Northern Ireland in relation to Northern Ireland. The Act deals with the use and keeping of such substances from the point of view of public and environmental protection and control of radioactive waste.

The Medicines Act 1968 introduces a comprehensive system of licensing for medical products. This system includes subordinate instruments which relate to trade in and use of such products [S.I. 1978, No. 1004; S.I. 1978, No. 1006; S.I. 1995 No. 2147].

As regards exports, a licence is required for the export of dual-use goods, including nuclear material and equipment. Exports of such goods from the United Kingdom is controlled by Council Regulation (EC) No. 3381/94 (EC OJ No. 367, 31 December 1994, p. 1) and associated Council Decision 94/942/CFSP (EC OJ No. 367, 31 December 1994, p. 8) as amended, which are directly applicable in Member States. However, licensing powers, penalties, enforcement and certain optional provisions of the EC Regulation, together with certain purely national controls, are given effect in the UK by the Dual-Use and Related Goods (Export Control) Regulations 1994 [S.I. 1994, No. 272] made under Section 2(2) of the European Communities Act 1972. Export controls are imposed for a variety of reasons, including non-proliferation policy and international treaty obligations and commitments, and these are matters that are taken into account in considering licence applications. The Secretary of State may grant licences and Community licences; a Community licence is an authorisation granted by a competent authority for the export of dual-use goods from the European Community.

The import of goods including nuclear materials and equipment into the United Kingdom is controlled by the Import, Export and Customs Powers (Defence) Act 1939. Section 1 of the Act, as amended by the Secretary of State for Trade and Industry Order 1970, empowers the Secretary of State to make by Order such provision as he thinks expedient for prohibiting or regulating in all cases or any specified classes of cases the importation into the United Kingdom of all goods or goods of any specified description.

The Import of Goods (Control) Order 1954 prohibits all goods (other than most goods from the Channel Islands) from being imported into the United Kingdom except under a licence granted by the Secretary of State. The granting of licences is carried out by the Import Licensing Branch of the Department of Trade and Industry. Under the 1954 Order the Secretary of State from time to time grants an Open General Import Licence (OGIL), the effect of which is to permit the importation into the United Kingdom of all goods except those specified in the Schedule. Each OGIL revokes the previous one. The current OGIL was granted on 4 December 1987 and has been frequently amended.

The effect of the 1954 Order and the current OGIL is that an individual licence is required for the importation into the United Kingdom of certain nuclear materials.

Controls on the import, export and supply and delivery of goods are also contained in Orders in Council made under the United Nations Act 1946 to give effect to United Nation trade sanctions. Orders exist in relation to Iraq, Libya, Serbia and Montenegro, the former Yugoslavia, Haiti, Liberia, Somalia, and Rwanda.

Council Regulation (Euratom) No. 1493/93 controls transboundary movements of radioactive sealed sources and radioactive waste between Member States of the European Union. The shipment of radioactive waste between Member States of the European Union, or into or out of the European Union, is also subject to Directive 92/3/Euratom, which has been implemented in the United Kingdom by the Transfrontier Shipment of Radioactive Waste Regulations 1993.

6. Radiation Protection

The protection of workers and the public against the hazards of ionising radiation is governed by several enactments and instruments, including the Ionising Radiation Regulations 1999 [S.I. 1999, No. 3232] (in Northern Ireland S.I. 1985, No. 273), the Radioactive Substances Act 1993, the Health and Safety at Work, etc. Act 1974, as well as the Medicines Act 1968 under which instruments have been made [*e.g.*, the Medicines (Radioactive Substances) Order 1978, S.I. 1978, No. 1004; the Medicines (Administration of Radioactive Substance) Regulations 1978, S.I. 1978, No. 1006; the latter Regulations were made under both the Medicines Act and the European Communities Act 1972].

The Medicines (Administration of Radioactive Substances) Regulations 1978 now implement Article 5(a) of Council Directive 80/836/Euratom, which requires a system of prior authorisation of those persons who are to administer radioactive substances to persons for the purposes of diagnosis, treatment or research.

The competent authority for the protection of workers and the public from the industrial use of ionising radiation is the Health and Safety Executive (HSE) [Health and Safety at Work etc. Act 1974, Section 11]. The safety of workers in nuclear installations is also governed by the Ionising Radiation Regulations 1985. The HSE is responsible through the Health and Safety Commission to the Secretary of State for the Environment, Transport and the Regions for radiological protection questions. The relevant Environment Agency (see Section 3 above, "Radioactive Material") has responsibility for regulation of the use of radioactive materials and disposal of radioactive waste; in doing so the Agencies have regard to UK Government policy for public and environmental protection. The Health Ministers (*i.e.* those responsible for health in England, Scotland, Wales and Northern Ireland) are the authorities with overall responsibility for all aspects of health protection.

The Health and Safety at Work Act 1974 [or the Health and Safety at Work (Northern Ireland) Order 1978] provides generally for health, safety and welfare in connection with work, including the nuclear field.

The Ionising Radiations Regulations 1999 are the principal instrument implementing the provisions of Council Directive 96/29/Euratom, laying down the basic safety standards for health protection of the general public and workers against the dangers of ionising radiation. Other legislation which contributes to implementation includes: the Radioactive Substances Act 1993 and associated orders; and the proposed Radiation (Emergency Preparedness and Public Information) Regulations

(REPPIR). REPPIR will implement the emergency preparedness provisions of the Directive. Until REPPIR are adopted, current provisions of the Ionising Radiations Regulations 1985 for special hazard assessments and related contingency plans are being retained. The opportunity has also been taken to incorporate into the Ionising Radiations Regulations 1999 key provisions of Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionising radiation during their activities in controlled areas.

The HSE is producing a range of supporting guidance on prior authorisation, outside workers, pregnant and breast-feeding workers, monitoring equipment and equipment used for medical purposes.

7. Radioactive Waste Management

The Radioactive Substances Act 1993 governs the disposal and accumulation of radioactive waste in the United Kingdom [Sections 13 and 14]. The disposal of radioactive waste may not be undertaken without an authorisation granted by the relevant Environment Agency (see Section 3 "Radioactive Material" *supra)* [Sections 16 and 47(1)]. The accumulation of radioactive waste may not be undertaken without an authorisation by the relevant Environment Agency [Section 16(2)], except in the case of nuclear licensed sites, which are covered by separate legislation.

The Secretary of State for Defence has responsibility for the disposal of radioactive waste at Ministry of Defence sites, but the Agencies have agreements with Ministry of Defence establishments that they administratively apply the requirements of the Radioactive Substances Act 1993. However, Ministry of Defence sites operated by civilian contractors, for example, naval dockyards at Devonport and Rosyth and the Atomic Weapons Establishment, are regulated under the terms of the Act.

The Electricity Act 1989 provides that the Secretary of State (in practice the Secretary of State for Trade and Industry) may, with the approval of the Treasury, make grants or loans for the storage or reprocessing of nuclear fuel, the treatment, storage or disposal of radioactive waste or the decommissioning of any nuclear installation [Schedule 12].

Part II of the Environmental Protection Act 1990 relates to the disposal and recovery of waste on land. While Part II of the Act does not apply to radioactive waste within the meaning of the Radioactive Substances Act 1993, Section 78 of this Act empowers the Secretary of State to make regulations providing for appropriate provisions of Part II to have effect (with or without modifications) for the purposes of dealing with radioactive waste.

Previously, waste on land was subject to the provisions of Part I of the Control of Pollution Act 1974. Section 30(5) of that Act contained a regulation-making power similar to that now found in Section 78 of the 1990 Act.

At present, radioactive waste which, apart from its radioactivity, is dangerous or difficult to dispose of ("special waste"), is controlled by the Control of Pollution (Special Waste) Regulations 1980 [S.I. 1980, No. 1709]. However, these Regulations were replaced from 1 September 1996 by the Special Waste Regulations 1996. The 1996 Regulations continue to ensure that any waste which may possess hazardous properties in addition to its radioactivity remains subject to stringent controls over its movement.

Part II.A of the Environmental Protection Act 1990 (inserted by the Environment Act 1995) relates to (non-radioactively) contaminated land. Section 78 (YC) empowers the Secretary of State to

make regulations providing for appropriate provisions of Part II.A to have effect (with or without modification) to radioactively contaminated land.

As regards the pollution of water, for the purposes of Part II of the Control of Pollution Act 1974 (pollution of water), the power under Section 30(5) was applied by Section 56(6). The Control of Pollution (Radioactive Waste) Regulations 1976 [S.I. 1976, No. 959] made under Section 30(5) [as applied by Section 56(6)] of the 1974 Act provide that Sections 43 and 44 of the 1974 Act (control of discharges of trade effluent into public sewers in England and Wales) have effect in relation to radioactive waste although no account is to be taken in exercising the controls under those sections of any radioactivity possessed by any effluent, as its radioactivity is taken into account in exercising controls under the Radioactive Substances Act 1993. (Note that Sections 43 and 44 of the 1974 Act have been repealed, and have been replaced by provisions to be found in Chapter III of Part IV of, and Schedule 8 to, the Water Industry Act 1991).

In addition, in relation to England and Wales, Section 98(2) of the Water Resources Act 1991 confers power for the Secretary of State to make regulations applying, with or without modifications, the provisions of Part III of the 1991 Act (which aim to prevent or control the pollution of water) in relation to radioactive waste. The Control of Pollution (Radioactive Waste) Regulations 1989 [S.I. 1989, No. 1158], made under Section 123 of the Water Act 1989, have effect as if made under Section 98(2) of the 1991 Act [see Section 2(2) of, and Schedule 2 to, the Water Consolidation (Consequential Provisions) Act 1991]. These Regulations provide for Chapter I of Part III of the Water Act 1989, and now [by virtue of paragraph 1(3) of Schedule 2 to the Water Consolidation (Consequential Provisions) Act 1991] the corresponding provisions in Part III of the Water Resources Act 1991, to have effect in relation to any radioactive waste, although no account is to be taken of any radioactivity possessed by it [see now Section 40 of the Radioactive Substances Act 1993].

The Control of Pollution (Radioactive Waste) (Scotland) Regulations 1991 apply the provisions of the Control of Pollution Act 1974 to radioactive waste in Scotland. Again, no account is taken of any radioactivity possessed by the waste.

The Dumping at Sea Act 1974, now replaced by the Food and Environment Protection Act 1985 (FEPA), enabled the United Kingdom to ratify the 1972 Oslo Convention on Prevention of Marine Pollution by Dumping from Ships and Aircraft, and the 1972 London Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter ratified on 17 November 1975. The United Kingdom also ratified the 1996 Protocol to the London Convention. The FEPA provides that substances and articles may not be dumped at sea from a British ship or aircraft without a licence [Section 5]. There is no definition of "substances" and "articles" and thus radioactive substances are not excluded from the prohibition under Section 5. In 1994, the UK Government accepted a complete ban on deep ocean disposal of Intermediate Level Waste and Low Level Waste, which had been adopted at the Consultative Meeting of the London Convention in 1993.

The Environment Act 1995 places general duties on the Environment Agencies which may impinge on their enforcement of the Radioactive Substances Act 1993. These include a duty to consider sustainable development, cost and benefits of any actions, special consideration of rural communities, as well as general consideration for protection of the environment.

Government policy in the United Kingdom was last set out in the White Paper, "Review of Radioactive Waste Management Policy: Final Conclusions" (Cm. 2919) (currently under review).

8. Non-Proliferation and Physical Protection

The Atomic Energy Act 1946 [Section 4] and the Nuclear Installations Act 1965, as amended by the Atomic Energy Authority Act 1971 [Schedule 1], confer wide powers on the Secretary of State (in practice the Secretary of State for Trade and Industry) to prevent any improper use of fissionable materials.

The United Kingdom ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 27 November 1968. The Nuclear Safeguards and Electricity (Finance) Act 1978 provides for giving effect to an international agreement of 6 September 1976 for the application of safeguards in the United Kingdom in relation to the Non-Proliferation Treaty [Agreement between the United Kingdom, the European Atomic Energy Community and the International Atomic Energy Agency – INFCIRC/2630, October 1978].

Furthermore, the United Kingdom ratified the 1996 Comprehensive Nuclear Test Ban Treaty on 6 April 1998.

As regards the physical protection of nuclear material, the Official Secrets Acts 1911-1920 make provision for the security of certain Crown property by declaring that certain activities in relation to any such property shall be a criminal offence. They also provide that certain activities by Crown servants and those who have contact with the Crown shall be offences.

Section 3(c) of the 1911 Act provides that particular premises may be declared by order to be prohibited places for the purpose of the Act. Section 6(3) of the Atomic Energy Authority Act 1954 brings any place belonging to or used for the purposes of the UKAEA within the definition of places which may be declared by order to be prohibited places. The current Order, made in 1994, declares two of the Authority's premises, Harwell and Windscale, to be such prohibited places [S.I. 1994, No. 968].

Further provision is made by Section 2 of the Nuclear Installations Act 1965, as amended by Section 17 of the Atomic Energy Authority Act 1971. This allows the Secretary of State to make orders applying Schedule 1 to the 1965 Act (added by the 1971 Act) to any premises in respect of which a permit under Section 2 of the Act has been granted for purposes other than research or development only. In particular, paragraph 3 of the Schedule brings any such site within the definition of places which may be declared to be prohibited places.

Section 19 of the 1971 Act [as amended by Section 16(4) of and Schedule 2 to the Official Secrets Act 1989] further provides that paragraphs 4-6 of the Schedule shall apply to any company registered in the United Kingdom and formed for the purposes of the Treaty of Almelo (relating to the gas centrifuge enrichment process).

These paragraphs have the additional effect of extending the powers of special constables in relation to those premises and allowing the Secretary of State to give directions for the security and safety of the site and restricting the termination of employment on certain grounds.

Orders have been made applying Schedule 1 to the 1965 Act to British Nuclear Fuels plc (BNFL) and Urenco (Capenhurst) Ltd. [S.I. 1971, No. 569 and 1993, No. 687], declaring certain premises of the Atomic Energy Authority (AEA) and BNFL to be prohibited places [S.I. 1994, No. 968] and designating Urenco Ltd. and CENTEC Centrifuge Techniques Ltd, formed to implement the Almelo Treaty on the gas centrifuge enrichment process, as companies to which stringent security measures apply for the purpose of Section 19 of the 1971 Act [S.I. 1971, No. 1434; S.I. 1973, No. 17].

The Nuclear Material Offences Act 1983 enabled the United Kingdom to ratify the 1979 Convention on the Physical Protection of Nuclear Material on 6 September 1991. The Act extends throughout the United Kingdom.

The scope of certain specified offences of a serious nature is extended so as to make it an offence in the United Kingdom to commit certain acts outside the United Kingdom in relation to, or by means of, nuclear material [Section 1].

It is an offence to receive, hold, or deal with nuclear material with the intention of doing any act which is a specified offence (offences against the person), or being reckless as to whether another person would do such an act; or to make threats that he or another person will do such an act by means of nuclear material, intending that the person to whom the threat is made shall fear that it will be carried out.

The Act provides that the new offences are extraditable offences under the Extradition Act 1870 and specifies that, where there is no extradition arrangement with a state which is a Party to the Physical Protection Convention, an Order in Council may be made under the 1870 Act applying that Act, as though the Convention itself constituted an extradition arrangement with that state [Section 5].

Nuclear material is defined by reference to the definition in the Convention [Schedule].

The security of nuclear generating stations, and laboratories for the examination of irradiated nuclear fuel by or on behalf of the operator of the generating station, is controlled by The Nuclear Generating Stations (Security) Regulations 1996 [S.I. 1996, No. 665], which were made under the Health and Safety at Work etc. Act 1974, and which came into force on 1 April 1996. They apply to generating stations and laboratories which are nuclear installations requiring a licence under Section 1 of the Nuclear Installations Act 1965.

The Regulations require the operator to ensure that, at all times while any nuclear fuel is on site, or in transit to or from a site, the site is subject to a security regime which conforms to a description ("security plan") of the security standards, procedures and arrangements adopted by the operator for the protection of the site. Before carrying out any work of alteration or extension to any construction which is part of the generating station or laboratory, the operator must also satisfy the Secretary of State that the security regime to which the site will be subject in the course of the work and thereafter will conform to an approved security plan. The operator is also required to take all reasonable steps to secure that no nuclear fuel is transported to or from the site except in accordance with an approved security plan.

In addition, the Regulations require the operator to comply with any directions given by the Secretary of State requiring the operator to adopt certain standards, procedures or arrangements specified in such directions. The operator is also required to have security assessments carried out periodically by a person approved by the Secretary of State, and to have a similar assessment carried out before bringing nuclear fuel for the first time onto the site or onto any newly altered or extended part of the generating station or laboratory.

The Regulations cease to apply to a site when there ceases to be any nuclear fuel kept or proposed to be kept on the site, and cease to apply to an operator when the operator's "period of responsibility" under the 1965 Act comes to an end.

The Secretary of State for Trade and Industry is responsible for the enforcement of the Regulations.

9. Transport

The transport of radioactive materials is governed by different regulations, depending on the mode of transport used. Essentially however, all the regulations reflect the International Atomic Energy Agency's recommended Regulations on the Safe Transport of Radioactive Materials [Safety Series No. 6], which are revised regularly.

The Secretary of State for the Environment, Transport and the Regions is the competent authority for road and rail transport in Great Britain, and air and sea transport in the UK. The Department of the Environment for Northern Ireland is responsible for road and rail in Northern Ireland.

The Radioactive Material (Road Transport) Act 1991 regulates the transport of radioactive materials by road, replacing Sections 5 and 7 of the Radioactive Substances 1948 Act (the 1948 Act has now been repealed). The Act clarifies and extends the Secretary of State's power to make regulations regarding, *inter alia*, the design, packaging, labelling, transport of packages of radioactive materials [Section 2], and to enforce such regulations. He may also appoint inspectors to enforce the regulations [Section 1]. This only covers Great Britain.

The equivalent legislation in Northern Ireland is The Radioactive Material (Road Transport) (Northern Ireland) Order 1992 [S.I. 1992, No. 234 (N.I. 2)].

The national regulations governing transport, by mode of transport, are as follows:

- *Roads in Great Britain* – The Radioactive Material (Road Transport) (Great Britain) Regulations 1996 [S.I. 1996, No. 1350]. They are enforced by the Department of the Environment, Transport and the Regions (DETR).

- *Driver Training in Great Britain* – The Carriage of Dangerous Goods by Road (Driver Training) Regulations 1996 [S.I. 1996, No. 2094]. They are enforced jointly by DETR and the Health and Safety Executive (HSE).

- *Roads in Northern Ireland* – The Radioactive Substances (Carriage by Road) Regulations (Northern Ireland) 1983 [S.R. 1983, No. 344]. The Radioactive Substances (Carriage by Road) (Amendment) Regulations (Northern Ireland) 1986 [S.R. 1986, No. 61]. They are enforced by the Department of Environment for Northern Ireland.

- *Driver Training in Northern Ireland* – The Road Traffic (Training of Drivers of Vehicles Carrying Dangerous Goods) Regulations (Northern Ireland) 1992 [S.I. 1992, No. 262]. The Road Traffic (Training of Drivers of Vehicles Carrying Dangerous Goods) (Amendment) Regulations (Northern Ireland) 1993 [S.I. 1993, No. 240]. These are the same as the Great Britain requirements above and are enforced by the Department of the Environment for Northern Ireland and the Department of Economic Development.

- *Rail in Great Britain* – The Packaging, Labelling and Carriage of Radioactive Material by Rail Regulations 1996 [S.I. 1996, No. 2090] ("RAMRail"): Approved Requirements for the packaging, labelling and carriage of radioactive material by rail 1996 edition. The Carriage of Dangerous Goods (Classification, Packaging and Labelling) and Use of Transportable Pressure Receptacles Regulations 1996 [S.I. 1996, No. 2092] ("CDGCPL"). The Carriage of Dangerous Goods (Amendment) Regulations 1999 [S.I. 1999, No. 303]. They are enforced jointly by the HSE and DETR.

- *Rail in Northern Ireland* – The Packaging, Labelling and Carriage of Radioactive Material by Rail Regulations (Northern Ireland) 1998 [S.R. 1998, No. 132] ["RAMRail(NI)"]. They are enforced by the Department of the Environment for Northern Ireland.

- *Sea* – The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997 [S.I. 1997, No. 2367]; Merchant Shipping Notice No. M1620, "The Carriage of Dangerous Goods and Marine Pollutants in Packaged Form on Ships". These implement the International Maritime Organisation's (IMO) International Maritime Dangerous Goods Code (IMDG Code) (Class 7) into UK legislation. They are enforced by the Marine Safety Agency, an agency of DETR.

- *Air* – The Air Navigation (No. 2) Order 1995 [S.I. 1995, No. 1970]; The Air Navigation (Dangerous Goods) Regulations 1994 [S.I. 1994, No. 3187 and Amendments 1996, No. 3100 and 1998, No. 2536]. These implement the International Civil Aviation Organisation's Technical Instructions for the Safe Transport of Dangerous Goods by Air (Class 7) into UK legislation. They are enforced by the Civil Aviation Authority.

- *Ports* – The Dangerous Substances in Harbour Areas Regulations 1987 [S.I. 1987, No. 37]. They are enforced by the HSE.

- *Inland Waterways* – There are no statutory regulations in the UK, but the British Waterways Board (BWB) does issue the following Terms and Conditions: Dangerous Goods BWB 1981, and Schedule of Dangerous Goods (The Green Book) BWB 1981 (Class 7).

In the case of international transport of radioactive materials, the United Kingdom has ratified the following international agreements:

- *Roads in Europe* – European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) (Class 7).

- *Rail in Europe* – Convention concerning the International Carriage by Rail (COTIF) Appendix B, Uniform rules concerning the contract for the International Carriage of Goods by Rail (CIM) Annex 1, Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) (Class 7).

These are now part of UK law via the statutory instruments listed above for road and rail.

The UK is also a member of the International Maritime Organisation and the International Civil Aviation Organisation.

10. Nuclear Third Party Liability

The basic legislation on nuclear third party liability in the United Kingdom is contained in the Nuclear Installations Act 1965, which implements the provisions of the 1960 Convention on Third Party Liability in the Field of Nuclear Energy ratified by the United Kingdom on 23 February 1966 and the 1963 Brussels Convention Supplementary to the Paris Convention, ratified on 24 March 1966.

The Nuclear Installations Act 1965 was amended by the Energy Act 1983. Part II of the 1983 Act is concerned with nuclear installations and has for its main purpose the amendment of the

third party liability provisions of the Nuclear Installations Act 1965 to give effect to the provisions of the two 1982 Protocols to amend the above-mentioned Paris and Brussels Conventions. The provisions of Part II of the 1983 Act increase the sums available to meet claims for nuclear damage.

The 1983 Act [Section 27] amended Section 16 of the 1965 Act to increase the liability limit for operators of licensed sites from British pounds (GBP) 5 million to GBP 20 million per incident. The lower limit of GBP 5 million is retained in the case of certain small prescribed sites (see below). The Act also provided for these two limits to be increased by order to avoid the need for further primary legislation if the liability limits in the Paris Convention are increased. Thus the operator's liability has been increased by order from GBP 20 million to GBP 140 million [a little above Special Drawing Rights (SDRs) 150 million] as from 1 April 1994 [S.I. 1994, No. 909]. Any such order requires approval by a resolution of the House of Commons before it is made.

The 1965 Act [Section 18] was further amended by the Energy Act 1983 [Section 28] to increase the total amount of funds available to meet claims from GBP 43 million to the pound sterling equivalent of SDRs 300 million. The amount may be increased by order with approval of the Treasury [Section 18(1B)]. Another amendment has been made to express in SDRs, in place of sterling, the minimum amount which must be left available (in an incident involving nuclear material in course of carriage) for general claims as opposed to claims in respect of damage to the means of transport. The minimum is set at SDRs 5 million which may be increased by order with the approval of the Treasury [Section 21(1) and (1A)].

The Nuclear Installations (Prescribed Sites) Regulations 1983 [S.I. 1983, No. 919] prescribe the sites, licensees of which are subject to a lower limit of liability under Section 16(1) of the Nuclear Installations Act 1965, as amended by the Energy Act 1983. Essentially, the sites prescribed are the sites of small installations [Regulation 3]. They are prescribed by reference to the type and designed thermal output of any nuclear reactor with its associated fuel, and by reference to the activity of other radionuclides which may also be present [Regulations 3 and 4]. The Regulations provide for cases where nuclear material of different levels of activity is present, as well as for overall limits of mass for fissile material [Regulation 3(3) and (5)].

Under the 1965 Act as amended [Section 7], nuclear site licensees are under an absolute duty, and are liable for breach of this duty, to ensure that no occurrences involving nuclear matter on their sites cause personal injury or damage to property and are under a similar duty as regards ionising radiation emitted on their sites. The damage must be physical damage to tangible property; it does not include pure economic loss or damage to incorporeal property or property rights [Case law: *Merlin v BNFL* (1990) 3WLA 393]. The same duty lies upon the UKAEA and the Crown [Sections 8 and 9]. This duty on the UKAEA applies whether or not a nuclear site licence has been granted in respect of the site [S.I. 1990, No. 1918]. Moreover, the Congenital Disabilities (Civil Liability) Act 1976 [Sections 3 and 4] provides that if a child is born disabled as the result of an injury to either parent caused by a breach of such a duty, the child's disabilities are to be regarded for the purposes of the 1965 Act as injuries caused on the same occasion as those caused to the parent.

The Nuclear Installations Act 1965 [Section 19] was also amended by the Atomic Energy Act 1989 [Section 4(1)] to modify the definition of "cover period" so as to prevent the grant of a new nuclear site licence from bringing the current cover period to an end where the new licence is in effect, a continuation of the old licence with amendments. [Section 19(2B) of the 1965 Act.] This is relevant to a nuclear operator's obligation to provide insurance cover not only for the current period but also for any cover period which ended in the last ten years.

II. INSTITUTIONAL FRAMEWORK

Nuclear legislation was introduced in the United Kingdom with the Atomic Energy Act 1946 [Section 1]. Responsibility for the development and control of nuclear activities was originally entrusted to the Minister for Supply and further detailed in the Radioactive Substances Act 1948, with provision made for the appropriate minister to make regulations to prevent injury to health from ionising radiations and to secure the safe disposal of radioactive waste. In parallel with the development of nuclear energy, this responsibility was successively transferred to the Lord President of the Council in 1953, to the Prime Minister in 1957, to the Minister for Science in 1959, to the Secretary of State for Education and Science in 1964, and to the Minister for Technology in 1965.

Between 1970 and 1974, these duties were discharged by the Secretary of State for Trade and Industry, from 1974 to 1992 by the Secretary of State for Energy, and since 1992 by the Secretary of State for Trade and Industry once more, though responsibility for the control of radioactive material and radioactive waste lies with the Secretary of State for the Environment, Transport and the Regions and the Scottish ministers in Scotland.

Following a review of governmental functions in 1970, a reorganisation of central government took place with a view to improving the efficiency of government. This entailed changes both in methods of operation between government departments and within the departments themselves and, consequently, had a direct effect on the general regime governing nuclear activities.

As a consequence of this review certain functions in the nuclear field, formerly discharged by several ministers, were unified. In particular, the Department of Trade and Industry was formed to take over the responsibilities for general industrial policy which were previously divided between the Board of Trade and the Ministry of Technology. The Secretary of State for Trade and Industry was given responsibility for atomic energy and most of the related functions under the Atomic Energy Act 1946, the Atomic Energy Authority Act 1954 and the Nuclear Installations Act 1965. Between 1974 and 1992, these functions were exercised by the Secretary of State for Energy. Since the abolition of that office in 1992, however, they have returned to the Secretary of State for Trade and Industry.

Major changes were made in those parts of the government machine dealing with the environment. In particular, the Ministries of Housing and Local Government, of Public Building and Works and Transport were merged into a Department of the Environment, under a Secretary of State for the Environment, with responsibility for questions involving protection against the hazards of ionising radiation, radioactive substances and waste. The Department of Transport was separated from the Department of the Environment in 1976. In 1997, the Departments of Transport and the Environment were re-united to form the Department of the Environment, Transport and the Regions.

The United Kingdom Atomic Energy Authority (UKAEA) was set up by the Atomic Energy Authority Act 1954 as the statutory body responsible for the general development of nuclear energy in the United Kingdom, subject to the Secretary of State's overall duty in this respect; since 1989 it has been reorganised, and now operates commercially as AEA Technology, and is further discussed below.

The Health and Safety Commission (HSC) and the Health and Safety Executive (HSE) were established by the Health and Safety at Work etc. Act 1974 as bodies corporate, generally responsible,

inter alia, for the regulation of hazardous activities, including risks arising from work with ionising radiations where these hazards arise from work-related activities.

1. Regulatory and Supervisory Authorities

No single authority has overall responsibility for nuclear energy in the United Kingdom. While the Secretaries of State for Trade and Industry and for the Environment, Transport and the Regions are competent for the development and the environmental protection aspects of nuclear energy respectively, they share those powers with other ministers when nuclear questions come within the latters' sphere of competence. In Scotland, Wales and Northern Ireland, in many cases the functions carried out by different ministers in England are exercised by the relevant ministers for these countries, (this should be assumed to be the case in the following text unless otherwise stated).

a) Secretary of State for Trade and Industry

Under the Atomic Energy Act 1946, the Secretary of State (in practice, the Secretary of State for Trade and Industry) has a duty to promote and control the development of atomic energy [Section 1]. He may make orders (though no such order has been made) which, except under his licence (a) prohibit the acquisition, production, treatment, possession, use, disposal, export or import of (i) uranium, thorium, plutonium or neptunium or their compounds or any other prescribed substance used for the production or use of atomic energy or for related research or (ii) any plant for the production or use of atomic energy or related research, or (b) prohibit the working of any specified minerals from which any of the above substances can be obtained [Section 10]. The Act also gives the Secretary of State powers to obtain information on materials, plant and processes; to authorise the entry and inspection of certain premises; to search for and to authorise other persons to search for certain minerals; and to acquire compulsorily substances, minerals and plant which are for the production or use of atomic energy or research into related matters, and rights under contracts relating to the production or use of atomic energy or related research [Sections 4, 5, 6, 8 and 9].

The Atomic Energy Authority Act 1954 which set up the United Kingdom Atomic Energy Authority (UKAEA) provides that the Secretary of State has the general duty of ensuring that the UKAEA attach proper degrees of importance to the various applications of atomic energy, and may give directions to the Authority [Sections 1 and 3]. He exercises general control over it and appoints the chairperson and members of the Authority and lays before Parliament an annual report on its activities.

As already mentioned, the Electricity Act 1989 (which reorganised the electricity industry in the United Kingdom – for further details see below) provides that the consent of the Secretary of State for Trade and Industry is required for the construction, extension or operation of a generating station (including a nuclear generating station) [Section 36].

Also, the Import, Export and Customs Powers (Defence) Act 1939 [Section 1] empowers the Secretary of State by order to make such provisions as he may think expedient for prohibiting or regulating the import of goods. So far as the importation of nuclear materials are concerned, under the provisions currently in force [Import of Goods (Control) Order 1954 [S.I. 1954, No. 23 as amended] together with the Open General Import Licence dated 4 December 1987 a licence is required from the Secretary of State for the import of certain radioactive substances.

The Secretary of State is responsible for granting licences for the export of dual-use goods, including nuclear materials and equipment, pursuant to the provisions described under Part I, Section 5 "Trade in Nuclear Materials and Equipment" of this study *supra*.

b) Secretary of State for the Environment, Transport and the Regions

Under the Radioactive Substances Act 1993, the Secretary of State for the Environment, Transport and the Regions and the National Assembly for Wales have powers to call in applications and issue directions to the relevant Environment Agency. Scottish ministers have similar powers with respect to the Scottish Environment Protection Agency (SEPA), and in Northern Ireland, the Department for the Environment for Northern Ireland has power to call in applications and make Regulations with respect to the Industrial Pollution and Radiochemical Inspectorate [see Part I "General Regulatory Regime", Section 3 "Radioactive Material" *supra*].

The Secretary of State also has the power to regulate the transport of radioactive material by road and rail in Great Britain, and air and sea in the UK. He is also the competent authority for those modes of transport in respect of the requirements of the IAEA's recommended Regulations on the Safe Transport of Radioactive Materials [Safety Series No. 6].

c) Minister for Agriculture, Fisheries and Food

Schedule 22 to, and Sections 211 and 212 of, the Environment Act 1995 have amended the Radioactive Substances Act 1993 to grant powers to the Minister and issue directions to the Environment Agency. These powers ensure that authorisations granted by the Agency will be adequate to ensure the continued radiological safety of food produced within the country. Under the Food Standards Act 1999 these powers will transfer to the Secretary of State for Health when the Food Standards Agency is created in April 2000. Scottish ministers and the National Assembly for Wales have similar powers.

d) Secretary of State for Health

The Secretary of State for Health and the other United Kingdom Health Ministers have responsibilities in matters of health, and they are administratively accountable for the National Radiological Protection Board (NRPB) [Radiological Protection Act 1970, Sections 1and 2].

e) Secretary of State for Education

As already mentioned, the Secretary of State for Education in England and Wales and Scottish ministers in Scotland must approve the use of radioactive substances in excess of 100 becquerels per gram in the course of instruction, as well as the use of electrical equipment emitting ionising radiation and containing components operating at a potential difference of more than 5 kilovolts. [In relation to England and Wales: Regulation 7 of the Education (Schools and Further and Higher Education) Regulations 1989, S.I. 1989, No. 351, made under Section 218(1)(e) of the Education Reform Act 1988; paragraph 7 of Schedule 1 to the Education (Special Needs) (Approval of Independent Schools) Regulations 1994, S.I. 1994, No. 651, made under Sections 172(6), 189(2) and 301(6) of the Education Act 1993. In relation to Scotland: the Dangerous Materials and Apparatus (Educational

Establishments) (Scotland) Regulations 1984, S.I. 1984, No. 668, made under Section 19A of the Education (Scotland) Act 1980].

2. Advisory Bodies

a) Medical Research Council (MRC)

The Medical Research Council (MRC) is an autonomous body established by Royal Charter. It is grant-aided through the Office for Public Service and Science, and its functions include advising the government and authorities discharging responsibilities in that field on the somatic and genetic effects of ionising radiations [Science and Technology Act 1965]. The Council advises on the biological bases on which radiation protection standards rest, in the light of its own and the latest international findings.

b) Nuclear Safety Advisory Committee

In September 1976, the Standing Royal Commission on Environmental Pollution, which was set up in 1970, presented to Parliament its Sixth Report, covering nuclear power and the environment. The Royal Commission expressed concern about "the need for a source of independent, expert advice to the government on technical matters and [matters] which are relevant to policy decisions on major and hazardous technological developments, whether nuclear or otherwise [...] the Health and Safety Executive have a responsibility to give such advice and [...] should develop the capability to do so."

The government agreed with this recommendation, and in 1977 the Health and Safety Commission set up the Advisory Committee on the Safety of Nuclear Installations. This Committee was renamed the Nuclear Safety Advisory Committee on 11 July 1997. The Committee consists of a chairperson and twenty members appointed for a three-year term, drawn from academic, scientific, and industrial circles, advised by a number of expert assessors from the nuclear industry.

The Committee's mandate is to advise the Health and Safety Commission and make recommendations on major issues affecting the safety of nuclear installations, including their design, siting, operation and maintenance which are referred to them or which they consider require consideration.

c) Radioactive Waste Management Advisory Committee

In its Sixth Report to Parliament, the Royal Commission on Environmental Pollution took the view that "the responsibility for developing the best strategy for dealing with radioactive wastes is one for the government, and specifically for a department concerned to protect the environment, not one concerned to promote nuclear power" and recommended that a Committee be established to advise the responsible ministers on broad policy issues affecting radioactive waste management.

The government accepted this recommendation and the Secretary of State for the Environment accordingly set up this Committee as a non-statutory body, offering independent advice. A majority of the members, including the chairperson, are independent scientists and the other members include environmentalists as well as specialists from nuclear, medical and research disciplines. The members are appointed by the Secretaries of State for the Environment, and for Wales and Scottish ministers.

The Committee's mandate is to advise the relevant ministers on major issues relating to the development and implementation of an overall policy for all aspects of the management of civil radioactive waste, and on any matters referred to it by these ministers.

3. Public and Semi-Public Agencies

a) United Kingdom Atomic Energy Authority (UKAEA)

The United Kingdom Atomic Energy Authority (UKAEA) is a statutory corporation which, while remaining in the public sector, has moved progressively away from its original role as the research and development body responsible for taking forward the mission of developing nuclear power technology in the United Kingdom. Although the Authority is still the repository of very considerable nuclear expertise and research capability it is now entrusted with the task of dealing with the legacy of past nuclear research (including decommissioning of redundant nuclear installations, the responsibility for the land and property holdings of the Authority, and certain activities which are not appropriate to be carried out on a commercial basis, such as research into nuclear fusion and the operations of the UKAEA Constabulary).

i) Legal status

The UKAEA was set up as a statutory corporation by the Atomic Energy Authority Act 1954 [Section 1] in implementation of the government's policy that the mission of developing atomic power in the United Kingdom should be carried out by an autonomous organisation outside the scope of direct ministerial control and free from day to day involvement by government in its activities. During its existence the Authority has been under the general supervisory authority of a succession of government departments. The Secretary of State for Trade and Industry has the "sponsorship" role at present. The Secretary of State can give directions to the Authority, and they must comply, but in the same section of the 1954 Act [Section 3] it is expressly provided that he should not concern himself with the detail of operations. The UKAEA therefore enjoys a significant degree of autonomy. It has certain powers which are normally attached to government agencies, such as the power to acquire land compulsorily for the performance of its functions, but it has not exercised such powers for many years and has never had significant regulatory functions. As already mentioned, nuclear installations operated by the UKAEA were not previously subject to licensing. Since 1990, this exemption has been removed [the Nuclear Installations Act 1965 (Repeal and Modification) Regulations 1990].

ii) Responsibilities

The original functions of the Authority, in effect the activities which it has legal power to carry out (because there is no legal obligation to carry on all or any of these activities), and which it retains, are to produce, use, and dispose of atomic energy and to carry out research into related matters; to manufacture, buy or acquire, store and transport any articles which, in its opinion, may be required in connection with the production and use of atomic energy; to produce, treat, transport and dispose of radioactive substances; and to disseminate information relating to and train persons in matters concerned with atomic energy and radioactive substances [Atomic Energy Authority Act 1954, Section 2(2)].

This mandate was extended to include research and development in non-nuclear fields as required by the Secretary of State [Science and Technology Act 1965, Section 4]. There have been numerous such requirements. There has also been an extension to certain activities related to treatment and disposal of wastes [Control of Pollution Act 1974, Section 101].

In 1986, the UKAEA was empowered to exploit commercially the intellectual property which it acquired through the performance of its functions [Atomic Energy Authority Act 1986]. This was the basis for the UKAEA's expansion into consultancy and the provision of specialised services.

These commercial operations of the UKAEA were privatised in 1996 under a new company: AEA Technology plc. [Atomic Energy Authority Act 1995].

The Authority must submit to the Secretary of State for Trade and Industry a report on its activities as soon as possible after the end of each financial year [Atomic Energy Authority Act 1954, Section 3(5)].

iii) Structure

The Authority consists of a chairperson and from four to fifteen members; all are appointed by the Secretary of State for Trade and Industry on a full-time or part-time basis [Atomic Energy Authority Act 1995].

Historically the UKAEA has on several occasions been divested of parts of its undertaking which were capable of independent commercial existence. For example, in 1971 the major fuel cycle operations were devolved to form what is now British Nuclear Fuels plc. (public limited company) while the Authority's radiochemical centre became an independent company, now Amersham International plc. [Atomic Energy Authority Act 1971]. This was in line with the original conception of the UKAEA's development. The Authority Weapons Group was also transferred to the Ministry of Defence in 1973.

The UKAEA was reorganised in 1994 into two divisions: Government Division and AEA Technology. The former was to continue as a public sector organisation with responsibilities broadly as outlined above. In preparation for privatisation, the latter was to carry on the commercial science, engineering and consultancy work that had been developed in more recent years. AEA Technology was vested as a separate company at the end of March 1996 and privatised by flotation in September 1996 [Atomic Energy Authority Act 1995].

iv) Financing

For a large part of its existence the UKAEA has been financed by Parliamentary grants to an amount determined by the Secretary of State, with the consent of the Treasury [Atomic Energy Authority Act 1954, Section 4]. In 1986 the Authority was placed on a trading fund basis [Atomic Energy Authority Act 1986]. This means that its assets were valued and capitalised to form a "commencing debt" on which the UKAEA is required to provide such financial return to the government as the Treasury may determine from time to time. The Authority was required to carry on business on a commercial basis, and was given appropriate borrowing and ancillary powers. The commencing capital debt and the capital of the outstanding loans borrowed from the National Loans Fund (NLF) were repaid in October 1996 from proceeds from the flotation of AEA Technology plc. [Atomic Energy Authority Act 1995, Section 10 and the UKAEA (Extinguishment of Liabilities)

Order 1996, S.I. 1996, No. 2511]. The UKAEA has now reverted to being a predominantly grant funded body.

The Department of Trade and Industry remains a substantial customer for services provided by the Authority.

The Authority is required to transmit to the Controller and Auditor General statements of accounts for each financial year [Atomic Energy Authority Act 1954, Section 4(3)].

b) Health and Safety Commission and Executive (HSC/HSE)

i) Legal status

The Health and Safety Commission (HSC) and the Health and Safety Executive (HSE), the latter being the Commission's operational arm, originally were set up as bodies corporate under the general authority of the Secretary of State for Employment [Health and Safety at Work etc. Act 1974, Sections 10, 11 and 12]. Subsequently, in July 1995, the Secretary of State for the Environment assumed responsibility for the administration of this Act 1974. Under an interdepartmental arrangement agreed in 1975, the Secretary of State for Trade and Industry is answerable to Parliament for all aspects of safety concerning the UK civil nuclear power industry, including responsibility for ensuring the adequacy of measures for protecting the health and safety of the public and those employed in the industry. Responsibility for certain civil nuclear emergency issues relating to Scottish nuclear sites has been devolved to the Scottish Executive. It is the Secretary of State for Trade and Industry who is accountable to Parliament for nuclear safety in Scotland as well as in England and Wales. The functions of the Commission and the Executive are performed on behalf of the Crown [Section 1(7)].

ii) Responsibilities

The general functions of the Commission are to do such things and make such arrangements as it considers appropriate for securing the health, safety and welfare of persons at work and others who may be affected by work activities, and to control the keeping and use of dangerous substances [Section 11]. This general mandate extends to all aspects of health protection related to nuclear activities.

The Commission is empowered to make agreements with any government department or person to perform on behalf of the Commission or the Executive any of their functions [Section 13]. It may also conclude agreements with any minister, government department or public authority to perform on their behalf functions which are exercisable by them, if the Secretary of State considers it appropriate to do so. The Commission may appoint persons or committees to provide it with advice in connection with its functions [see Section 2, b) "Nuclear Safety Advisory Committee" above] and has power to direct investigations and inquiries [Section 13]. It may furthermore formally approve and issue codes of practice with the consent of the Secretary of State, following consultation with appropriate bodies and government departments.

The HSE is the authority responsible for the licensing of nuclear installations in the United Kingdom. Certain provisions of the Nuclear Installations Act 1965 relating to licensing are relevant statutory provisions for the purposes of the Health and Safety at Work etc. Act 1974. The HSE has a

duty to make adequate arrangements for the enforcement of the relevant statutory provisions [Section 18]. The Executive is empowered to appoint inspectors to carry into effect the relevant statutory provisions within its field of responsibility [Section 19].

The Nuclear Installations Inspectorate (NII) (a branch of the Executive) ensures the compliance with all statutory requirements concerning the safety of the workforce and the public in relation to nuclear installations. The Inspectorate also regulates the safety aspects of design, construction and operation of nuclear installations. In this respect, the NII can subject the grant of a nuclear site licence to any conditions it deems necessary in the interest of safety. Its staff includes safety assessors whose principal task is to examine those facets of nuclear installations which are significant for safety and to recommend, where necessary, the improvements that should be made.

The Commission must submit to the Secretary of State as soon as possible after the end of each accounting year, a report on its activities [Schedule 2, paragraph 14].

iii) Structure

The Commission consists of a chairperson and not less than six members, all appointed by the Secretary of State for the Environment. Before appointing the members of the Commission, other than the chairperson, the Secretary of State, as to three of them, consults organisations representing employers, as to three others, organisations representing employees, and as to any other members he may appoint, organisations representing local authorities, and all organisations the activities of whose members are pertinent to the purposes of the Health and Safety at Work etc. Act 1974 [Section 10(2) and (3)].

The Executive consists of a director-general and two other members. The Commission appoints the Director-General of the Executive with the approval of the Secretary of State; the other two are appointed by the Commission, also with his approval after consultation with the Director-General [Section 10(5)].

iv) Financing

The Secretary of State is empowered, with the consent of the Treasury, to pay the Commission such sums as he considers appropriate for the carrying out of its work [Section 43].

The Commission is required to prepare each year a statement of accounts for the Secretary of State and the Comptroller and Auditor General; the latter examines the statement, certifies it and lays a copy of it before Parliament [Schedule 2, paragraph 14].

c) National Radiological Protection Board (NRPB)

The National Radiological Protection Board (NRPB) was established by the Radiological Protection Act 1970 [Section 1 as amended by the Health and Safety at Work Act etc. 1974, Section 77]. The functions of the Board are [Section 1]:

- by means of research and otherwise, to advance the acquisition of knowledge about the protection of mankind from radiation hazards; and

- to provide information and advice to persons (including government departments) with responsibilities in the United Kingdom in relation to protection from radiation hazards either of the community as a whole or of particular sections of the community.

The functions of the Board were extended by the National Radiation Protection Board (Extension of Functions) Order 1974 [S.I. 1974, No. 1230], which provided that the Board's existing functions mentioned above should also be exercised in respect of the dangers of radiation which is electromagnetic but not ionising. The Board has power to provide technical services to persons concerned with radiation hazards and to make charges for those services and for providing information and advice [Radiological Protection Act 1970, Section 1(2)].

The Health Ministers (the ministers respectively responsible for health in England, Scotland, Wales and Northern Ireland) gave two directions to the Board on 9 August 1977 under the Radiological Protection Act, requiring the Board to advise on radiation protection standards, to specify emergency reference levels of dose and guidance on their derivation, for those with responsibilities for the protection of the public in the event of an accident involving, or likely to involve, radiation doses to the public in excess of dose limits [Section 1(7)].

The Board is a body corporate, consisting of a chairperson and not less than seven nor more than twelve other members; the chairperson and members of the Board are appointed by the Health Ministers [Section 2, as amended by S.I. 1980, No. 970]. In practice, by arrangements between the Health Ministers, appointments are made by the Secretary of State for Health after consultation with the Medical Research Council (MRC) and the UKAEA [Sections 1(4), 1(8) and 2(1)].

To avoid duplication of activities, the Board has assumed responsibility for the Radiological Protection Service of the MRC and carries on in place of the UKAEA activities related to the effect of radiation hazards in relation to health and safety. Section 77 of the Health and Safety at Work etc. Act 1974 amends Section 1 of the 1970 Act by requiring the Board, when carrying out tasks which relate to those of the Health and Safety Commission, to act in consultation with the Commission and to have regard to its policies. It empowers the Board, on the direction of the Health Ministers, to enter into an agreement with the Commission to carry out its functions relating to ionising or other radiation.

The Board is financed from receipts from charges it makes for the provision of services and from funds provided by Parliament through the Secretary of State for Health [1970 Act, Sections 1(2)(b) and 3].

The Board must prepare each year a statement of accounts and other records for submission to the Secretary of State for Health, who in turn lays them before Parliament with his own report, after the statement has been examined and certified by the Comptroller and Auditor General [Section 3(4)].

The Board carries out pilot studies and research on its own volition in addition to undertaking such work under contract. In 1974, the MRC and the Board established a Joint Committee on Radiological Protection to improve liaison between the two bodies with regard to research on radiobiology.

d) Environment Agencies

The Environment Agency, a non-departmental public body, was set up under the Environment Act of 19 July 1995. The Environment Agency is vested with extensive powers and has statutory

duties to protect and improve the environment across England and Wales with principal functions of pollution prevention and control, water resources, flood defence, fisheries, recreation, conservation and navigation. Its Environmental Protection Directorate has responsibility for radioactive substances, integrated pollution control, waste regulation and quality and water quality functions.

The Scottish Environment Protection Agency (SEPA) has similar, but not identical, powers to the Environment Agency in the fields of pollution prevention and control. SEPA also has functions in other fields such as conservation, including water and flood monitoring advice.

In Northern Ireland, the Environment and Heritage Service became an agency within the Department of the Environment for Northern Ireland on 1 April 1996. Its role is to build on the work of its predecessor, the Environment Service, which brought together Countryside and Wildlife, Environmental Protection and Historic Monuments and Buildings.

The Service is responsible for implementing environmental policy in Northern Ireland within the framework of Northern Ireland legislation and EC Directives and other provisions. It protects wildlife sites, habitats and species, and protects and promotes the countryside. The Service maintains water quality, regulates pollution, promotes environmental quality, oversees waste management and is responsible for the control of radioactive materials. Historic monuments, buildings and shipwrecks are identified, recorded and protected, and sites in state care are conserved and preserved for the public.

Since April 1996, the power to grant authorisations to discharge radioactive waste has been exercisable by the Environment Agency alone, after consulting the Food Standards Agency or the Secretary of State for Wales and the Health and Safety Executive (HSE).

The Minister (or the Secretary of State for Wales) and the Secretary of State for the Environment, Transport and the Regions jointly have the powers to call for proposals and determine applications for the disposal of radioactive waste and to place directions on the Agency. In Scotland the power is exercisable by SEPA after consulting the Scottish ministers and the HSE.

In discharging its functions, the principal aim of the Environment Agency as expressed in the Environment Act 1995 is to protect or enhance the environment taken as a whole so as to contribute towards attaining the objective of achieving sustainable development. SEPA has a similar aim, although not directly enshrined in statute, that is, "to provide an efficient and integrated environmental protection system for Scotland which will both improve the environment and contribute to the government's goal of sustainable development".

The Environment Agency's legal powers are vested in its board; members of the board are appointed by the Secretaries of State for Environment, Transport and the Regions and for Wales, and by the Minister of Agriculture, Fisheries and Food. SEPA's legal powers are also vested in its board members who are appointed by Scottish ministers.

The Environment Agency is responsible for enforcing the provisions of the Radioactive Substances Act 1993, the Transfrontier Shipment of Radioactive Waste Regulations 1993 and Council Regulation (Euratom) No. 1493/93of 8 June 1993 on Shipments of Radioactive Substances between Member States. SEPA is responsible for enforcing the same legislation in Scotland.

Most of the Environment Agency staff are located in eight regions across England and Wales. Its head office is located in Bristol. In each region there is a statutory Regional Environmental Protection Advisory Committee which is consulted on major policies. SEPA staff are located in three

regions across Scotland, each with a headquarters within the region. Its head office is located in Stirling.

The Agencies consult widely in exercising their function under the Radioactive Substances Act particularly for determination of applications for disposal of radioactive waste. Documents are made available for public scrutiny at agency and at local authority offices.

Government policy for radioactive waste management is taken into account by the Agencies. The most recent statement of policy was in the 1995 White Paper Cm. 2919. Work is underway to develop statutory guidance to the Agencies on regulation of radioactive discharges into the environment, and to develop a National Radioactive Discharge Strategy. The Agencies' role and responsibilities and those of the HSE impinge on each other. Memoranda of Understanding between the organisations have been agreed to ensure effective co-ordination so that the possibility of conflicting requirements being placed on licensees and others is eliminated, and to minimise duplication.

e) British Nuclear Fuels plc. (BNFL)

i) Legal status

In 1971, as part of the reorganisation of the UKAEA, British Nuclear Fuels Ltd. was set up as a private limited company and subsequently transformed into a public limited company. The fuel cycle operations previously undertaken by the UKAEA were transferred to BNFL, together with the related property, rights and obligations (Atomic Energy Authority Act 1971). BNFL is responsible to the Secretary of State for Trade and Industry. Originally, shares in BNFL were issued to the UKAEA, but with effect from 3 August 1981 were transferred to the Secretary of State by the British Nuclear Fuels Ltd. (Transfer of Shares) Order 1981 [S.I. 1981, No. 868] made under Section 11 of the 1971 Act.

The Secretary of State has power to dispose of shares held by him in any nuclear company (including BNFL, but in this case no more than a minority stake) whether or not the disposal is consistent with promoting or controlling the development of atomic energy [Atomic Energy (Miscellaneous Provisions) Act 1981].

ii) Responsibilities

BNFL provides the full range of nuclear fuel cycle services to the UK and international markets, including enrichment (through its associated company, Urenco Ltd.), uranium hexafluoride production, fuel manufacture, reprocessing and waste management. BNFL also provides world-wide nuclear fuel transport services, runs a successful power generation business and has a thriving engineering business. BNFL is also committed to research and development in order to support and develop its business.

iii) Structure

BNFL is managed by a board of eleven directors, (including non-executive directors) appointed in accordance with the Company's Articles of Association, one of whom is the chairperson and

another the chief executive. The Company Secretary convenes the annual general meeting at the direction of the board.

The Company is organised into a head office at Risley which provides, via a small central team, overall strategy direction and control to four business groups and six Function/Process Owners. Central services, such as Corporate Strategy and Legal, provide certain services to the rest of the company. The four Business Groups are: Fuel, Magnox Generation, Thorp, and Waste Management and Decommissioning. The six Functions are: Technology and Operations, Safety, Health and Environment (SHE), Commercial, Finance, Public Affairs and Human Resources.

BNFL's UK operations span five sites in North West England and Southern Scotland. BNFL also has a number of overseas offices. Export success is strengthened through its wholly-owned subsidiary, BNFL Inc., based in North America, and its offices in Japan, China, South Korea, South Africa, Germany, Belgium and France.

iv) Financing

The initial capital was subscribed by the Secretary of State with the consent of the Treasury [Atomic Energy Authority Act 1971, Section 11(4)]. The Secretary of State may, with the approval of the Treasury, make loans to the Company [Section 12(1)]. Under the Nuclear Industry (Finance) Act 1977, the Secretary of State is empowered, with the consent of the Treasury, to guarantee any loans made to BNFL, including the loan interest. The 1977 Act imposed new limits on the amount of public finance that may be committed to BNFL under the 1971 and 1977 Acts. The limit initially set by the 1977 Act was British pounds (GBP) 300 million. The initial limit of GBP 300 million was raised to GBP 1 000 million by order under Section 2(1)(a) of the 1977 Act [S.I. 1987, No 875]; and to date, the limit has been increased from GBP 1 500 million to GBP 2 000 million by the Atomic Energy Act 1989 [Section 1].

The board submits an annual report and a statement of accounts, audited by independent auditors, to its shareholders at the end of each financial year.

f) Amersham International plc.

Also as part of the reorganisation of the UKAEA [Atomic Energy Authority Act 1971], Amersham International Ltd. was set up as the Radiochemical Centre Ltd., a private limited company, at the same time as BNFL. With effect from 1 April 1971, the Radiochemical Centre Ltd. took over the UKAEA's activities in connection with the production and marketing of radioactive materials [Atomic Energy Authority Act 1971, Section 2, and S.I. 1971, No. 478]. The company, which has been transformed into a public limited company, has subsidiaries in a number of countries, including Australia, France, Germany, Japan and the United States. On 1 October 1981, the shares held by the UKAEA in Amersham International Ltd. were transferred to the Secretary of State [The Amersham International Ltd. (Transfer of Shares) Order 1981, S.I. 1981, No. 850]. The Secretary of State then divested himself of the ownership of the company, whose shares are now wholly owned by the private sector. [The Atomic Energy (Miscellaneous Provisions) Act 1981, Section 1(3), provides that the Secretary of State's power to dispose of shares is exercisable whether or not the disposal is consistent with promoting or controlling the development of atomic energy].

g) The National Nuclear Corporation Ltd. (NNC)

The National Nuclear Corporation Ltd. (NNC) was set up in 1973 as a private limited company whose shareholders were the UKAEA, General Electric Company plc. (GEC) and British Nuclear Associates Ltd. (representing companies engaged in the nuclear construction industry). The NNC was responsible for the design, construction and marketing of nuclear power plants.

In 1977, the Secretary of State was empowered to incur, with the consent of the Treasury, out of money provided by Parliament, any expenditure necessary for the acquisition of shares in the NNC or any of its subsidiaries [Nuclear Industry (Finance) Act 1977].

In 1988 the NNC became a wholly owned subsidiary of GEC, and is now a major project management and technical consultancy company operating in both the nuclear and non-nuclear sectors. It has an issued share capital of GBP 10 million.

h) United Kingdom Nirex Ltd.

i) Legal status

The United Kingdom Nuclear Industry Radioactive Waste Executive (NIREX) was set up in 1982. It was incorporated in 1985 as United Kingdom Nirex Ltd., a private limited company with shares held by the UKAEA, BNFL, the Central Electricity Generating Board (CEGB) and the South of Scotland Electricity Board (SSEB). The Secretary of State for Energy held a special share which gave it ultimate control over land on which waste disposal facilities are sited if need be in perpetuity. In 1990 the CEGB and SSEB shares were transferred to Nuclear Electric plc. and British Energy Generation Ltd. respectively. In April 1992, the special share was transferred to the Secretary of State for Trade and Industry. On 31 March 1996 the ordinary shareholdings were further redistributed. Current shareholders are BNFL, British Energy Generation Ltd., British Energy Generation (UK) Ltd., Magnox Electric plc. and the UKAEA.

ii) Responsibilities

The Company's principal activity is to carry out research, development and design with a view to developing and managing commercial facilities for radioactive waste disposal.

The government has overall responsibility for radioactive waste strategy. The role of the Company, working within that strategy, is to provide disposal services for solid intermediate and low-level radioactive waste to its shareholders and other UK users of radioactive materials, such as hospitals, industries, etc. The ordinary shareholders are expected to be the majority users of the Company's services. High-level waste is managed by its producers, BNFL and the UKAEA.

iii) Structure

Nirex is based at Harwell and is managed by a board of directors. The board comprises two directors nominated by each shareholder (although for the time being shareholders have agreed to nominate only one director) together with such external directors as the shareholders may from time to

time agree. As at 1 April 1999, three such external directors were in post, including the chairperson and the managing director.

iv) Financing

Nirex is funded by loans from its shareholders who have agreed to provide, by way of such loans, all funds in excess of the sums from time to time paid up on the issued share capital of the Company which may be necessary for the conduct of the business of the Company.

The directors submit a report on the Company's activities and a statement of accounts, audited by independent auditors, to its shareholders at the end of each financial year.

Note on the restructuring of the electricity industry

On 31 March 1990, the electricity industry in England and Wales and Scotland was completely restructured in accordance with the provisions of the Electricity Act 1989. The Central Electricity Generating Board (CEGB) which had until then been responsible for generating all electricity and its transmission and distribution throughout England and Wales was divided into four companies, National Power, PowerGen, both fossil-fuel generators, National Grid plc., for the transmission of electricity, and Nuclear Electric plc. The first three were privatised in 1990/91, while Nuclear Electric plc. remains in public ownership having been renamed Magnox Electric plc. in 1996 (see below). At the same time, the two public utilities responsible for generating, transmitting and distributing electricity in Scotland, North of Scotland Hydro-Electric Board and South of Scotland Electricity Board (SSEB) were also reorganised for purposes of privatisation. Two separate companies were created, Scottish Power plc. and Hydro-Electric plc., to take over the non-nuclear business of the previous bodies, and these were privatised in 1991. British Energy Generation (UK) Ltd. (formerly called Scottish Nuclear Ltd.), set up in parallel, took over the nuclear power plants in Scotland and remained in public ownership until the restructuring and privatisation programme in 1996 (see below).

In May 1995, a government review concluded that the early privatisation of the United Kingdom's advanced gas cooled reactor (AGR) stations and pressurised water reactor (PWR) stations was feasible. A reorganisation took place with effect from 31 March 1996, whereby Nuclear Electric plc. transferred the business of its five AGR stations and its PWR station to British Energy Generation Ltd. (formerly called Nuclear Electric Ltd.), a newly incorporated company, while retaining its Magnox stations. At the same time, British Energy Generation (UK) Ltd., while retaining its two AGR stations, transferred its Magnox station to Magnox Electric plc. A newly incorporated company, British Energy plc., was created as the parent company of British Energy Generation Ltd. and British Energy Generation (UK) Ltd. On 26 June 1996, a prospectus was published offering shares of British Energy plc. for sale by way of public flotation. The sale took place on 15 July 1996 when the shares were listed on the London Stock Exchange. Lastly, the most recent development is the merge of BNFL with Magnox Electric plc. on 30 January 1998.

i) Magnox Electric plc.

i) Legal status

Magnox Electric plc. (formerly Nuclear Electric plc.) was set up as a public limited company in 1990 and is state-owned, with its shares held by the Secretary of State for Trade and Industry. Since 30 January 1998, the company has been a wholly-owned subsidiary of BNFL.

ii) Responsibilities

Magnox Electric owns nine nuclear power stations in the United Kingdom – six operating Magnox stations and three Magnox stations (including the Magnox station transferred from Scottish Nuclear Ltd. under the 1996 restructuring) which are being decommissioned. Most of the electricity produced by Magnox Electric is sold under contract to the Regional Electricity Companies (RECs) in England and Wales.

iii) Structure

The Company is headed by a board of directors, whose appointments must be approved by the Secretary of State for Trade and Industry. The board consists of five executive directors, one of whom is the chairperson, and four non-executive directors. The day to day management of the Company is the responsibility of the chief executive in consultation where appropriate with the chairperson and the directors. The government expects Magnox Electric to act in a commercial manner.

iv) Financing

Magnox Electric derives its income primarily from sales of electricity. It may obtain grants from the Secretary of State for Trade and Industry.

The directors publish a report on the Company's activities and a statement of accounts, audited by independent auditors in September each year relating to the previous 1 April to 31 March financial year.

j) British Energy Generation Ltd.

Under the 1996 restructuring and privatisation programme the five AGR stations and the PWR station, previously under the control of Nuclear Electric plc. (renamed Magnox Electric plc.), were transferred to British Energy Generation Ltd.

British Energy Generation Ltd., along with British Energy Generation (UK) Ltd., has as its parent company British Energy plc., whose shares were sold and listed on the London Stock Exchange in July 1996, privatising all the AGR and PWR stations in the United Kingdom.

k) Scottish Electricity Generator Companies

In accordance with the Electricity Act 1989 [Section 67(4)], the property, rights and liabilities of the Scottish Boards were, with effect from 31 March 1990, transferred by order to three companies nominated by the Secretary of State [The Electricity Act 1989 (Transfer Date) (Scotland) Order 1990, Section 24, S.I. 1990, No. 197]. The companies nominated for this purpose were two Scottish electricity generator companies (Scottish Power and Hydro Electric) and a Scottish nuclear generator company (Scottish Nuclear) [The Electricity Act 1989 (Nominated Companies) (Scotland) Order 1989, S.I. 1989, No. 2448].

l) British Energy Generation (UK) Ltd.

i) Legal status

British Energy Generation (UK) Ltd. (previously Scottish Nuclear Ltd.) was set up as a limited company in 1990 and was state-owned under the authority of the Secretary of State for Scotland. In 1996, as part of the restructuring and privatisation programme, it transferred its Magnox station to Magnox Electric plc., while retaining its two AGR stations. It was made a subsidiary of British Energy plc., which was sold by way of public flotation and its shares listed on the London Stock Exchange in July 1996.

ii) Responsibilities

British Energy Generation (UK) Ltd. operates the two nuclear power plants in Scotland, but does not supply electricity directly to customers. It sells all the nuclear electricity produced under contract to Scottish Power and Hydro Electric. It was also responsible for the decommissioning of Hunterston A nuclear power plant, but under the 1996 restructuring programme this Magnox station was transferred to Magnox Electric plc. [formerly Nuclear Electric plc., see *supra*, Section (i)].

m) Regional Electricity Companies in England and Wales

In accordance with the Electricity Act 1989 [Section 65], the property, rights and liabilities of the twelve Area Boards, previously responsible for acquiring bulk supplies of electricity from the electricity producers and for distributing such supplies to the customers in their respective areas, were, with effect from 31 March 1990, transferred by order to twelve Regional Electricity companies in England and Wales, set up for that purpose [The Electricity Act 1989 (Commencement No. 1) Order 1989, S.I. 1989, No. 1369, and the Electricity Act 1989 (Transfer Date) (England and Wales) Order 1990, S.I. 1990, No. 225].

UNITED STATES

[cont'd]

I. GENERAL REGULATORY REGIME

1. Introduction

The centrepiece of nuclear legislation in the United States is the Atomic Energy Act of 1954, a comprehensive statute which replaced the Atomic Energy Act of 1946 [Atomic Energy Act of 1954, as amended, United States Code (USC) 2011 *et seq*.].[1]

In the United States, the Federal Government has assumed most responsibility for regulating nuclear energy. For example, federal legislation and administrative regulations govern facility licensing. Usually, the States can regulate those nuclear activities that the Federal Government has chosen not to address so long as the State regulation does not conflict with federal law. However, in the nuclear field, courts recently have struck down State efforts to regulate high-level radioactive waste disposal and transport of radioactive materials, on the basis that federal regulation is pervasive in the nuclear field. States can adopt more stringent standards for radioactive air pollutants than federal standards governing the same activities. Sometimes, the States agree to assume control over an activity which normally would be regulated by the Federal Government. Pursuant to agreements with the Nuclear Regulatory Commission (NRC), under Section 274 of the Atomic Energy Act of 1954, 31 States, called "Agreement States", regulate materials covered by the agreement, such as by-product, source and special nuclear material for the protection of the public health and safety from radiation hazards. If the NRC finds that to do so is necessary to protect public health and safety, the NRC may terminate or suspend all or part of any such agreement. Further, the NRC retains regulatory responsibility for: construction and operation of any production or utilisation facility or uranium

1. In the United States, federal laws generally are cited as "xx USC, Section xxx" which refers to a title and section of the United States Code. The US Code is arranged by subject matter, for example Title 42 contains public health and safety laws, including the Atomic Energy Act of 1954 and the Nuclear Waste Policy Act of 1982. Laws are sometimes also cited as "xx Stat. xxx" which refers to the Statutes at Large, a chronological compilation of all American legislation without regard to subject matter.

   Later in this study, citations to the Code of Federal Regulations (CFR) appear. When an Administrative agency promulgates a regulation, it usually publishes the proposed rule in the Federal Register (Fed. Reg.). After public comment, the final rule is published in the Register. Citations to the Register appear as "xx Fed. Reg. xxx" meaning volume and page number. It is also included in the Code of Federal Regulations, updated yearly. The CFR is arranged into titles which do not correspond numerically to parallel subject areas in the USC. For example, while most nuclear regulations can be found in 10 CFR, they do not appear in Title 42 of the USC which addresses nuclear law. The CFR is arranged into titles, subdivided into chapters, parts and then into subparts and sections.

   This synopsis sometimes refers to Executive Orders issued by the President. Usually these documents articulate policy, confirm international understandings, or create advisory bodies. They are cited by number and date.

enrichment facility; export from or import into the United States of by-product, source or special nuclear material, or any production or utilisation facility; and disposal of such other by-product, source, or special nuclear material as the NRC determines should not be disposed of without a licence.

Congress enacted a general framework of legislation governing nuclear energy centred around the Atomic Energy Act of 1954 which marked a transition from the Federal Government's monopoly over production and use of atomic materials to a regime in which private industry would also play a role in their production and use. Military uses of nuclear energy remained however exclusively the domain of the Federal Government. Initially, the Atomic Energy Commission (AEC) constituted an independent agency to oversee the peaceful use of atomic energy. Congress abolished that agency, when it enacted the Energy Reorganization Act of 1974 which created the NRC and transferred to it all the licensing and related regulatory functions previously assigned to the AEC. The remainder of the AEC's functions were transferred to the Energy Research and Development Administration (ERDA). The Department of Energy Organization Act of 1977 abolished ERDA and vested the Department of Energy (DOE) with power over most other aspects of nuclear energy.

2. Mining Regime

Despite some uranium mining activity in the United States, the Atomic Energy Act does not address mining in any detail. [42 USC 2099-2198]. Since the early 1950s, the Atomic Energy Commission and its successors have made estimates of American uranium ore reserves and potential uranium supplies.

The NRC is responsible for licensing extraction of source material, defined as uranium or thorium or any ores containing those materials in such concentration as the NRC may determine by regulation. In 1999, six uranium recovery facilities were licensed to operate. Several other mills were in shut-down or decommissioning status [42 USC 2092, 2014 and 2111] (for details of the licensing process, see Section 3 "Radioactive Substances, Nuclear Fuel and Equipment" *infra*).

The Bureau of Mines in the Department of the Interior (DOI) controls all federal lands with valuable mineral deposits. Commercial operators can lease the land in order to mine uranium or other minerals, but the land is reserved from sale by the Federal Government. The DOE also issues permits specifically for uranium exploration.

The DOE can require detailed reports on mining of source material, but not prior to actual removal from its place in nature. Regulations must not discourage independent prospecting for new deposits. The Atomic Energy Act empowers the DOE to purchase any real property which might contain deposits of source material. The DOE can issue leases or permits to prospect for source material on federal lands and, by virtue of an executive order, can allow prospecting in national parks. In concert with permit requirements, no individual, partnership or corporation can benefit directly from confidential information learned about mineral deposits while participating in the DOE or NRC projects conducted on public land [42 USC 2095-2098].

3. Radioactive Substances, Nuclear Fuel and Equipment

Pursuant to the Atomic Energy Act, the NRC can issue licences to transfer or receive, own or possess, and import or export special nuclear material, source material, or by-product material. Although the legislation discusses each category separately, the provisions are similar [42 USC 2073, 2092 and 2111].

On 21 July 1995, the NRC issued a final rule on Import and Export of Radioactive Waste. The rule amended NRC regulations governing the Export and Import of Nuclear Equipment and Material to conform to principles of the International Atomic Energy Agency (IAEA) International Code of Practice for the Transboundary Movement of Radioactive Waste. Before the amendments, the rules were predominantly concerned with nuclear proliferation significance. In the light of IAEA safety standards, the amendments step up controls on radioactive waste and require specific licences to export or import "radioactive waste", including mixed waste. The definition of "radioactive waste" effectively excludes certain categories of shipments from the requirements for specific licensing. The rule also distinguishes for different treatment a separate category of "incidental radioactive material" [60 Fed. Reg. 37556 (1995); 10 CFR Part 110]. The NRC will consult with the Department of State and other federal agencies regarding proposed exports of radioactive waste. For all proposed exports and imports, consultation with transit countries will occur to ensure that necessary approvals will be obtained.

a) Special nuclear material

The term "special nuclear material" means plutonium, uranium enriched in the isotopes 233 or 235, and any other material which the NRC determines to be special nuclear material. It also includes any material artificially enriched by any of the foregoing substances, but the term does not include source material. In order to add substances to the list, the NRC must find such material capable of releasing substantial quantities of atomic energy and that the determination that the material is special nuclear material is in the interest of the common defence and security. The President must also give his written assent. Congress has thirty days to disapprove the action [42 USC 2014(a), 2071].

The NRC can issue licences to use special nuclear material for research and development activities [described at 42 USC 2051], in the context of medical therapy [described at 42 USC 2134], or by commercial entities [described at 42 USC 2133] for purposes consistent with the intent of the Act [Section 53(a)-(c); 42 USC 2073(a)-2073(c)]. Originally the AEC (predecessor to the NRC) could distribute special nuclear material by sale, lease with option to buy, or in return for in-kind services. Now, the government generally requires facility operators to buy special nuclear material. The DOE itself establishes a reasonable price scale and may agree to repurchase any unused material.

The NRC can regulate licences by explicitly defining all conditions and limits of ownership, by forbidding assignment of licences, and ensuring that no licensee will be able to construct an atomic weapon. Except when provisions of the Price-Anderson Act apply for indemnification against third-party liability, licensees must hold the government and the NRC harmless for any losses resulting from the use or possession of the material [42 USC 2073(e)]. The DOE must allocate sales of such material on the basis of the project's probable contribution to basic research, to the development of peaceful uses of atomic energy, or to the economic and military strength of the United States [42 USC 2073(f)].

The DOE controls the unlicensed foreign distribution of special nuclear material, while the NRC licences exports. Many of the export regulations reflect the provisions of the Nuclear Non-Proliferation Act (this aspect is dealt with under Section 7 "Non-Proliferation and Exports", *infra*). Subject to certain price limitations, the government can purchase back special nuclear material produced abroad which is generated by the use of special nuclear material, originally leased or sold by the United States, which was not consumed during the course of an agreement for co-operation, or any uranium remaining after irradiation [42 USC 2074(a)]. There is a statutory exemption from the export licensing requirement for the DOE to supply small amounts of special nuclear material contained in

laboratory samples or medical devices to foreign users or when needed in an emergency [42 USC 2074(d)].

A person subject to the Atomic Energy Act may engage in the production of special nuclear material outside the United States only if this activity is pursuant to the Nuclear Non-Proliferation Act and agreements negotiated in accordance with its provisions, or if specifically approved by the Secretary of Energy. Any approval by the Secretary of Energy shall be made only with the concurrence of the Department of State and after consultation with the Department of Commerce, the Department of Defense and the NRC [42 USC 2077].

b) Source material

The term "source material" is defined as uranium, thorium or any other material which the NRC determines to be source material. It also includes ores containing one or more of the foregoing materials in such concentration as the NRC may establish by regulation [42 USC 2014(z)]. If the Commission seeks to enlarge the definition of source material, it must find that the material is essential to the production of special nuclear material and that its designation as source material is in the interest of the common defence and security. The President must agree in writing and Congress has an opportunity to review the determination [42 USC 2091].

A person needs a general or specific licence to transfer, own, export or import, or extract source material except that licences are not required for quantities of source material which, in the opinion of the NRC, are unimportant. Provisions involving foreign and domestic distribution of source material generally parallel those for special nuclear material [42 USC 2092-2094, 10 CFR Part 40]. There are, however, special reporting requirements with respect to ownership, possession, extraction, and refining of source material [42 USC 2095].

c) By-product material

The term "by-product material" means any radioactive material (except special nuclear material) yielded in, or made radioactive by exposure to the radiation incident to the process of producing or utilising special nuclear material. It includes the tailings or wastes produced when source material is milled [42 USC 2014(e)].

Licensing requirements similar to those for possession of special nuclear material or source material apply to by-product material. The Department of Energy is to encourage maximal development of peaceful application for by-product material. To this end, the government can distribute by-product material with or without charge to qualified users, subject to health and defence considerations. Any price schedule inaugurated by the DOE must not discourage private enterprise from competing with government sources. The NRC can exempt certain users from the necessity of a licence, or may decide that, for certain types of by-product material, the strict structure of a licensing scheme is not warranted. The government controls the export of by-product material with a system somewhat similar to that for special nuclear and source material [42 USC 2111 and 2112].

Licences for ownership of by-product material in the form of mill tailings must contain conditions to ensure that the licensee will comply with decontamination or decommissioning requirements. Ownership of by-product material at sites where ores were processed primarily for their source material content and where such by-product material is deposited reverts to the Federal

Government or to the States, if they have exercised an option to acquire it, following termination of the licence (see Section 6 "Radioactive Waste Management", *infra*).

The NRC is responsible for overseeing compliance with decontamination and decommissioning requirements. When land or by-product ownership passes to the United States, the DOE becomes the competent authority to monitor the facilities in conjunction with State agencies [42 USC 2113(b)].

d) State programmes

The NRC administers over 5 000 licences, and 31 States handle an additional 16 500 licences pursuant to agreements with the NRC pursuant to Section 274(b) of the Atomic Energy Act [42 USC 2021]. Under these agreements, the NRC continues to issue licences for construction and operation of production or utilisation facilities; export from or import into the United States of by-product, source or special nuclear material or any production or utilisation facility; disposal of source, by-product or special nuclear material into the ocean or sea; transfer, storage or disposal of radioactive waste resulting from separation in a production facility of special nuclear material from irradiated nuclear reactor fuel (*i.e.* a reprocessing plant); manufacture and distribution of consumer products containing radioactive material (*e.g.* smoke detectors, ceramics, and watches) [10 CFR Part 150, Section 150.15]. In addition, the NRC has retained authority over licensing and regulation of spent nuclear fuel in an independent spent fuel storage installation (ISFSI) and spent nuclear fuel and high-level radioactive waste in a monitored retrievable storage installation (MRS) constructed by the DOE and licensed pursuant to 10 CFR Part 72.

4. Nuclear Installations[2]

a) Initial licensing

The NRC licenses all commercial nuclear power reactors in the United States pursuant to authority conferred by the Atomic Energy Act and the Energy Reorganization Act of 1974. Within the NRC, the Office of Nuclear Material Safety and Safeguards licenses fuel cycle facilities and the Office of Nuclear Reactor Regulation issues reactor licences [42 USC 5801, 5843 and 5844].

The NRC has two different approaches for licensing of nuclear power plants. From the beginning of commercial nuclear power plant licensing under the Atomic Energy Act of 1954, nuclear power plants were licensed in a "two-step" process involving issuance of a construction permit allowing a utility to construct a nuclear power plant, followed by issuance of an operating licence allowing the utility to operate the plant. The NRC's current licensing requirements under this two-step approach are contained in 10 CFR Part 50. In 1989, the Commission adopted a new approach for licensing of nuclear power reactors in 10 CFR Part 52, and that approach was made part of the Atomic Energy Act in 1992 [the Energy Policy Act of 1992 added new Sections 185(b) and 189(a)(1)(B) to the Atomic Energy Act]. Each of these two approaches are briefly described below.

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2. Nuclear reactors owned and operated by the US Department of Energy and the US Department of Defense are not licensed or regulated by the NRC, and are not covered here. In addition, the licensing and regulation of non-power reactors (*e.g.* research reactors), as well as other nuclear facilities such as waste disposal sites, uranium mills, storage centres, burial sites, or other installations are not covered here. See under Mining, Exports, Waste Management and Transport, respectively.

i) "Two-Step" licensing under 10 CFR Part 50

The formal construction permit licensing process begins with filing of a construction permit application containing information addressing safety, environmental impact and physical protection for the proposed design of the plant, as well as antitrust information. If the NRC determines that the application is complete, it accepts the application by formally docketing it and publishing a notice in the Federal Register, and distributing the application to relevant federal, state and local agencies and officials.

The NRC staff undertakes a safety review of the proposed design for the nuclear power plant in accordance with the Standard Review Plan (SRP), a guide containing requirements for each system, component, and structure important for safety. Once the staff finish the Safety Evaluation Report, the Advisory Committee on Reactor Safeguards (ACRS), a statutorily-created committee which advises the Commission with regard to the hazards of existing or proposed reactor facilities and the adequacy of proposed reactor safety standards, completes its review and meets with NRC staff and the applicant. It then submits a letter report to the NRC presenting the results of its independent analysis and recommending whether NRC should issue a construction permit. In accordance with the National Environmental Policy Act of 1969 (NEPA), the NRC conducts an environmental review of the application and prepares an environmental impact statement (EIS) which evaluates the environmental impacts of constructing and operating the proposed plant. A draft EIS is first proposed and published for comment, followed by a final EIS which addresses all comments received. This environment review is parallel to, but separate from consideration of safety aspects of the application. The NRC also conducts a preliminary antitrust review, and refers the application to the US Attorney General's Office for its advice on antitrust. Once the Attorney General provides its advice in a report, the NRC publishes the Attorney General's advice, together with the NRC's final determination on antitrust issues.

A public hearing is required to be held on the construction permit application. An Atomic Safety Licensing Board (ASLB) presides at the hearing and issues an initial decision as to whether a construction permit should be granted. Issues which may be raised by interested parties include safety, environmental, and antitrust issues related to issuance of the construction permit. The initial decision may be appealed to the Commission. Following final NRC action on any appeal, a dissatisfied party can petition for review by the appropriate US Court of Appeals. Otherwise, the Director of the Office of Nuclear Reactor Regulation issues the construction permit.[3]

Two or three years before the scheduled completion of construction, the utility files an application for an operating licence. The purpose of the NRC review at this stage is to determine whether the nuclear power plant has been constructed in accordance with the design approved in the construction permit and the Commission's regulations, and that there is reasonable assurance that the plant can be operated without endangering the public health and safety. While environmental impacts of issuance of the operating licence are required to be evaluated in a supplemental EIS, the review is limited to changes that have occurred since the construction permit EIS. No further consideration of alternative sites is necessary in the supplemental EIS. Finally, as a general matter, an antitrust review

3. The NRC can issue a Limited Work Authorization (LWA) in advance of the final decision on a construction permit if: (1) all environmental and site selection issues for the construction permit have been resolved, and (2) the Atomic Safety and Licensing Board (ASLB) concludes that there is reasonable assurance that the proposed site would be suitable from the standpoint of radiological health and safety for a reactor of the general size and type proposed. The LWA may also authorise installation of the structure foundation, if the ASLB determines there are no unresolved safety issues relating to the installation of the foundation.

is not required at the operating licence stage. A public hearing on the operating licence application is not mandatory, but may be conducted on petition by an interested party or at the NRC's option.

ii) Licensing under 10 CFR Part 52

10 CFR Part 52 was adopted by the NRC to obtain early resolution of safety issues, facilitate standardisation of plant designs, and simplify the "two-step" licensing process, through:

- Early Site Permits which resolve site suitability issues, including suitability of the site for emergency preparedness, and the existence of environmentally-superior sites;
- Design Certification rule making for specific nuclear power plant designs; and
- Combined Construction Permit and Operating Licences, which avoid the need for issuance of a construction permit and a separate operating licence.

Any person authorised to hold a construction permit under 10 CFR Part 50 may apply for an Early Site Permit under 10 CFR Part 52. The application must indicate the number, type, and thermal power level of the nuclear plants which may be placed on the site, and information which will allow the NRC to determine whether the site is suitable for construction and operation of nuclear power plants, in accordance with the relevant siting requirements in 10 CFR Parts 50 and 100, as well as the suitability of the site from environmental and emergency preparedness standpoints. The NRC Staff must prepare an EIS which addresses the applicable requirements of 10 CFR Part 51, including a review to determine whether there are any obviously superior sites. An Early Site Permit may be referenced by any applicant for a construction permit and operating licence under 10 CFR Part 50, or an applicant for a combined licence under Part 52.[4]

Any person may submit an application requesting the NRC to conduct a design certification rule making which approves a nuclear power plant design. The application must contain sufficient information for the NRC to make a final safety conclusion with respect to the adequacy of the design and must describe the inspections, tests, analysis and acceptance criteria (ITAAC) to be used in determining whether a plant referencing the design has been constructed in accordance with the design. The safety of the design is judged in accordance with technically-relevant requirements in 10 CFR Part 50. Once a design certification rule is adopted by the NRC, it may be referenced by any applicant for a construction permit or operating licence under Part 50 or a combined licence under Part 52, and all issues relating to the adequacy of the certified design are treated as resolved in the subsequent proceeding.

Finally, Part 52 authorises the NRC to issue combined construction permits and operating licences (combined licences). The application for a combined licence must include all the administrative and technical information required by 10 CFR Part 50. The application may (but is not required to) reference a design certification. Whether it references a design certification or not, the combined licence application must include the ITAAC for determining whether, once construction is completed, the plant has been constructed in accordance with the combined licence, the NRC's requirements, such that there is reasonable assurance that the facility will operate in accordance with

4. The Early Site Permit also allows the holder to perform the site preparation work that would be authorised under a LWA in 10 CFR Section 50.10(e)(1), if the Environmental Impact Statement for the Early Site Permit has determined that there would be no significant environmental impact stemming from such activities which cannot be redressed.

the combined licence. As with construction permits under 10 CFR Part 50, both an environmental review and antitrust review are conducted, and a mandatory hearing is held prior to issuance of the combined licence where interested parties may raise safety, environmental, and antitrust issues related to issuance of the combined licence. Before the plant may operate, the NRC must find that the acceptance criteria in the ITAAC have been met. The public has an opportunity to request a hearing to determine whether the ITAAC have been met.

b) Operation and inspection, including nuclear safety

Each operating licence contains detailed provisions relating to safety and environmental protection. The licensed facility undergoes periodic inspection during its operating life.

Each reactor site has at least a senior resident inspector and a resident inspector who devote their full attention to it during operation. NRC's regional offices also conduct numerous specialist inspections. There are team inspections run out of either the NRC regional offices or headquarters. The results of the NRC inspection activities are documented in publicly available inspection reports which reflect matters requiring further attention.

On a broader level, reactors are subject to a revised oversight process based on accepted performance indicators with a focus on a more risk-informed and performance-based evaluation and emphasis on a licensee's corrective action programmes.

In response to specific operational occurrences, the NRC may establish an Augmented Inspection Team (AIT) or Incident Investigation Team (IIT), depending on the severity of the occurrence. These teams are composed of experts representing disciplines of particular relevance to the events. They serve to identify issues of specific concern to the facility in question as well as issues of more generic concern to the regulated industry.

In addition to the NRC's direct involvement described above, licensees are required by NRC regulations, as well as by specific licence provisions, to submit certain types of information to the NRC. This may be done on a regular basis or in response to a particular event at the facility. Over the life of a facility, changes to the facility itself or to its operating requirements may be sought by the licensee. Although licensees may make certain changes without NRC approval, those with greater safety significance do require prior NRC approval through a formal amendment process.

In those situations in which the NRC, as a result of its oversight activities, identifies violations of regulatory requirements or other conditions which may significantly affect public health and safety, the NRC has a range of enforcement actions available to it. It may, for example, impose civil penalties, or may order modification, suspension or revocation of licenses.

At the international level, the USA ratified the 1994 Convention on Nuclear Safety on 11 April 1999.

c) Operating licence renewal

The Atomic Energy Act allows a nuclear power plant operating licence to be renewed. The NRC's procedures and requirements for renewal of operating licences are set forth in 10 CFR Part 54. Under current NRC requirements in 10 CFR Part 54, a renewed licence may be issued for a period not exceeding 20 years from the expiration of the current operating licence.

d) Decommissioning

The NRC has the statutory responsibility for protection of public health and safety and the environment related to the possession and use of source, by-product, and special nuclear material under the Atomic Energy Act. One part of NRC's responsibility is to assure safe and timely decommissioning of nuclear facilities which it licenses, and to provide guidance to licensees on how to plan for and prepare their sites for decommissioning. Decommissioning, as currently defined by the NRC, means to remove nuclear facilities safely from service and to reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the licence.

Decommissioning activities do not include the removal and disposal of spent fuel which is considered to be an operational activity or the removal and disposal of non-radioactive structures and materials beyond that necessary to terminate the NRC licence. Disposal of non-radioactive hazardous waste not necessary for NRC licence termination is not covered in the NRC regulations but would be treated by other appropriate agencies having responsibility over these wastes. If nuclear facilities are to be re-used for nuclear purposes, applications for licence renewal or amendment or for a new licence are to be submitted according to the appropriate existing regulation. Re-use of a nuclear facility for other nuclear purposes is not considered decommissioning because the facility remains under licence.[5]

Decommissioning activities are initiated when a licensee decides to terminate licensed activities. Once licensed activities have ceased, licensees are required to decommission their facilities so that their licences can be terminated. At present, this requires that radioactivity in land, groundwater, surface water, buildings, and equipment resulting from the licensed operation be reduced to levels that allow the property to be released for unrestricted use. Licensees must then demonstrate that all facilities have been properly decontaminated and that, except for any residual radiological contamination found to be acceptable to remain at the site, radioactive material has been transferred to authorised recipients. Confirmatory surveys are conducted by NRC, where appropriate, to verify that sites meet NRC radiological criteria for decommissioning.

Several hundred NRC materials licences under 10 CFR Parts 30, 40, and 70 are terminated each year. The majority of these licences involve limited operations, produce little or no radioactive contamination, and do not present complex decommissioning problems or potential risks to public health or the environment from residual contamination.

The NRC has a programme underway to effect timely decommissioning of about two dozen sites, which warrant special NRC oversight either because they have not been decommissioned properly in the past or have been engaged in the decommissioning process for an extended period. The NRC established a Site Decommissioning Management Plan (SDMP) in 1993 for effecting timely decommissioning of these problem facilities. Sites being handled under the SDMP vary in degree of radiological hazard, cleanup complexity and cost.

The decommissioning of commercial nuclear power plants is addressed in 10 CFR Section 50.82, which was adopted in 1996 [61 Fed. Reg. 39278, 21 July 1996].

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5. In 1997, the NRC issued regulations which set forth residual radioactive release criteria for licence termination in 10 CFR Part 20 [62 Fed. Reg. 39058; 21 July 1997]. The criteria apply to all facilities licensed by the NRC, with limited exceptions. The regulations allow for restricted use under carefully defined circumstances. The criteria apply to decommissioning of nuclear facilities that operate through their normal lifetime, as well as to those that may be shut down prematurely.

The regulation specifically addresses the timing of termination of the authority to operate. The operator must submit two separate certifications, one when the reactor will shut down permanently and the other when all fuel is permanently removed. Once both certifications have been submitted the reactor can no longer operate and the operator becomes eligible for reductions in fees and other responsibilities. The operator must also submit a Post Shutdown Decommissioning Activities Report (PSDAR) with a schedule of activities through to and including termination. The PSDAR must contain an estimate of costs and a discussion that supports a conclusion that the decommissioning activities are within the parameters of environmental impact statements that were previously considered in the grant of the utility's operating licence, as well as those considered in the generic environmental statement for the 1988 decommissioning Rule.

After submission of the PSDAR, a public meeting will be held in the vicinity of the site. However, after 90 days, in the absence of any NRC objection, the licensee may proceed with intended activities. NRC surveillance of the ongoing decommissioning activities will be facilitated by a new requirement to update the Safety Analysis Report (SAR) every two years. At the conclusion of the decommissioning activities before the licence is terminated, the NRC must approve by licence amendment (with any legal process that entails) the residual radioactivity level that the licensee makes a commitment to meet, and the survey procedures that will demonstrate that the approved level of residual radioactivity has been met for release of the reactor site for unrestricted use.

e) Emergency response

Prior to the accident at the Three Mile Island nuclear plant in March 1979, there were no statutory requirements for offsite preparedness to cope with a nuclear plant emergency. The NRC's regulations, however, required applicants for nuclear power plant construction permits to submit, as part of the application, a description of means of responding to a radiological emergency.

The Three Mile Island accident, though it resulted in no significant offsite radiological exposures, revealed the need for better and more formalised emergency planning. In the NRC Authorization Act for Fiscal Year 1980, [Public Law No. 96-295, 94 Stat. 780], Congress directed the NRC to establish standards for State emergency response plans, and to issue facility operating licences only upon a finding of an adequate State, local, or utility emergency plan. Findings on the adequacy of State and local emergency plans were to be made in consultation with the Federal Emergency Management Agency (FEMA). Although the statutory provision has long since expired, the NRC continues to have in place a system of emergency planning that includes such elements as emergency notification systems (*e.g.* sirens) and periodic emergency exercises and drills.

For full power licensing, the NRC must find that emergency planning provides "reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency" [10 CFR, Section 50.47(a)]. After a required review by FEMA, the NRC and its adjudicatory boards evaluate an offsite emergency plan under 16 planning standards promulgated by the Commission [10 CFR Section 50.47(b)]. "Failure to meet the applicable standards [...] may result in the Commission declining to issue an operating licence," unless an exception applies, for example where "deficiencies in the plan are not significant for the plant in question" [10 CFR Section 50.47(c)(1)].

As regards transport, the Department of Transportation (DOT), the FEMA, and representatives of industry and State governments have developed a model emergency response planning programme for use by shippers and carriers. These agencies, assisted by the Department of Energy (DOE), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA), have

published a handbook for State and local governments: *Guidance for Developing State, Tribal, and Local Radiological Emergency Planning and Preparedness for Transportation Accidents*, FEMA-REP-5 (1 June 1992). FEMA has issued a revised Emergency Response Plan. The Plan which represents the combined effort of 12 federal agencies, including FEMA, EPA, DOT and the NRC, details the federal response in case of a transportation emergency. The Plan recognises that the primary responsibility for responding to a transportation emergency belongs to State and local governments. The DOT's regulations also include emergency response information for use in the mitigation of accidents involving radioactive material [49 CFR 172.600-172.604]. The NRC has also issued a policy statement on responding to transportation emergencies [49 Fed. Reg. 12335, 29 March 1984].

It should be noted that at the international level, the USA ratified both the 1986 Convention on Early Notification of a Nuclear Accident and the 1986 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency on 19 September 1988.

5. Radiation Protection

a) Protection of workers

Worker protection requirements apply to all NRC licensees. The regulatory goal is to keep workers informed about the health problems associated with exposures to radiation and methods of minimising exposures, and to encourage workers to bring matters regarding occupational radiation protection to the attention of NRC inspectors. Licensees must post various documents including operating procedures and any notice of violation. Workers are to be instructed in health protection procedures, and appropriate responses to warnings of exposure. Individual workers must receive notification and reports in writing containing information on annual exposure. At the time of termination of a worker's contract, licensees must supply each worker with a written report on exposures received during the workers' period of employment [10 CFR 19.11-19.13].

The NRC inspects facilities to ensure compliance with the NRC radiological health and safety standards. Representatives of workers and the licensee may be provided with the opportunity to accompany the inspectors. If there are fears of non-compliance at a particular facility, a worker or worker's representative can request an unscheduled inspection, but the NRC can decide that an inspection is unwarranted if an informal review reveals no reasonable grounds to believe a violation has occurred. In such case, the appropriate NRC official shall notify the worker or worker's representative in writing of such determination [10 CFR 19.1419.17].

Permissible radiation dosages are subject to an annual limit [10 CFR 20.1201]. Before a licensee may permit a worker to undertake assignments in restricted areas, he must obtain information about the worker's prior occupational exposure.

Each licensee must take various preventive measures such as radiation protection equipment, surveys of hazards, personnel monitoring, and display of signs, labels, and signals [10 CFR Part 20, Subpart F-J]. Each licensee must train employees in precautionary techniques [10 CFR 19.12].

Licensees must also comply with applicable requirements of the Occupational Health and Safety Act, administered by the Occupational Safety and Health Administration within the Department of Labor, as well as applicable State health and safety laws.

b) Protection of the public

The NRC has established basic standards applicable to all its licensees to protect against hazards arising from licensed activities [10 CFR Part 20]. These pivotal regulations establish permissible dose levels for radiation exposure, such as occupational dose limits [Subpart C], dose limits for individual members of the public [Subpart D], precautionary procedures [Subpart J], and waste disposal [Subpart K]. The focus of Part 20 is occupational dose and emission levels resulting from licensed activities. It neither controls nor monitors radiation exposure from background sources. In 1991, the NRC issued revised standards to reflect scientific information, changes in the basic philosophy of radiation protection and to conform with recommendations of international radiation protection organisations [56 Fed. Reg. 23360, 21 May 1991].

All phases of nuclear facility construction and operation as well as the regulation of nuclear materials are subject to public health, safety and environmental constraints [42 USC 2011 *et seq.*]. Executive Order No. 12898 directs all federal agencies to develop strategies for considering "environmental justice" in their programmes, policies and activities. "Environmental justice" is described in the Executive Order as "identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programmes, policies, and activities on minority populations and low-income populations". The NRC has implemented procedures to consider environmental justice when preparing documents pursuant to the National Environmental Policy Act of 1969 [42 USC 4321-4370(c)]. Licensees must also comply with other applicable environmental laws, including the Federal Water Pollution Control Act of 1972 [42 USC 1251-1387] and the Clean Air Act of 1974 [42 USC 7401-7671(q)]. Under the latter statute and the Comprehensive Environmental Response, Compensation, and Liability Act (commonly referred to as CERCLA or "Superfund") [42 USC 9601 *et seq.*], radioactive emissions are by definition classified as "hazardous pollutants". The Department of Transportation (DOT) and the Environmental Protection Agency (EPA) either develop standards or assist in their development.

In addition to meeting existing regulatory criteria, an applicant for a NRC operating licence, in a final safety analysis report, must predict emission levels during various postulated accident situations. During each licence review, NRC completes an assessment of facility biological impact pursuant to the Endangered Species Act. The NRC also reviews the socio-economic impacts of siting decisions.

An Executive Order requires the Executive Branch to submit to the NRC a concise environmental review for the Commission to consider in its review of appropriations for the export of power reactors or waste facilities [Executive Order 12114, Section 4.1, 1979].

The Radiation Control for Health and Safety Act of 1968 amends the Public Health Services Act. This statute authorises the Federal Government to promulgate standards to control emission from electronic products. Regulation extends to ionising or non-ionising electromagnetic radiation as well as particle, sonic, infrasonic and ultrasonic radiation [82 Stat. 1179, Section 357].

The regulations promulgated under the 1968 Act are performance standards. They apply, in some instances, to warnings, labels, and instructions. Manufacturers must notify the government, distributor and consumer of any danger with reasonable promptness, disclosing as much information as possible about adverse effects without compromising trade secrets [21 CFR Parts 1000 and 1002].

The NRC licenses hospitals and physicians to use radioactive materials in diagnosis and treatment. NRC reviews facilities, personnel, programme controls, and equipment described in each application to ensure safety of the public, including patients, and workers. In the United States, however, most authority to regulate non-radiological health and safety matters rests with individual

States. Indeed, a majority of States are so-called "Agreement States" and regulate radiological health and safety in programmes that are compatible with the NRC's requirements.

6. Radioactive Waste Management

Three agencies share responsibility for the United States' radioactive waste management policy. The NRC must formulate and implement regulations ensuring storage and disposal methods that are safe for long-term waste management. The DOE has the lead responsibility for developing technologies and programmes for handling, treatment, storage, transport and disposal of commercial spent nuclear fuel, high level waste, and all defence-generated waste. The Environmental Protection Agency (EPA) must establish the maximum allowable release of radionuclides to the biosphere, as part of its authority under the Atomic Energy Act of 1954 to develop generally applicable environmental radiation protection standards [42 USC 2011-22961]. The EPA radiation protection standards, entitled "Radiation Protection Programs" [40 CFR Subchapter F (190 Series)], are generally implemented by the DOE for activities within its jurisdiction and by the NRC for its commercial licensees. In some areas, where the EPA has not yet promulgated regulations, the DOE and NRC rely on their own orders or regulations.

a) High-level waste

The Nuclear Waste Policy Act of 1982 was signed into law on 7 January 1983, and was extensively amended on 22 December 1987. Most recently, the Nuclear Waste Policy Act was amended on 24 October 1992 by enactment of the Energy Policy Act of 1992 [42 USC 10141]. The Nuclear Waste Policy Act established the Federal Government's responsibility and policy for disposing of high-level radioactive waste and spent nuclear fuel. The Act authorises the Secretary of Energy to conduct site characterisation activities at Yucca Mountain, Nevada, to determine its suitability as a repository. Any such repository would be subject to licensing by the NRC. In general, the Department's activities and facilities are not subject to such licensing.

The Act also established a Nuclear Waste Fund composed of payments made by the generators and owners to ensure that the costs of carrying out activities relating to disposal are borne by the generators and owners. Nearly all commercial spent nuclear fuel to be disposed of is owned by utilities that operate nuclear power plants and those ratepayers ultimately pay for disposal. The relevant fees are described in the Standard Contract for Disposal of Spent Nuclear Fuel and/or High-Level Radioactive Waste [10 CFR Part 961] which was executed between the utilities and the Department. A methodology was also developed, through rule making, to allocate the costs for disposal of federal defence-related waste in a repository. In 1993, Congress established a Defense Nuclear Waste Disposal Fund and makes annual appropriations for the Federal Government's share of disposal costs associated with high-level radioactive wastes from the weapons complex.

Pursuant to the Atomic Energy Act and the Nuclear Waste Policy Act, the NRC issued in 1981 a final rule entitled Disposal of High-Level Radioactive Wastes in Geologic Repositories [10 CFR Part 60], which prescribes rules governing the licensing of a geologic repository site, constructed or operated pursuant to the Nuclear Waste Policy Act. The rule contains siting, design, and performance criteria, as well as criteria for monitoring and testing. The rule adopts a multi-barrier approach, by providing design criteria for the waste package as well as for the geologic repository operations area.

The EPA issued environmental radiation protection standards in 1985 [40 CFR Part 191], which were remanded by a federal court in 1987 [Natural Resources Defense Counsel v. EPA, 824 F.2d 1258 (1st Cir. 1987)]. The court required that the EPA address, *inter alia*, the different time frames for protection of individuals (1 000 years) and total or "cumulative" population dose (10 000 years) as well as ground-water protection issues. As noted earlier, Congress enacted the Energy Policy Act in 1992, which required a study by the National Academy of Sciences (NAS) to address:

- the reasonableness of a health-based standard based on individual dose;
- the ability of post-closure oversight to prevent an unreasonable risk of breaching the repository's barriers or increasing the exposure of the public to radiation beyond allowable limits; and
- the capability to make scientifically supportable predictions of the probability of human intrusion for 10 000 years.

The NAS study, issued in August 1995, addresses new public health and safety standards for the Yucca Mountain site to be issued by the EPA, based upon and consistent with the NAS study. The standards must prescribe the maximum annual effective dose equivalent to individual members of the public from releases to the accessible environment from radioactive materials stored or disposed of in the repository. EPA published standards on 27 August 1999 [40 CFR Part 197], and the NRC must modify its technical criteria to be consistent with the EPA standards. The NRC published proposed technical criteria on 22 February 1999 [10 CFR Part 63]. The NRC's criteria must assume, to the extent consistent with the NAS study, that engineered barriers and the DOE post-closure oversight of the site shall be sufficient to:

- prevent any activity at the site that poses an unreasonable risk or breaches the repository's engineered or geological barriers; and
- prevent any increase in the exposure of individual members of the public to radiation beyond allowable limits.

The Energy Policy Act also directs the DOE to continue to oversee the repository site to prevent any activity that poses an unreasonable risk of breaching the engineered or geologic barriers, or increasing the exposure of individual members of the public to radiation beyond allowable limits.

In 1997, Congress required that the DOE prepare and submit to the Congress and the President in 1998 a "Viability Assessment" describing the following:

- the preliminary design concept for the critical elements for the repository and waste package;
- a total system performance assessment, based on the design concept and the scientific data and analysis available by 1998, that describes the probable behaviour of a repository in the Yucca Mountain geologic setting;
- a plan and cost estimate for the remaining work required to complete and submit a licence application to the NRC; and

- an estimate of the costs to construct and operate a repository in accordance with the design concept.

The "Viability Assessment", published by the DOE in December 1998, provided Congress, the President and the public with information on the technical and economic feasibility of a repository at Yucca Mountain and clarified the critical issues to be addressed before the Secretary of Energy decides whether to recommend Yucca Mountain for a repository.

An environmental impact statement, which accompanies any site recommendation and licence application, was published for public comment in July 1999 and is scheduled to be finalised in 2000. A decision by the Secretary on whether to recommend Yucca Mountain is scheduled for 2001, after issuance of a final environmental impact statement. If a decision is made to recommend the Yucca Mountain site, a licence application would be submitted in 2002. Emplacement would commence in 2010 and would be completed in 2033, according to present schedules.

Waste Isolation Pilot Plant (WIPP)

In 1980, Congress authorised construction of the Waste Isolation Pilot Plant (WIPP) as a research and development facility to demonstrate safe and permanent disposal of transuranic radioactive waste resulting from the defence activities of the United States. In 1991, the DOE completed construction of WIPP in a mine constructed 655 metres below ground surface in an ancient salt dome on approximately 10 240 acres 26 miles east of Carlsbad, New Mexico. In 1992, Congress passed the Waste Isolation Pilot Plant Land Withdrawal Act (WIPP Act) [Public Law No. 102-579] which details how the DOE should proceed with developing the facility. The WIPP Act prohibits, for example, disposal of high-level radioactive waste or spent nuclear fuel at WIPP as the facility can only serve for disposal of transuranic or "TRU" waste resulting from defence activities, such as manufacture of nuclear weapons. The Act establishes the EPA as the regulator of many of the DOE's activities at WIPP. Thus, the EPA is responsible under the WIPP Act for both issuing disposal regulations [Subparts B and C of 40 CFR Part 191] and determining whether the DOE is in compliance with those regulations. Under Section 8 of the WIPP Act, the EPA must certify that the DOE has complied with the EPA radioactive waste disposal standards before WIPP can function as a disposal facility.

Much of the waste destined for disposal at WIPP is in the form of "transuranic mixed waste" or "TRU-mixed" waste, a combination of radioactive components and hazardous waste components, the majority of which is currently stored at 23 DOE sites in 16 States. The EPA regulates hazardous wastes in the United States pursuant to the 1988 Resource Conservation and Recovery Act (RCRA) [42 USC 6901 *et seq.*]. States are authorised by RCRA to develop and implement their own hazardous waste programmes in lieu of the federal programme administered by the EPA. In general, a State programme must, subject to EPA approval, be "equivalent" to and "consistent" with the federal programme and other authorised State programmes and provide for adequate enforcement.

On 18 May 1998, the EPA issued its certification that WIPP will comply with its radioactive waste disposal regulations [40 CFR Part 191] which constituted its final approval under the WIPP Act for emplacement of TRU waste to commence. However, the State of New Mexico has sought to enjoin the shipment of mixed-TRU waste to WIPP on the ground that the DOE does not have a RCRA permit to operate a facility for mixed TRU waste and that the DOE does not have "interim status" under RCRA which could allow it to dispose of TRU-mixed waste without an actual RCRA permit. On 16 November 1998, the DOE provided to the State of New Mexico results of confirmatory samplings of TRU waste at Los Alamos National Laboratory showing that the TRU waste under consideration

contained hazardous contaminants which were "either below regulatory limits or below detection limits". The DOE maintains that this TRU waste can be shipped to the WIPP facility prior to obtaining a RCRA Part B permit since the TRU waste in question does not require a hazardous waste permit. In 1999, WIPP began receiving shipments of TRU waste.

West Valley Demonstration Project

In order to demonstrate the solidification of liquid high-level wastes, Congress passed the West Valley Demonstration Project Act, authorising a high-level waste project in West Valley, New York [42 USC 2021(a)]. This project, at the first commercial fuel-reprocessing site, will demonstrate solidification of waste by vitrification or other technology. The DOE has primary responsibility for the project, with NRC monitoring activities.

b) Low-level waste

The Low-Level Radioactive Waste Policy Amendments Act [42 USC 2021(b) *et seq.*] originally enacted in 1980 and substantially amended in 1985, establishes the policy for disposal of commercial low-level radioactive wastes, providing that such waste can be most safely and efficiently managed by States and State compacts on a regional basis. It declares that each State is responsible for disposal of low-level radioactive waste generated within its borders, with the exception of low-level radioactive waste owned or generated by the DOE, the United States Navy, or the Federal Government as a result of any research, development, testing or production of any atomic weapon. The Act further invites States to form compacts as necessary for the establishment and operation of regional disposal facilities.

The Act provided that States with an existing regional disposal facility (there were three: in Barnwell, South Carolina; Richland, Washington; and Beatty, Nevada) would make capacity available to other States or compact regions for a seven-year period through 1992, thus providing a transition period for States or compact regions without disposal sites to construct facilities. However, those three "sited compact regions" would not be required to provide disposal capacity for waste in excess of certain volume limitations established under the Act, and could, under certain conditions and with Congressional consent, restrict use of regional disposal facilities to waste generated within the compact region beginning in 1993. During the transition period, disposal of waste generated outside of a sited compact region could be subject to escalating surcharges. Further, the Act provided for milestones to be met by each unsited compact or State towards siting disposal facilities. Failure to meet milestones would result in added surcharges on waste disposal and eventual loss of access to the three available disposal facilities. An escrow account was also established composed of a percentage of the surcharge fee to be repaid to States or compact regions meeting the milestones.

To date, Congress has consented to 10 regional compacts, comprising 44 States, via the Omnibus Low-Level Radioactive Waste Interstate Compact Consent Act (1986), the Appalachian States Low-Level Radioactive Waste Compact Consent Act (1987), the Southwestern Low-Level Radioactive Waste Compact Consent Act (1988), and the Texas Low-Level Radioactive Waste Disposal Compact (1998). The so-called Texas Compact is a disposal compact between the States of Maine, Vermont and Texas. On 22 October 1998, the Texas Natural Resource Conservation Commission voted unanimously to deny the licence application of the Texas Low-Level Radioactive Waste Disposal Authority to construct a disposal facility in Hudspeth County, Texas. The Texas legislature abolished the Authority on 30 May 1999. The Texas legislature will meet again in 2001.

The NRC regulations divide low-level waste management into an operational and post-operational phase (*i.e.* pre-closure and post-closure of the site). The rules aim to protect individuals against inadvertent exposure, protect the public from general releases into the environment, and maintain stability of the disposal site, and prevent inadvertent intrusion. The regulations include classification of waste, procedural criteria for licensing and technical criteria for sites [10 CFR Part 61]. The NRC has licensed disposal of special nuclear material at two commercial burial sites, and is assisting in the closing of another site.

The Energy Policy Act of 1992 [Public Law No. 102-496, 42 USC 2023] added a new section to the Atomic Energy Act which provides for State authority to regulate radiation below the level of regulatory concern of the NRC. Section 276(a) provides that no provision of that Act, or the Low-Level Radioactive Waste Policy Act, may be construed to prohibit or otherwise restrict the authority of any State to regulate, on the basis of radiological hazard, the disposal or offsite incineration of low-level radioactive waste, if the NRC exempts such waste from regulation.

c) Disposal at sea

Congress adopted a policy regulating disposal at sea of all material which could adversely affect human health, welfare, the marine environment, or the economic potential of the ocean waters by passing the Marine Protection Research and Sanctuaries Act of 1972. The Act applies to United States registered vessels or aircraft, or foreign craft dumping materials in territorial waters. The Act specifically identifies radioactive waste as a controlled substance, regardless of whether it is generated by a civilian or military source: no one can dump high-level waste. In specific instances, the EPA may allow dumping of low-level waste if disposal would not unreasonably endanger human health or the marine environment or its economic potential. In reviewing applications, the EPA considers the volume and concentration of the material to be dumped, the projected disposal site, disposal method, and the persistence of any permanent adverse effects [33 USC, Section 1414].

On 6 January 1983, Congress enacted a two-year moratorium on ocean disposal of low-level radioactive waste except for small amounts to be disposed of for research or demonstration purposes [33 USC 41414(i)]. It should be noted that the United States ratified the 1972 London Convention on the Prevention of Marine Pollution by the Dumping of Wastes and Other Matter on 6 May 1974. The United States, in November 1993, as a Party to this Convention, adopted a resolution which effectively prohibited all sea dumping of radioactive waste.

d) Uranium mill tailings

In passing the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA), Congress found that mill tailings at active and inactive uranium milling operations may pose a significant health hazard, especially through potential radon diffusion into the environment. Under Title I of UMTRCA, on co-operation with interested States, Indian tribes, and site users, Congress provided for assessment and remedial action at inactive sites and, where appropriate, for reprocessing tailings to extract any remaining uranium or unstable materials. In addition, Title II of UMTRCA establishes a programme to regulate mill tailings during uranium or thorium ore processing at active mill operations and after termination of such operations in order to stabilise and control such tailings in a safe and environmentally sound manner, and to minimise or eliminate radiation health hazards to the public [42 USC 7901 *et seq.*].

The DOE is directed to designate inactive uranium processing sites for remedial action, and to complete any remedial action at such locations where States have contributed a percentage of cleanup costs [42 USC 7912].

Relying on the advice of the EPA, the DOE is directed to develop remedial action priorities at each site. When appropriate, the DOE can require States to purchase real property for disposal sites. If a property owner voluntarily undertook remedial action prior to the date of enactment of the above-mentioned Act, it may ask for reimbursement. When necessary, the DOE can purchase lands for potential disposal sites, and in some cases can utilise land owned by the Department of the Interior [42 USC 7916].

The DOE, after promulgation of health and safety standards by EPA, can solicit proposals from private parties who want to reprocess mill tailings. Then the DOE must decide whether or not such mill tailings should be reprocessed and whether recovery of residual minerals at each site is practical, depending upon source material concentration remaining in the residue. A person allowed to recover any mineral must remit a share of the resulting profit to the DOE in order to repay the DOE for any remedial actions in rehabilitating the units. The DOE has undertaken remedial actions at inactive uranium mill processing sites [42 USC 7918].

e) Formerly Utilized Sites Remedial Action Program (FUSRAP)

The DOE has been involved in a Formerly Utilized Sites Remedial Action Program (FUSRAP) since 1974. This is a major environmental effort to clean up sites contaminated from past activities under the Manhattan Project since World War II involving uranium ore and other radioactive materials. The DOE has examined almost 400 sites, reviewing old records and performing radiological surveys. Remedial action has been underway since 1979. By 1992, 33 sites in 13 States had been identified as requiring remedial action. On 30 September 1997, Congress ordered the DOE to transfer FUSRAP to the Army Corps of Engineers.

7. Non-Proliferation and Exports

The United States ratified the 1968 Treaty on the Non-Proliferation of Nuclear Weapons on 5 March 1970.

Rules governing nuclear export controls are contained in the Atomic Energy Act, as amended by the Nuclear Non-Proliferation Act of 1978 [42 USC 2074, 2077, 2094, 2139, 2139(a), 2141, 2153-2153(f), 2155, 2155(a), 2157-2160(a)]. Exports of production or utilisation facilities and special nuclear material (except some plutonium 238 and other special nuclear material exempted by the Commission) must take place pursuant to an agreement for co-operation. Such agreements are negotiated by the Department of State, with the technical assistance and concurrence of the DOE. They are also reviewed by the members of the NRC. The Atomic Energy Act provides that an agreement for peaceful nuclear co-operation must be approved by the Secretary of Energy and the Secretary of State and, upon their recommendation, by the President, who must make certain statutory determinations and authorise execution of the agreement. The Atomic Energy Act mandates that numerous specified provisions be contained in these agreements. An agreement for peaceful nuclear co-operation does not commit the United States to any specific exports or other co-operative activities, but rather establishes a framework of conditions and controls to govern subsequent commercial transactions, if any.

Any agreement for nuclear co-operation between the United States and another nation must contain assurances that the co-operating country will undertake safeguards to protect special nuclear material purchased or produced under the agreement, so long as the material is in its possession or under its jurisdiction regardless of the duration of the agreement [42 USC 2153, 2156].

The NRC cannot issue export licences or exemptions unless it makes certain findings and until it is notified by the Secretary of State that in the judgement of the executive branch, the proposed action will not be inimical to the common defence and security. The Secretaries of Energy, Commerce, and Defense, the Director of the Arms Control and Disarmament Agency and the Nuclear Regulatory Commission co-operate to complete this executive branch judgement. Whenever there are several applications involving one nation, the Commission may render a single opinion as regards compliance with the statutory criteria if there are no materially changed circumstances from the terms of the preceding contract. Such a decision is not subject to judicial review. With Congressional approval, the President can overrule an NRC decision not to permit export.

International Atomic Energy Agency (IAEA) safeguards govern all-important nuclear exports. Some minor components are not covered. Foreign governments cannot transfer United States origin special nuclear materials to other nations unless the United States approves the action. Prior approval must be obtained from the United States for any reprocessing of nuclear material originating in the United States [42 USC 2156-2158]. Source or special nuclear material exported from the United States may not be enriched after export except as authorised specifically in an agreement for co-operation. No major critical components of any enrichment, reprocessing or heavy water production facility may be exported except as specifically authorised in an agreement for co-operation [42 USC 2153(a), 2164].

a) Exports of source material, special nuclear material, production or utilisation facilities and sensitive nuclear technology

The Atomic Energy Act of 1954 specifies the criteria that the NRC must determine have been satisfied before it can issue an export licence. The criteria that are applied to exports of source material, special nuclear material, production or utilisation facilities and any sensitive nuclear technology to non-nuclear weapon States are:

- IAEA safeguards will be applied to the materials or facilities exported and to any special nuclear material used in or produced through the use of such materials;
- no material, facilities, or sensitive nuclear technology exported will be used for a nuclear explosive device or for research on or development of such a device;
- adequate physical security measures will be maintained with respect to the exported facilities or material and any special nuclear material used in or produced through the use of the facility or material;
- no materials, facilities, or sensitive technology to be exported and no special nuclear material produced through the use of such material will be retransferred to the jurisdiction of any other nation or group of nations without the prior consent of the United States;
- no material to be exported and no special nuclear material produced through the use of such material may be reprocessed, and no irradiated fuel elements containing such material

removed from a reactor, shall be altered in form or content without the prior approval of the United States;

- no sensitive technology may be exported unless the foregoing five conditions will be applied to any nuclear material or equipment which is produced or constructed through the use of the sensitive technology exported;

- the recipient nation must have full-scope safeguards; and

- the export must not be inimical to the common defence and security of the United States.

All of the criteria specified above except for the first and the seventh are applied to exports to nuclear-weapon states.

In 1992, the Atomic Energy Act of 1954 was amended to include criteria, in addition to those summarised above, which would apply to exports of highly enriched uranium. Specifically, the NRC is precluded from issuing licences for the export of highly enriched uranium to be used as fuel or a target in a nuclear research or test reactor unless it determines:

- there is no alternative fuel (fuel enriched to less than 20% ^{235}U) or target of lesser enrichment that can be used in the reactor;

- the proposed recipient of that fuel has provided assurances that whenever an alternative fuel or target can be used, it will use that alternative; and

- the US Government is actively developing an alternative fuel or target that can be used in the reactor.

Before taking action on most applications, the NRC receives the Executive Branch's views, which the Department of State provides to the NRC, after consulting with the Departments of Defense, Energy, and Commerce and the Arms Control and Disarmament Agency.

b) Exports of components

The NRC is also responsible for the licensing of components for production or utilisation facilities which are not defined as production or utilisation facilities, but are especially designed or prepared for use in such a facility or are especially relevant from the standpoint of export control because of their significance for nuclear explosive purposes. NRC regulations specify the components which must be licensed by the NRC. Other components for production and utilisation facilities, including dual use and balance of plant items, are licensed by the Department of Commerce under the terms of the Export Administration Act.

Before issuing a licence authorising the export of a component to a non-nuclear weapon state, the NRC must determine:

- IAEA safeguards will be applied;

- the component will not be used in or for research and development of a nuclear explosive device;

- the component will not be retransferred without the prior consent of the United States; and
- the export would not be inimical to the common defence and security of the United States.

All of these criteria, except for the first one, are applied to exports to nuclear weapons states.

c) Exports of by-product material

The NRC also licenses the exports of by-product material. Before issuing an export licence the NRC must determine that the export would not be inimical to the common defence and security of the United States. The NRC's regulations generally authorise the export of some by-product materials; others require a specific licence from the NRC.

d) Conduct resulting in the termination of exports or economic assistance

The Atomic Energy Act also provides that certain actions (taking place after 10 March 1978) such as detonation of a nuclear explosive device, termination or abrogation of IAEA safeguards, or material violation of an IAEA safeguards agreement, will result in the termination of exports of nuclear equipment, materials, or sensitive technology to nations which have engaged in such conduct.

The Foreign Assistance Act precludes economic assistance to countries which deliver nuclear enrichment equipment or technology to other countries or receive such equipment, unless equipment is subject to IAEA safeguards and will be placed under multilateral auspices and management when available.

e) Subsequent arrangements

Under the Atomic Energy Act, subsequent arrangements, such as approval for retransfers or reprocessing, or arrangements for the storage or disposition of irradiated fuel elements must be approved by the DOE, with the concurrence of the Department of State, and in consultation with the NRC and the Department of Defense [42 USC 2160].

f) Technology exports

The Atomic Energy Act provides that exports of nuclear technology relating to the production of special nuclear material must be approved by the DOE. The DOE has promulgated regulations found in 10 CFR Part 810 which indicate which activities have been generically authorised and which require a specific authorisation. When an activity requires specific authorisation, the DOE must find that the activity for which the export will be utilised will not be inimical to the interest of the United States.

g) Information and restricted data

A major component of the national domestic safeguards system is the control and declassification of restricted data. The term "Restricted Data" means all data concerning :

- design, manufacture or utilisation of atomic weapons;
- the production of special nuclear material;
- the use of special nuclear material in the production of energy.

The DOE reviews restricted data and declassifies as much as possible in order to enlarge public understanding and disseminate technical information. [42 USC 2014, 2161, 2162 and 2163]. The Department of Defense participates in this process and the Central Intelligence Agency (CIA) participates when the information to be reviewed for declassification involves the atomic energy programmes of other nations. The energy agencies can divulge restricted data to other nations when authorised by an international agreement, but cannot reveal information about design and fabrication of nuclear weapons. In co-operation with regional defence organisations, the United States may share certain types of weapons information [42 USC 2164].

The Office of Personnel Management can supervise security checks on licensees or persons holding government contracts. There are elaborate criteria for determining employee access to restricted data, and appellate procedures under the aegis of a Personnel Security Board. When necessary, the President can involve the Federal Bureau of Investigation (FBI) in security checks [42 USC 2165].

Through rule making, including appropriate notice and comment procedures, the NRC can preclude unauthorised public disclosure of information about the licensee security measures and material accounting procedures if disclosure would endanger public health or the common defence by increasing the likelihood of theft, diversion or sabotage [42 USC 2167].

8. Physical Protection

The NRC has regulations to deter, prevent and respond to the unauthorised possession or use of special nuclear material, and to the sabotage of nuclear facilities. In general, safeguards for fuel facilities emphasise protection against theft or diversion of special nuclear material, while those for power reactors stress protection against radiological sabotage.

Only a few of the licensed fuel cycle facilities must meet the stringent requirements for physical protection required of facilities having Category I quantities of materials, *i.e.* over 5 kg of highly enriched uranium, or more than 2 kg of plutonium. Regulations stipulate special training for guards and provide for communication with central alarm facilities. Frequent emergency testing maintains system efficiency. In the case of radiological sabotage, plant operators must establish special communications with local law officials. Security guards have authority to use deadly force if they reasonably believe it necessary for their own self-defence or the defence of others [10 CFR 73.26(e)(3)].

Most other fuel cycle facilities (those that do not have Category I quantities of materials) are subject to rules on licensee fixed site and in-transit requirements for physical protection of special nuclear material. These rules control access to plants by mandating various detection systems. Entry controls and constant surveillance ensure security. Only authorised material placement and movement occur. Isolation zones permit security personnel to seal off potential threats.

Another aspect of NRC regulations concerning physical protection is found in 10 CFR Parts 70 and 74 relating to accounting and inventory control to detect losses of nuclear material. Those

regulations concern material control and accounting at fixed sites and documenting transfer of special nuclear material and source material at enrichment facilities.

Furthermore, the President is authorised to suspend nuclear co-operation with any nation or group of nations which has not ratified the 1979 Convention on the Physical Protection of Nuclear Material. The United States ratified the latter Convention on 13 December 1982.

9. Transport

The Department of Transport (DOT) and the NRC share federal responsibility for safety in the transport of radioactive material. The DOT regulates the transportation of radioactive material under the Transportation Safety Act of 1974, which incorporates the Hazardous Material Transportation Uniform Safety Act. The NRC's regulatory authority is based upon the Atomic Energy Act of 1954, and the Nuclear Waste Policy Act of 1982.

To avoid duplication, the two agencies have delineated their roles in a Memorandum of Understanding (MOU) (44 Fed. Reg. 38690). Under the MOU, the NRC is responsible for developing safety standards for shipping packages used for the domestic transport of large quantities of radioactive material (*i.e.* Type B packages) or fissile material. The DOT is responsible for developing domestic safety standards for smaller quantity shipping packages (*i.e.* Type A packages), developing and implementing safety requirements for carriage, and for implementing package safety requirements for import and export shipments. The DOT, as the designated US competent authority, also represents the US at the IAEA in developing international package safety standards. Under the MOU, the NRC advises the DOT on technical matters involving IAEA package standards.

The shipment of radioactive material is subject to DOT's regulations in 49 CFR Parts 171 to 180. These regulations include requirements for packaging, labelling and marking of packages, placarding of vehicles, carrier performance and training, emergency response information, routing and shipping papers. A final rule of 30 August 1995 [60 Fed. Reg. 188, September 1995, pp. 50292-50336] amended the Hazardous Materials regulations to harmonise them with those of the IAEA. The amendments require the offerors and carriers to maintain written radiation protection programmes, provide revisions to the definition and packaging for low specific activity radioactive materials, and require use of the International System of Units for the measurement of activity in a package of radioactive material. However, the basic standards for packaging radioactive materials remain unchanged. The DOT's regulations also include individual "modal" requirements for air (Federal Aviation Administration), rail (Federal Railroad Administration), highway (Federal Highway Administration) and vessel (US Coast Guard).

The DOT's regulations limit the amount of material which may be transported at any one time. Special tables incorporated into the regulations dictate the minimum distance which may exist between packages and people, animals, or other radioactive parcels if the packages are stored in a warehouse, depot, or rail car. Special decontamination requirements apply when rolling stock is used to transport radioactive materials [49 CFR 174.700].

When a shipper plans to transport radioactive material by road, special precautions in the DOT regulations govern storage and loading of packages and the gross weight to be carried. In addition, the NRC imposes special handling and surveillance requirements similar to those outlined for rail transport. There are also DOT spatial limitations on shipment placement within vehicles and special reporting requirements in case of an accident [49 CFR 177.834, 177.842, 177.843].

The Coast Guard assisted by the National Cargo Bureau, Inc., inspects cargo stowed for shipment on inland waterways or the high seas. If a foreign ship does not enter internal waters of the United States, it may transit the territorial sea without meeting American packaging requirements as long as the shipment is in compliance with the International Maritime Dangerous Goods Code of the International Maritime Organisation (IMO).

In addition to DOT regulations, NRC licensees are subject to the requirements in 10 CFR Parts 71 and 73. First, Part 71 covers package standards for Type B and fissile material packages, quality assurance requirements for package users and manufacturers, and notification requirements for certain waste shipments. Second, Part 73 includes safeguards requirements to protect special nuclear material from theft or sabotage. For example, for shipments of irradiated reactor fuel and strategic special nuclear fuel, the NRC can require approved route plans (for safeguards purposes), armed escorts, vehicle immobilisation, communication equipment, surveillance, and periodic reporting under Part 73. Part 73 also requires that shippers provide prior notification to State governors of spent fuel shipments.

An amendment to the Energy Reorganisation Act of 1974 [Public Law No. 79-94] forbids the NRC to license any air shipment of plutonium except for medical use, except in certified safe containers. Two packages, certified in 1978 and 1981, are available for use, and are able to withstand the crash of a high speed jet aircraft as well as crushing, puncturing, slashing, fire, and deep underwater immersion [42 USC 5841].

In 1987, Congress enacted two additional restrictions. First, Congress forbade the transportation of spent fuel or high level radioactive waste by the DOE except in packages that have been certified by the NRC for such purpose [42 USC 10175]. Second, Congress prohibited the transportation of plutonium by air through the air space of the United States from one foreign nation to another foreign nation unless the NRC certifies to the Congress that the container can withstand without rupture, a drop test from the maximum cruising altitude of the aircraft, and that the package can withstand the stresses produced during a worst case aircraft accident. The packages certified under Public Law No. 79-94 are exempted from this restriction.

10. Nuclear Third Party Liability

The federal legislation on nuclear indemnity and limitation of liability in the US, the Price-Anderson Act, forms part of the Atomic Energy Act of 1954, as amended. Originally enacted in 1957 for a ten-year term, the Price-Anderson Act was amended several times; its duration was extended to 1 August 1977 in 1965, to 1 August 1987 in 1975 and currently by the Price-Anderson Amendments Act of 1988, to 1 August 2002. The Price-Anderson Act governs liability and compensation in the event of a nuclear incident arising from the activities of NRC licensees and DOE contractors. While permitting individual States to largely retain their jurisdiction over matters relating to civil liability, the Price-Anderson Act sets forth requirements governing maximum available insurance, liability limits and channelling of compensation claims in order to achieve the goal of fair and adequate compensation of nuclear damage. The system originally provided stability and security to an infant nuclear power industry at a time when a lack of nuclear risk experience made it difficult for insurers to calculate costs. It also made it possible for the US Government to secure private contractors for its nuclear research needs.

The Price-Anderson Act is administered by the NRC with respect to all nuclear power plants which are subject to NRC licensing, and by the DOE with respect to the nuclear activities undertaken on its behalf by its contractors.

Given that liability is generally determined by the tort law of the State where the nuclear incident occurs, the Price-Anderson Act does not purport to channel such liability to the operator as is the case under some other legal systems; rather it ensures that anyone who is held liable will be indemnified. The Act defines "public liability" as any legal liability resulting from a nuclear incident or precautionary evacuation, except employees' claims for workers compensation, claims arising out of an act of war or claims for loss of or damage to onsite property.

The Price-Anderson Act defines a "nuclear incident" as "any occurrence, including an extraordinary nuclear occurrence, within the United States causing, within or outside the United States, bodily injury, sickness, disease, or death, or loss of or damage to property, or loss of use of property, arising out of or resulting from the radioactive, toxic, explosive, or other hazardous properties of source, special nuclear or by-product material."

The 1966 amendments introduced the notion of an "extraordinary nuclear occurrence" with a view to strengthening the protection of the public by eliminating the legal defences that would normally be available under State tort law systems. An extraordinary nuclear occurrence is essentially an event causing a significant release of nuclear material offsite or a significant increase in radiation levels offsite and in respect of which the Federal Government (either NRC or DOE) determines that there has, or will be, substantial damage to persons or property. Any determination by the NRC or the Secretary of Energy in this respect is final and conclusive. The elimination of the specified defences effectively results in strict liability. It is also to be noted that in the event of an extraordinary nuclear occurrence, the Price-Anderson Act would prevent the operation of any State statute of limitations which would have the effect of barring claims filed more than three years from the date on which the claimant first knew, or should reasonably have known, of his injury or damage and the cause thereof [42 USC 2209(n)(1)].

In addition to nuclear incidents, precautionary evacuations have also been covered by the Act since the 1988 amendments. A precautionary evacuation may be ordered by the responsible governmental entity, even if there has been no nuclear release from a nuclear installation, if the event has posed an "imminent danger of bodily injury or property damage". Evacuated persons are entitled to recover the costs they incur as a result of the evacuation.

As to liability amounts, the limitation of liability for nuclear power plants was originally set in 1957 at United States dollars (USD) 560 million, with first USD 60 million coming from the nuclear insurance pool and USD 500 million coming from the US Government through indemnification agreements. Over the years, the insurance portion gradually increased and the government's funding responsibility gradually decreased, to the point where the US Government's indemnification obligation was phased out and replaced by a system of retrospective assessments, called standard deferred premiums, which are paid by the operators of the power plants. The combined effect of this new two-tiered system of compensation is that the current limit of liability has now increased to USD 9.7 billion [42 USC 2209(b)].

Under the first tier, plant licensees must maintain financial security in an amount equal to the maximum liability insurance available from private sources, currently USD 200 million. Two private nuclear insurance pools hold premium reserves under an Industry Credit Rating Plan to assure the availability of funds in the event of a nuclear incident. Under this Plan, a portion of the annual premiums is set aside as a reserve either for payment of losses or for eventual refund to policyholders.

Under the second tier, retrospective premiums are payable by all plant operators to cover liability for damage exceeding the first tier. In the event of an incident, each operator would be charged a prorated share of the excess damage up to a statutory maximum of USD 83.9 million per

reactor per incident. Given the number of currently operating reactors, this maximum approximates USD 9.4 billion. The limit of liability will increase as the number of operating power reactors increases by USD 83.9 million per reactor. This premium is adjusted for inflation every five years. An additional 5% may be added to cover legal defence costs. NRC collects the premium and guarantees payment to victims whose claims have been accepted or adjudicated. The NRC's revised regulations for financial protection and indemnity agreements appear at 10 CFR Part 140.

Mandatory coverage exists only for nuclear power plants with a rated capacity of 100 MWe or more and for certain research and test reactors. The NRC has the power to extend this coverage to other nuclear installations, but has not as yet done so. Thus, for example, fuel fabrication plants and reprocessing facilities are not covered by the mandatory provisions and must rely on private insurance and defences under State law.

As regards DOE contractor activities, there is mandatory coverage for DOE contractors and any other person who may be liable for public liability resulting from a nuclear incident or precautionary evacuation arising out of or in connection with any contractual activity on behalf of DOE [42 USC 2210]. The DOE indemnification covers such persons up to the statutory limit for a nuclear incident at a commercial power plant in the United States (USD 9.7 billion). With respect to a nuclear incident outside the United States, the indemnity is limited to USD 100 million and only covers contractual activity on behalf of DOE that involves material owned by the US Government.

With regard to jurisdiction over damage claims arising from a nuclear incident, it is the United States District Court in the district where the nuclear incident takes place, which shall hear such claims without regard to the citizenship of any party or the amount in controversy. Where the nuclear incident takes place outside the United States, jurisdiction lies with the United States District Court for Columbia.

Unless the Price-Anderson Act is again renewed before its expiration date of 1 August 2002, coverage will not be available for any nuclear power plant that commences operation after that date. Such expiration will not, however, jeopardise coverage for existing facilities which remains in effect until they are decommissioned. Both the NRC and the DOE filed reports with Congress recommending that the Act be continued without significant changes.

II. INSTITUTIONAL FRAMEWORK

Many governmental organisations, both federal and state, contribute to United States nuclear regulation, power production, and research. Some private organisations are active in this area as well. This introduction section will provide an overview to explain the interrelationships among these bodies.

The Federal Government assumes primary responsibility for regulating nuclear energy; moreover, federal grants and contracts fund a major portion of academic and private research and development. Until 1974, the Atomic Energy Commission (AEC) served as the umbrella agency

charged with responsibility for all civilian and military projects involving atomic energy. In that year, the AEC was abolished and two successor agencies took over its mission.

The Nuclear Regulatory Commission (NRC) assumed the regulatory role and the Energy Research and Development Administration (ERDA) inherited the promotional activities. Later the ERDA was incorporated into the Department of Energy (DOE). The NRC is an independent agency, with commissioners appointed by the President.

Various advisory bodies assist federal agencies. Under the Federal Advisory Committee Act, most advisory bodies must be fairly balanced in terms of points of view represented and the functions to be performed; the meetings are normally open to the public. Usually these committees consist of experts who advise on technical matters or policy issues. In some instances, special working groups composed of representatives from many government agencies work together as planning groups, serving in an advisory capacity.

State governments also regulate aspects of nuclear energy. States take major responsibility for emergency planning. State and local government agencies ranging from law enforcement to public health and environmental agencies participate in nuclear energy policy (see Part I of this study *supra*). Pursuant to 42 USC 2021, the NRC is authorised to relinquish a portion of its jurisdiction over nuclear materials to the States. This is done by having the NRC and the governor of an interested State enter into an agreement providing the State with authority to regulate the materials covered by the agreement to protect public health and safety from radiation hazards. Such an agreement may cover source materials, by-product materials, and small quantities (generally, quantities not sufficient to form a critical mass) of special nuclear materials, though the primary focus of the State programmes is usually by-product material. There are currently 30 Agreement States.

Colleges and universities play a major role in nuclear research and development. These institutions receive grants and contracts from federal agencies to finance research. A few actually assume total responsibility for operating government-owned laboratories.

Many public and semi-public bodies recommend policy alternatives. There are numerous societies of scientists and engineers which also set up working groups to study nuclear policy, and publish journals and informative reports.

Environmentalist and consumer groups can present oral and written testimony at Congressional hearings to consider proposed legislation and at public meetings held by the NRC for the purpose of receiving input on issues before the agency. They often intervene in the licensing process, and initiate litigation.

Finally, private industry plays an important role in the energy field. Public utilities lobby for legislative proposals. The major nuclear entities have established the Nuclear Energy Institute (NEI) which represents the industry before the Congress, the NRC, and other relevant bodies. The private sector has set up research groups such as the Electric Power Research Institute (EPRI) which conduct research on a non-profit basis. Some corporations operate government-owned laboratories under contract.

1. Regulatory and Supervisory Authorities

As mentioned previously, the NRC and the DOE share most authority over nuclear affairs. A list of other federal agencies having oversight functions are arranged by the cabinet-level department

to which they belong; for instance, the United States Geological Survey (USGS) is a part of the Department of the Interior.

a) Nuclear Regulatory Commission (NRC)

i) Legal Status

In 1974, Congress passed the Energy Reorganisation Act creating the Nuclear Regulatory Commission (NRC) to assume the licensing function of the former Atomic Energy Commission (AEC). This independent regulatory body enjoys its own legal personality. While the NRC is responsible to the President, it exercises considerable independence in regulatory matters [42 USC 5801 and 5841].

ii) Responsibilities

The NRC is responsible for licensing and regulating nuclear materials and facilities, and for conducting research in support of the licensing and regulatory process as mandated by the Atomic Energy Act and other applicable statutes. Its responsibilities include protecting the environment, safeguarding materials and plants in the interest of national security, and assuring conformity with antitrust laws. The NRC acts through standards setting and rule making, technical reviews and studies, issuance of licences, permits and authorisations, inspection and investigation, evaluations of operating experience, and undertaking of confirmatory research.

The NRC issues licences for transfer, delivery, acquisition, ownership, possession, or import of special nuclear material, source material, and by-product material. It licenses medical and academic facilities as well as commercial power reactors. Licensing extends to both construction and operation of facilities and includes licensing of operating personnel (see Part I of this study).

The NRC maintains an active inspection and enforcement programme. It investigates violations and initiates enforcement proceedings. The NRC can seek judicial remedies such as injunctions, and can assess fines and penalties.

The NRC enters into co-operative agreements with States to help them assume the responsibility for regulating certain aspects of nuclear energy, such as medical applications and transport. The co-operating State assumes responsibility for narrowly circumscribed facets of the regulatory function, normally assigned to the NRC [42 USC 2021 and 2152].

Under the Price-Anderson Act, the NRC enters into indemnification agreements with nuclear reactor licensees for liability arising out of a nuclear incident. It investigates the causes of major incidents and reports to Congress.

iii) Structure

The Energy Reorganization Act of 1974 established the NRC as an independent regulatory agency with five commissioners, of whom no more than three may be members of the same political party. The President, with the advice and consent of the Senate, appoints the commissioners, who must be United States citizens. Each commissioner serves for five years and, during that time, may not

engage in any other business or vocation. The President may remove a commissioner only for neglect of duty, inefficiency, or malfeasance in office. Each commissioner enjoys full access to all data relating to NRC duties, and each has equal authority and responsibility in decision-making. In order for the NRC to act, a majority of members present must concur; however, a quorum requires the presence of three commissioners [42 USC 5841].

The President appoints one of the five commissioners as chairperson who acts as the principal executive officer and the official spokesman of the Commission. The chairperson is responsible for preparing policy planning and guidance for Commission consideration, and for conducting the administrative, organisational, budgetary and certain personnel functions of the NRC [42 USC 5841 and 5801].

Executive Director for Operations (EDO)

The position of the Executive Director for Operations (EDO) is established by statute. As the head of the NRC staff, the EDO reports to the chairperson and is subject to the chairperson's supervision and direction, as provided in Reorganization Plan No. 1 of 1980. The EDO is the chief operational and administrative officer of the Commission, and is authorised and directed to discharge such licensing, regulatory, and administrative functions of the NRC and to take actions as are necessary for day-to-day operations of the Commission. The EDO supervises and co-ordinates policy development and operational activities of the NRC's three major programme offices (Nuclear Reactor Regulation, Nuclear Material Safety and Safeguards, and Nuclear Regulatory Research) as well as the Incident Response Operations function, NRC regional offices, and such other offices as those of Enforcement, Administration, State Programs, Human Resources, Investigations, and Small Business and Civil Rights.

Office of the Chief Financial Officer (CFO)

The Office of the Chief Financial Officer (CFO) is responsible for the NRC's Planning and Budgeting, and Performance Management Process and for all of the NRC's financial management activities. The CFO must report directly to the head of the Commission. The CFO establishes planning, budgeting, and financial management policy for the Commission and provides advice to the chairperson and the Commission on these matters. The CFO develops and maintains an integrated Commission accounting and financial management system; establishes policy and directs oversight of Commission financial management personnel, activities, and operations; prepares and transmits an annual report which includes the Commission's audited financial statement to the chairperson and the Director, Office of Management and Budget; monitors the financial execution of NRC's budget in relation to actual expenditures, controls the use of Commission funds to ensure that they are expended in accordance with applicable laws and standards, and prepares and submits to the chairperson timely cost and performance reports; and reviews, on a periodic basis, fees and other charges imposed by the NRC for services provided and makes recommendations for revising those charges as appropriate. The CFO provides an Commission-wide management control programme for financial and programme managers to comply with the Federal Managers' Financial Integrity Act of 1982, and is responsible for implementing the Chief Financial Officers Act and the Government Performance and Results Act at the NRC. The CFO represents the NRC on the Federal CFO Counsel.

Office of the Chief Information Officer (OCIO)

The Office of the Chief Information Officer (OCIO) must report directly to the head of the Commission. The Chief Information Officer is responsible for ensuring the proper management of information resources. More specifically, the OCIO plans, directs, and oversees the delivery of centralised information technology (IT) infrastructure, applications, and information management (IM) services, and the development and implementation of IT and IM plans and policies to support the mission of the Commission. The Office advances the achievement of NRC's mission by assisting management in recognising where IT can add value while transforming or supporting Commission operations. The OCIO also provides principal advice and assistance to the chairperson, the commissioners, and other Commission executives to ensure that Commission IT and IM resources are selected and managed in a manner that maximises their value, manages risks, and is consistent with federal laws and regulations. The CIO represents the NRC on the Federal CIO Council.

Supporting the Executive Director for Operations, and reporting to him through the Deputy Executive Director for Management Services, are the Offices of Administration, Human Resources, and Small Business and Civil Rights:

Executive Council

In 1997, the Commission established an Executive Council consisting of the EDO, CFO and CIO to provide Commission wide administrative management and planning of NRC operations. The Council ensures that the Commission planning, budgeting, financial and human resource management, information technology and programmatic decisions, are fully integrated.

Office of Congressional Affairs (OCA)

The Office of Congressional Affairs (OCA), which reports directly to the chairperson, serves as the primary contact point for all NRC communications with Congress. OCA provides advice and assistance to the chairperson, Commission, and NRC staff on all NRC relations with Congress and views of Congress toward NRC policies, plans, and activities; maintains liaison with congressional committees and members of Congress on matters of interest to the NRC; serves as primary contact point for all NRC communications with Congress, reviewing and concurring in all outgoing correspondence to members of Congress; co-ordinates NRC internal activities with Congress; plans and develops NRC's legislative programme; and monitors legislative proposals, bills, and hearings.

Office of Public Affairs (OPA)

The Office of Public Affairs (OPA), reports directly to the chairperson. OPA develops policies, programmes, and procedures for the chairperson's approval for informing the public of NRC activities. OPA also prepares, clears, and disseminates information to the public and the news media concerning NRC policies, programmes, and activities; keeps NRC management informed on media coverage of activities of interest to the Commission; plans, directs, and co-ordinates the activities of public information staffs located at regional offices; conducts a co-operative programme with schools; and carries out assigned activities in the area of consumer affairs.

Office of the General Counsel (OGC)

The Office of the General Counsel (OGC) reports directly to the Commission. OGC staff directs matters of law and legal policy, providing opinions, advice, and assistance to the Commission with respect to all of its activities; reviews draft Commission opinions on public petitions seeking direct Commission action and rule-making proceedings; monitors adjudicatory proceedings, and reviews draft Commission adjudicatory decisions; provides interpretation of laws, regulations, and other sources of authority, and the legal form and content of proposed official actions; represents and advises staff offices in all programmatic activities and administrative litigation in connection with licensing and enforcement; prepares or concurs in all contractual documents, interagency agreements, delegations of authority, regulations, orders, licenses, and other legal documents, and prepares legal interpretations thereof; represents the NRC in administrative proceedings related to such matters as personnel, procurement, and EEO; reviews and directs intellectual property work; represents and protects the interest of the NRC in legal matters, in court proceedings, and in relation to other government agencies, administrative bodies, committees of Congress, foreign governments, and members of the public; provides legal advice to the Commission (including staff), and represents the Commission in courts of appeals proceedings to review Commission orders and rules; and, in co-operation with the Department of Justice, represents the Commission in court proceedings affecting the Commission's programmes in the federal district courts and the Supreme Court.

Office of the Secretary of the Commission (SECY)

The Office of the Secretary of the Commission (SECY), which reports directly to the Commission, provides general management services to support the Commission and to implement Commission decisions. SECY also advises and assists the Commission and staff on the planning, scheduling, and conduct of Commission business; and maintains the official adjudicatory dockets of the Commission. It also directs and administers the NRC history programme, and integrates automated data processing and office automation initiatives into the Commission's administrative systems. Additionally, SECY manages the Commission Decision Tracking System. Finally it is responsible for the implementation of the Federal Advisory Committee Act and maintains liaison with certain boards and advisory committees.

Office of International Programs (IP)

The Office of International Programs (IP), which reports directly to the Commission, provides assistance and recommendations to the chairperson, the Commission, and NRC staff on international issues. IP staff provides overall co-ordination for NRC's international activities, including nuclear exports and imports, international safeguards, international physical security, non-proliferation matters, and international co-operation and assistance in nuclear safety and radiation protection; plans, develops, and implements programmes, in concert with other NRC offices, to carry out policies established in these areas; plans, develops, and manages international nuclear safety information exchange programmes, and co-ordinates international research agreements. IP obtains, evaluates, and uses pertinent information from other NRC and US Government offices in carrying out assigned responsibilities; manages NRC's foreign intelligence responsibilities; and establishes and maintains working relationships with individual countries and international nuclear organisations, as well as other involved US Government agencies. The Office also assures that all international activities carried out by the Commission are well co-ordinated internally and government-wide and are consistent with the NRC and US policies.

Office of Commission Appellate Adjudication (OCAA)

The Office of Commission Appellate Adjudication (OCAA), which reports directly to the Commission, is responsible for monitoring cases pending before presiding officers; providing the NRC with an analysis of any adjudicatory matter requiring a Commission decision (*e.g.* petitions for review of initial licensing board decisions, certified questions, interlocutory referrals, stay requests), including available options; drafting any necessary decisions pursuant to the Commission's guidance after presentation of options; and in significant cases consulting with the Office of the General Counsel in identifying options to be presented to the Commission and in drafting the final decision to be presented to the Commission.

Advisory Committees

The Commission currently has several advisory committees chartered under the Federal Advisory Committee Act. This Act imposes certain constraints on advisory committees, primarily that they give advance notice of their meetings, and, unless certain exemptions apply, hold them open to the public.

These Committes include, *inter alia*:

- the *Advisory Committee on Reactor Safeguards (ACRS)*: the ACRS, consisting of 10 members with expertise in scientific and engineering disciplines, is NRC's only statutory advisory committee. It provides advice on potential hazards of proposed or existing reactor facilities, the adequacy of proposed safety standards and such other matters as the Commission may request. The statute requires that the ACRS review certain types of applications such as those for construction permits or operating licenses for power reactors or test reactors.

- the *Advisory Committee on Nuclear Waste (ACNW)*: the ACNW, consisting of four members with expertise in scientific and engineering disciplines, renders advice on nuclear waste management issues as directed by the Commission on the basis of periodic reviews of ACNW proposals.

Office of Nuclear Reactor Regulation (NRR)

The Office of Nuclear Reactor Regulation (NRR), which reports directly to the EDO, is one of the NRC's three major statutory programme offices. NRR employs approximately 20% of the Commission's personnel. NRR staff is responsible for ensuring the public health and safety through licensing and inspection activities at all nuclear power reactor facilities in the United States. NRR is responsible for the oversight of all aspects of licensing and inspection of manufacturing, production, and utilisation facilities (except for facilities reprocessing fuel and performing isotopic fuel enrichment), and receipt, possession, and ownership of source, by-product, and special nuclear material used or produced at facilities licensed under 10 CFR Part 50. NRR staff develops policy and inspection guidance for programmes assigned to the regional offices and assesses the effectiveness and uniformity of the region's implementation of those programmes. It identifies and takes action in co-ordination with the regional offices regarding conditions and licensee performance at such facilities that may adversely affect public health and safety, the environment, or the safeguarding of nuclear facilities and assesses and recommends or takes action in response to incidents or accidents. NRR staff is responsible for licensing issues and regulatory policy concerning reactor operators, including the

initial licensing examination and requalification examinations; emergency preparedness, including participation in emergency drills with federal, state, and local agencies; radiation protection; security and safeguards at such facilities, including fitness for duty; and the inspection of nuclear component supplier facilities. NRR responsibilities include the technical review, certification, and licensing of advanced nuclear reactor facilities and the renewal of current power reactor operating licenses.

Office of Nuclear Material Safety and Safeguards (NMSS)

The Office of Nuclear Material Safety and Safeguards (NMSS), which reports directly to the EDO, is one of the NRC's three major statutory programme offices. It employs approximately 12% of the Commission's personnel. NMSS is responsible for ensuring the public health and safety through licensing, inspection, and environmental reviews for all activities regulated by the NRC, except operating power and all non-power reactors, and for the safeguards technical review of all licensing activities, including export/import of special nuclear material, excluding reactors. The Office develops and implements NRC policy for the regulation of activities involving the use and handling of radioactive materials, such as: uranium recovery activities; fuel fabrication and development; medical, industrial, academic, and commercial uses of radioactive materials; safeguards activities; transportation of nuclear materials, including certification of transport containers, and reactor spent fuel storage; safe management and disposal of low-level and high-level radioactive waste; and management of related decommissioning. Its safeguards responsibilities include developing overall Commission policy, monitoring and assessing the threat to the environment including liaison with intelligence agencies as appropriate, and those licensing and review activities appropriate to deter and protect against threats of radiological sabotage and threats of theft or diversion of special nuclear material at fuel facilities and during transport. The NMSS identifies and takes action to control safety and safeguards issues for activities under its responsibility, including consulting and co-ordinating with international, federal, state, and local agencies, as appropriate.

Office of Nuclear Regulatory Research (RES)

The Office of Nuclear Regulatory Research (RES), which reports directly to the EDO, is one of the NRC's three major statutory programme offices. It employs approximately 7% of the Commission's personnel. RES recommends and implements programmes of nuclear regulatory research. It independently proposes regulatory outcomes in the form of improvements to NRC's regulatory programmes/processes to achieve enhanced safety, efficiency or effectiveness based on the results of this research. It co-ordinates research activities with the programme offices, as appropriate, and co-ordinates the development of consensus and voluntary standards for Commission use. Based on research results and experience gained, the Office resolves safety issues for nuclear power plants and other facilities regulated by the NRC including those issues designated as Generic Safety Issues. It assesses the effectiveness of selected NRC programmes, including the regulations and guidance, with regard to risk reduction potential, burden reduction potential, and the degree to which margins exist in design and operations of licensed facilities, and conducts research to reduce uncertainties in areas of potentially high risk or safety significance. The Office leads the Commission initiative for co-operative research with the DOE, the nuclear industry, universities and international partners; and co-ordinates research activities outside the Commission, including appointment of staff to committees and conferences. It maintains technical capability to develop information for resolution of nuclear safety issues and provides technical support and consultation to the programme offices in the specialised disciplines involved. It also provides independent analysis of operational data and assessment of operational experience through the review, analysis and evaluation of the safety performance of facilities licensed by the NRC. The Office collects, analyses, and disseminates

operational data; assesses trends in performance from this data; evaluates operating experience to provide insights into and improve the understanding of, the risk significance of events; and produces periodic performance indicator, and Accident Sequence Precursor Reports. RES also manages the NRC power reactor backfit programme, including the Committee to Review Generic Requirements (CRGR), to assure that new regulatory requirements (unless needed to assure adequate protection of the public health and safety) are justifiable on a cost-benefit basis.

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

The ACMUI, which reports directly to the EDO, consists of 12 members: qualified physicians and scientists and other representatives of the medical community, including a patients' representative. The ACMUI considers medical questions referred to it by the NRC staff (primarily the Office of Nuclear Material Safety and Safeguards) and gives expert opinions on the medical uses of radioisotopes. It also advises the NRC staff, as required, on matters of policy.

Incident Response Operations

Incident Response Operations, which reports directly to the EDO, develops and directs the NRC programme for investigation of operational incidents. It develops and directs the NRC programme for response to incidents, and is the Commission incident response interface with the FEMA and other federal agencies. It also exercises oversight of the regional response programmes; manages the NRC Operations Center; and receives, screens, and promptly communicates to the cognisant offices operational event information reported to the Operations Center.

Office of State Programs (OSP)

The Office of State Programs (OSP) reports to the EDO through the Deputy Executive Director for Materials, Research and State Programs. It is responsible for establishing and maintaining effective communications and working relationships between the NRC, states, local governments, other federal agencies and Indian tribe organisations. It serves as primary contact for policy matters between the NRC and these external groups; keeps the NRC apprised of these groups' activities as they may affect the NRC; and conveys to NRC management these groups' views toward NRC policies, plans, and activities. It administers the Agreement States Program providing training and technical assistance and reviewing the adequacy and compatibility of the States' radiation control programmes, which now have responsibility for some two-thirds of all materials licensees in this country. State Programs assists the States in such high priority areas as the development of programmes for the disposal of low-level waste and the control of uranium milling sites. State liaison officers appointed by State governors, and NRC Regional State Liaison Officers, attached to each of NRC's regional offices, serve as primary contact points between the Agreement States and the NRC.

Office of Enforcement (OE)

The Office of Enforcement (OE) is subject to oversight by the Deputy Executive Director for Reactor Programs. The NRC's enforcement programme has been developed to support the NRC's overall safety mission in protecting the public and the environment. Consistent with that purpose, enforcement action should be used as a deterrent to emphasise the importance of compliance with regulatory requirements, and to encourage prompt identification and prompt, comprehensive

correction of violations. Violations are identified through inspections and investigations. All violations are subject to civil enforcement action and may also be subject to criminal prosecution. The Commission uses three primary enforcement sanctions: Notices of Violation, civil penalties, and orders. A Notice of Violation identifies a requirement and how it was violated, and formalises a violation. A civil penalty is a monetary fine issued under authority of Section 234 of the Atomic Energy Act. Civil penalties may be assessed up to USD 110 000 per violation per day. Notices of Violation and civil penalties are issued based on violations. Orders may be issued for violations, or in the absence of a violation, because of a public health and safety issue.

Office of Investigations (OI)

The Office of Investigations (OI) was created in 1982 as a commission-level office independent of the EDO and the NRC staff. In 1989, pursuant to a congressional directive, the Commission placed OI under the EDO in order to emphasise that the office's primary role is to support the regulatory activities of the NRC, especially the Office of Enforcement. The Director of OI reports directly to the Deputy EDO for Reactor Programs. OI has a field office in each region.

OI develops policy, procedures, and quality control standards for investigations of licensees, applicants, their contractors or vendors, including the investigations of all allegations of wrongdoing by other than NRC employees and contractors. OI plans, co-ordinates, directs, and executes administrative affairs of the Office, including the development and maintenance of a management information system. The Office maintains current awareness of inquiries and formal investigations; keeps Commission principals currently informed of matters under investigation as they affect public health and safety matters; and co-ordinates liaison with other agencies and organisations to ensure the timely exchange of information of mutual interest.

Office of Human Resources

The Office of Human Resources provides overall leadership and management of Commission-wide human resources (HR) policy programmes. It develops and implements both short- and long-range human resources strategic plans consistent with Commission-wide programmatic goals and objectives; and assists and advises NRC management in the planning and implementation of HR goals consistent with Commission policies and mission. The Office plans and implements NRC human resources policies, programmes, and services providing organisation and position management analysis; recruitment and employment services; labour and employee relations services, and workforce information and analysis. It plans and implements Commission-wide training and development policies and programmes designed to establish, maintain, and enhance the skills employees need to perform their current jobs effectively and to meet the future skill needs of the Commission. It oversees the NRC occupational safety and health programmes including the workers' compensation and employee assistance programmes; and provides advice and support for the planning, development, implementation, oversight, and evaluation of HR information systems.

Most recently the Technical Training Center in Chattanooga, Tennessee was consolidated into the Office Of Human Resources to integrate technical and non-technical training within one organisational unit and to develop a consolidated and prioritised Commission training budget and planning process. The Technical Training Center programme includes training in the area of reactor technology, probabilistic risk assessment, radiation protection, fuel cycle, and regulatory skills to provide the necessary technical and regulatory foundation to support staff activities and decisions. Training is provided for inspectors, license reviewers, operations centre duty officers, licensing project

managers, technical reviewers, reactor technology instructors, and other NRC staff. Technical training for the NRC is highly dependent on the full-scope simulators, classroom information technology systems, and office technology systems that constitute the infrastructure at the Center.

Office of Small Business and Civil Rights (SBCR)

The Office of Small Business and Civil Rights (SBCR) is responsible for the development, implementation and management of three major programmes – Affirmative Action, which includes affirmative employment initiatives and a managing diversity process; Civil Rights; and the Small Business Procurement Preference Program. The mission of SBCR is to facilitate equal employment opportunity for all NRC employees and applicants through an on-going affirmative employment process; to provide for prompt, fair and impartial processing of EEO complaints and to eliminate or modify procedures or practices that give rise to valid complaints; and to ensure that small, minority, and women-owned businesses have full and fair opportunity to participate in NRC procurement activity.

Office of Administration (ADM)

The Office of Administration (ADM) provides centralised services in the areas of contracts and property management, facilities and security, and administrative services including rule-making and Commission directives support, transportation, parking, translations, audio-visual services, food services, mail distribution, furniture, supplies, and safety equipment. The Director, ADM, administers the NRC security and classification programmes.

Regional Offices

NRC's four regional offices are located in the Philadelphia (Region I), Atlanta (Region II), Chicago (Region III), and Dallas (Region IV) areas (a field office, located near San Francisco, was consolidated with Region IV in October 1998). Approximately 30% of the Commission's personnel are stationed in the Regions. Each regional office is headed by a regional administrator, appointed by the Executive Director for Operations, who is responsible for executing established NRC policies and assigned programmes relating to inspection, enforcement, licensing, State agreements reviews, State liaison, and emergency response within the region's boundaries.

For regionalised programmes, the regional offices perform an implementation function for the sponsoring headquarters programme office, from which they take direction. Included among the responsibilities of Regional Offices are the inspection and evaluation of engineering, construction, and operational activities of power reactors; implementation of nuclear material safety, licensing and inspection, emergency preparedness, and safeguards licensing functions assigned to the region; co-ordination of the NRC's Incident Response Program for activities within the region; issuance of notices of violation and proposed civil penalties (subject to further approval of headquarters, depending on severity); review of Agreement State regulatory programmes; and provision of technical assistance to Agreement States in carrying out their regulatory programmes.

Office of the Inspector General (OIG)

A 1988 Amendment to the Inspector General Act of 1978, a statute designed to promote integrity and efficiency in government programmes, provided for the appointment of NRC's first Inspector General. NRC is the only independent regulatory commission with an IG appointed by the President and confirmed by the Senate. Under the statute the IG reports directly to the NRC Chairperson.

The OIG provides policy direction for and conducts, supervises, and co-ordinates audits and investigations relating to all NRC programmes and operations; reviews existing and proposed legislation and regulations and makes recommendations concerning their impact on the economy and efficiency of NRC programmes and operations and on the prevention and detection of fraud and abuse in such programmes and operations; recommends policies for, and conducts, supervises, or co-ordinates other activities for the purpose of promoting economy and efficiency in the administration of, or preventing and detecting fraud and abuse in, NRC programmes and operations; recommends policies for and conducts, supervises, or co-ordinates relationships between the NRC and federal, state and local agencies, and non-governmental entities relating to the promotion of economy and efficiency in the administration of, or prevention and detection of fraud and abuse in, NRC programmes and operations or identification and prosecution of participants in fraud or abuse; keeps the Chairperson and Congress fully and currently informed concerning fraud and other serious problems, abuses, and deficiencies relating to the administration of NRC programmes and operations; recommends corrective actions and reports on the progress made in implementing corrective actions; complies with GAO standards for audits of federal establishments, organisations, programmes, activities, and functions; and expeditiously refers criminal matters to the Department of Justice.

iv) Financing

Under the Omnibus Budget Reconciliation Act of 1990, those regulated by the NRC are required to pay fees which collectively total approximately 100% of the NRC budget. The NRC collects fees for review of licence applications, construction permits, operating licences, licence amendments, and renewals; assesses fees for inspections; and also imposes an annual fee on its licensees. Although the NRC collects substantially all of its budget through its fee recovery programme, the NRC remits the fees to the federal Treasury. The moneys, therefore, are not available for Commission disbursement until Congress has appropriated the funds [42 USC 2214].

b) Department of Energy (DOE)

i) Legal status

With enactment in 1977 of the Department of Energy Organization Act [42 USC 7101 *et seq.*], the United States Congress combined the energy management functions of the Federal Government into a single cabinet-level Executive Branch agency charged with co-ordinating federal energy policy and programmes. This agency, the Department of Energy (DOE), is the successor to the Energy Research and Development Administration and heir to the research, development, and demonstration functions of the former Atomic Energy Commission. In this capacity, it is charged with and carries out non-defence nuclear missions pursuant to broad legislative authorities that include the Atomic Energy Act of 1954, as amended [42 USC 2011 *et seq.*], the Nuclear Waste Policy Act of 1982, as amended [42 USC 10101 *et seq.*], the National Competitiveness Technology Transfer Act of 1989

[15 USC 3701 *et seq.*], and the Energy Policy Act of 1992 [42 USC 10141 note, 42 USC 2297 *et seq.*, 42 USC 2061].

(ii) Responsibilities

The DOE conducts and supports an extensive array of activities related to the nuclear fission and fusion fuel cycles, including research, development, and demonstration; training and education, and technology transfer in the following areas:

- production, processing, and utilisation technologies, including support for advanced fission reactor development and development and demonstration of fusion energy as a potential commercial power source;
- environmental impacts and aspects of biomedical, physical and safety science related to nuclear power production;
- research in fundamental nuclear physics, the results of which feed into applied technology;
- management of high-level radioactive waste and spent nuclear fuel and support for the national low-level radioactive waste programme;
- international efforts to ensure nuclear safety, prevent nuclear proliferation, and assure stable energy supplies in crisis situations;
- safe transportation of radioactive materials;
- production for, and application of nuclear power systems in support of other federal agency missions, including the space missions of the Department of Defense and the National Aeronautics and Space Administration (NASA).

To assist it in discharging its responsibilities, the DOE also monitors, accumulates and disseminates to other federal agencies and to the public information from domestic and world energy markets; negotiates bilateral and multilateral energy agreements in consultation with the NRC, the Department of State and other agencies; and ensures that countries purchasing US nuclear fuel conform to IAEA safeguards.

In international nuclear transactions, the DOE administers US nuclear export policy in conjunction with the NRC and the Departments of State and Commerce, as provided for in the Nuclear Non-Proliferation Act of 1978 and the Atomic Energy Act of 1954. It also approves contracts for the sale of special nuclear materials and enrichment services to foreign nations; participates in reviews of export licences for equipment, reactors, and nuclear materials, and approves re-transfers of US origin nuclear material by foreign governments.

iii) Structure

Line Operations

The DOE is headed by the Secretary of Energy, who articulates national energy goals, plans for strategic programme implementation to meet the nation's short and long-term energy needs, and advises the President on energy issues and in the formulation of major national energy policies.

The Deputy Secretary acts on behalf of the Secretary in the Secretary's absence and, together with the Under Secretary, is responsible to the Secretary for DOE programmes that involve:

- overseeing and supporting the development of applied nuclear energy resources and technologies and constructing and operating the DOE's civilian research and test reactors;

- discharging the Secretary's responsibilities for the disposal and storage of high-level radioactive waste and spent nuclear material, including supporting related research, development, and demonstration activities and managing the Nuclear Waste Fund [see subsection (iv) "Financing", *infra*];

- managing the DOE basic research and development programmes and non-proliferation and security activities;

- managing the DOE's technical information resources and science education initiatives, the latter of which includes university reactor fuel assistance and other reactor research and training programmes in the universities, the private sector, and at the national laboratories; and

- planning for the use and overseeing the management of the DOE Laboratory Complex, in which many of the research and development programmes are conducted or facilitated and much of the civilian technology transfer takes place.

Below the level of these officials, the Assistant Secretaries and the Director of Energy Research are assigned specific responsibilities from among those enumerated in the DOE Organization Act. Assignments that relate to one or more aspects of the nuclear fuel cycle include:

- resource applications;

- environmental responsibilities;

- international and policy matters;

- national security;

- intergovernmental policies and relations;

- nuclear waste management; and

- public and congressional relations.

In addition to Secretariat assignments, the Director of Energy Research is, by law, advisor to the Secretary on the DOE research programmes and the operations and health of the multi-purpose laboratories. As such, the Director plays a major role in institutional planning for the Laboratory Complex.

The Office of Civilian Radioactive Waste Management was established by the Nuclear Waste Policy Act. The Director of the Office is responsible for carrying out the functions of the Secretary of Energy under the Act and is appointed by the President, by and with the consent of the Senate.

The Field Establishment

The DOE Operations Offices oversee and administer the contracts under which DOE installations, including the Laboratory Complex described below, are operated and, on a daily basis, perform a number of services related to or in support of DOE grants, co-operative agreements, and research and development agreements involving transfers of technology to the private sector. Through their managers, these Offices co-ordinate on and inform the DOE Headquarters of these field activities, as appropriate. The Operations Offices are located in Albuquerque, New Mexico; Chicago, Illinois; Idaho Falls, Idaho; Las Vegas, Nevada; Oakland, California; Oak Ridge, Tennessee; Aiken, South Carolina, and Richland, Washington.

The DOE carries out many of its missions through the use of its Laboratory Complex. Featuring many unique and state-of-the-art facilities, a number of the individual laboratories, including all of the multi-programme laboratories, have research and development capabilities in subject-matter that relates to one or more elements of the nuclear fission or nuclear fusion fuel cycle.

The laboratories within the complex, with few exceptions, are operated for the DOE by private-sector Management and Operating (M&O) Contractors, a regime that was initiated during the Manhattan Project[6] and carried over to the AEC through the Atomic Energy Acts of 1946 and 1954. Their facilities are available to non-DOE researchers, engineers, and technicians through "work-for-others" and user-facility arrangements on the basis of non-interference with DOE programmes. The DOE policy requires full cost recovery for work-for-others and for proprietary user facility access; non-reimbursable, non-proprietary user access is granted for meritorious, peer-reviewed proposals. In addition, consortia of non-DOE parties working with one or more of the laboratories under Cooperative Research and Development Agreements (CRADAs) are provided access to laboratory facilities.

Within the Laboratory Complex, the Idaho National Engineering Laboratory, Idaho Falls, Idaho, concentrates on nuclear reactor research and development, nuclear safety research, and radioactive waste technology development, and the Argonne National Laboratory, Chicago, Illinois and Idaho Falls, Idaho, devotes substantial resources to the design and testing of advances in fission-reactor technology.

The other DOE multi-programme laboratories are: Brookhaven National Laboratory, Upton, New York; Lawrence Berkeley Laboratory, Berkeley, California; Lawrence Livermore National Laboratory, Livermore, California; Los Alamos National Laboratory, Albuquerque, New Mexico; Oak Ridge National Laboratory, Oak Ridge, Tennessee; Pacific Northwest Laboratory, Richland, Washington, and Sandia National Laboratories, Albuquerque, New Mexico and Livermore, California.

6. This project was initiated by President Roosevelt in 1943 to develop a nuclear weapons programme.

Federal Energy Regulatory Commission

The Federal Energy Regulatory Commission is an independent agency established within the DOE by the DOE Organization Act. It is responsible for overseeing domestic interstate operations of electric utilities, with the goal of ensuring that adequate energy supplies are available at reasonable prices, while allowing producers sufficient latitude to operate in the free marketplace. The Commission deals with nuclear energy to the extent that its decisions influence the determination of an overall energy mix.

Nuclear Waste Technical Review Board

The Nuclear Waste Policy Act established an independent Nuclear Waste Technical Review Board within the Executive Branch. The Board is charged by law with evaluating the technical and scientific validity of activities taken by the Secretary of Energy pursuant to the Nuclear Waste Policy Amendments Act of 1987, including site characterisation activities for the geologic high level radioactive waste repository and activities relating to the packaging and transportation of high-level radioactive waste and spent nuclear fuel. Statutory investigative powers are available to it in carrying out its responsibilities. It reports its findings, conclusions, and recommendations not less than twice per year to Congress and to the Secretary.

United States Uranium Enrichment Corporation (USEC)

The Energy Policy Act of 1992 (EPACT) (Public Law No. 102-486) amended the Atomic Energy Act of 1954 and created the United States Uranium Enrichment Corporation (USEC) as a wholly owned government corporation to operate the DOE's uranium enrichment programme and enrichment plants [42 USC 2297(b)]. The EPACT required that the USEC operate as a business enterprise, acquiring uranium for enrichment, low-enriched uranium for resale, highly-enriched uranium for conversion into low-enriched uranium, and selling enriched uranium and related services to the DOE, domestic and foreign persons [42 USC 2297(b)-2]. The USEC was directed to lease the DOE's uranium enrichment operations at the Portsmouth and Paducah Gaseous Diffusion Plants. These plants, now managed by the USEC, are regulated by the NRC. The USEC began operations on 1 July 1993 and its privatisation was completed in 1998.

iv) Financing

The DOE receives the primary funding for its nuclear programmes from the United States Treasury through the Congressional appropriations process. As previously indicated, the Laboratory Complex generates revenues from the performance of reimbursable work-for-others and for proprietary use of facilities on a full-cost recovery basis. These revenues, to the extent they are not applied, under M&O contract provisions, to the upkeep and maintenance of the facilities, are however offset against DOE appropriations.

c) Department of Labor

This cabinet-level Department has overall responsibility for worker safety. The Department of Labor also has jurisdiction in the first instance over any complaint by a nuclear industry employee that he or she has been discriminated against or discharged for "whistleblower" activities. Whistleblower

activities include notifying the NRC or the employer about statutory or regulatory violations, testifying before Congress or in another governmental proceeding regarding nuclear matters; and refusing to engage in unlawful practices if the employee has identified the alleged illegality to the employer [42 USC 5851].

In addition, the Occupational Health and Safety Administration (OSHA), an organisation within the Department of Labor, develops and promotes occupational health and safety standards, conducts inspections, and issues penalties. The Mine Safety and Health Administration develops mine safety and health standards, proposes penalties for violations of the standards, investigates accidents and co-operates with States in developing mine safety and health programmes.

d) Department of Transportation (DOT)

This cabinet-level Department works with the NRC to regulate the safety of transporting radioactive materials. Within the Department of Transportation (DOT), the Research and Special Programmes Administration has issued regulations which govern all modes of transport of hazardous materials, including radioactive materials and radioactive wastes.

e) Environmental Protection Agency (EPA)

The Environmental Protection Agency (EPA) assumes overall responsibility for United States environmental quality. The EPA issues standards and guidance to limit human exposure to radiation. The EPA works with the public, industry, the States and other government agencies to inform people about radiation's risks and to promote actions that reduce human exposure. The EPA measures environmental levels of radiation and assesses radiation's effects on people and the environment. The EPA is also empowered to establish standards for disposal of radioactive wastes.

Within the Agency, the Office of Radiation Programs, managed by the Office of the Assistant Administrator for Air, Noise, and Radiation, has the specific authority to establish generally applicable environmental standards for releases of radiation into the environment and to promulgate rules limiting emission of hazardous pollutants into the atmosphere. It provides technical assistance to State radiation protection agencies, setting up a surveillance and inspection system for measuring radiation levels in the environment. The NRC is responsible for promulgating rules that implement EPA standards in NRC-licensed facilities.

2. Advisory Bodies

Each federal agency may have a number of advisory committees which assist it in developing policies, priorities, or research plans. As an example the following listing is arranged according to the federal agency to which the panel is responsible.

a) DOE Advisory Committees

The DOE uses the expert consideration, counsel, and recommendations of advisory bodies that address, wholly or as a part of their activities, programmes or issues associated with the nuclear fission and nuclear fusion fuel cycles.

Nuclear Energy Research Advisory Committee

The Nuclear Energy Research Advisory Committee was established on 1 October 1998 to advise the Secretary of Energy through the Director of the Office of Nuclear Energy, Science and Technology on: 1) periodic reviews and recommendations concerning the Nuclear Energy Research and Development Program within the Office of Nuclear Energy, Science and Technology; 2) long-range plans, priorities and strategies to address more effectively scientific aspects of nuclear energy research and development; 3) appropriate levels of funding to develop those plans, priorities, and strategies and maintaining appropriate balance between the different elements of the programme; 4) national policy and scientific aspects of nuclear energy research issues of concern to the Department of Energy as requested by the Secretary or the Director of the Office of Nuclear Energy, Science and Technology.

Advisory Committee on Human Radiation Experiments

This Advisory Committee established by the President in 1994 to investigate human radiation experiments carried out or sponsored by the United States Government during the period 1944 through 1974 has completed its work and issued a final report in October 1995. The Committee examined eight different categories of experiments: 1) with plutonium and other atomic bomb materials; 2) the Atomic Energy Commission's programme of radioisotope distribution; 3) nontherapeutic research on children; 4) total body irradiation; 5) research on prisoners; 6) human experimentation in connection with nuclear weapons testing; 7) intentional environmental releases of radiation; 8) research involving uranium miners and residents of the Marshall Islands.

Basic Energy Sciences Advisory Committee

The Basic Energy Sciences Advisory Committee was established on 16 October 1986 to advise the Secretary of Energy, through the Director of Energy Research, on elements of the Department's Basic Energy Sciences Program. This Programme includes a broad range of basic research into materials and chemical science, engineering and geosciences, applied mathematical sciences, energy biosciences, and advanced energy projects. In materials sciences, for example, research addresses the limitations that frequently restrict the performance of current energy systems and the development of future energy systems that will use advanced structural materials and testing techniques for improved operations.

Biological and Environmental Research Advisory Committee (BERAC)

The Biological and Environmental Research Advisory Committee (BERAC) was established on 22 November 1983 to conduct periodic reviews of elements of the DOE Biological and Environmental Research Program and provide advice on long-range plans, priorities and strategies to address more effectively the scientific aspects of energy-related biological and environmental issues of DOE policies and programmes.

High Energy Physics Advisory Panel/Nuclear Science Advisory Committee

The High Energy Physics Advisory Panel was established on 13 January 1967 to advise the DOE on the national high energy physics research programme. This programme includes studies of

the basic underlying structure of matter and energy and of the fundamental forces. The Nuclear Science Advisory Committee, a joint DOE/National Science Foundation advisory panel, provides advice concerning basic nuclear research programmes that concentrate on how the fundamental particles and forces combine to form atomic nuclei. In carrying out their advisory responsibilities, these Committees assess the adequacy of current facilities, the institutional balance of support needed for optimised scientific productivity, and the training of scientists. The programmes within their cognisance include those which have provided the bedrock for much of today's technological society, including nuclear power.

The Secretary of Energy Advisory Board

The Secretary of Energy Advisory Board, established on 2 January 1990 to succeed the Energy Research Advisory Board, provides expert guidance to the Secretary on DOE's research and development, and energy programmes, activities, and operations. The Secretary may charge this Board with the study of any aspects of any programs or operations within the DOE's cognisance, including those involving research and development in nuclear power (fission and fusion), future directions and operations of the Laboratory Complex, and high-level waste and spent nuclear fuel management and disposal.

National Electric and Magnetic Fields Advisory Committee

The National Electric and Magnetic Fields Advisory Committee was established on 14 January 1993 pursuant to the Energy Policy Act of 1992 to advise the Secretary of Energy and the Director of the National Institute of Environmental Health Sciences, under the US Department of Health and Human Services, on the design and implementation of a programme that will concentrate on the possible human health effects of electric and magnetic fields, and on issues of concern to State regulatory and health agencies, electric utilities, electric equipment manufacturers, labour unions, and the public with regard to the measurement assessment and management of these fields.

b) Advisory Committees to the Department of Health and Human Services

Two Groups, the Medical Radiation Advisory Committee (Radiation Study Section), and the Radiopharmaceutical Drugs Advisory Committee, help develop regulations and set research priorities for the Food and Drug Administration of the Public Health Service.

3. Public and Semi-Public Agencies

The following federal agencies sometimes exert regulatory authority over some aspects of nuclear energy; however, the major thrust of their activities is research oriented or advisory in nature. For example, while the Department of Commerce regulates the export of technology, it also develops measurement standardisation schemes. The Department of Defense overlaps into the civilian sector. Agencies are listed alphabetically by cabinet-level department, followed by independent federal agencies, and, finally, a few semi-public groups.

A. Cabinet-Level Departments

a) Department of Agriculture

This cabinet-level department advises the DOE and the NRC about potential impact of nuclear facility siting in rural areas and on lands controlled by the Forest Service. Within the Department, the Science and Education Administration funds research in the life sciences and studies and promotes the use of radioisotopes in agriculture.

b) Department of Commerce

This Department licenses exports of certain components for nuclear plants. Within the Department, the National Institute of Standards and Technology develops improvements in radiation measurement and instrument calibration. The National Oceanic and Atmospheric Administration researches the occurrence of radionuclides in estuaries. It studies the effect of radioactive materials on marine organisms and seeks application of radioactive tracers to fisheries problems.

c) Department of Defense (DOD)

Within the Department of Defense (DOD), several agencies study medical applications of nuclear technology, such as the Armed Forces Radiobiology Research Institute which develops biomedical applications of isotopes and examines long-term effects of radiation exposure, and the Uniformed Services University of the Health Sciences which does research on nuclear safety and dosimetry.

d) Department of Health and Human Services (DHHS)

Under the auspices of the Department of Health and Human Services (DHHS), the Public Health Service sponsors health research.

The Office of Radiological Health operates programmes to reduce exposure to hazards of ionising as well as non-ionising radiation. It prepares standards for safe exposure limits, and develops methods for controlling exposure, especially to radiation emitted by electronic products.

The National Cancer Institute of Health, Radiation Oncology Branch undertakes clinical and laboratory research for direct medical management of cancer patients, concentrating on simulating cellular kinetics in the laboratory in order to better sequence radiotherapy.

The Food and Drug Administration (FDA), an organisation within the DHHS, regulates to assure the safety of new devices and drugs, whether or not they contain by-product material, as they are placed in service. The FDA regulates the manufacture and distribution of radiopharmaceuticals, biologics and medical devices for safety and efficacy; the NRC regulates radiation safety associated with the actual use of these products. The FDA authority is exercised at the investigational, pre-market review, and manufacturing site level, and in its post-market surveillance, which includes user facilities when serious problems are reported.

e) Department of the Interior

Three separate agencies within this cabinet-level department assist in developing nuclear resources. The United States Geological Survey (USGS) conducts field and laboratory investigations supporting the DOE waste disposal efforts, and collaborates with the DOE on earth science technology. It conducts research on processes related to nuclear waste disposal and characterisation of potential disposal sites. It consults with the NRC on earth science matters related to regulation of waste repositories and the licensing of nuclear facilities. Finally, the USGS is implementing a nuclear hydrology programme to study the movement of radioactive material in groundwater.

The Denver Federal Center makes field and laboratory studies of radioactive minerals and radiogenic isotopes related to geochronology. It is also conducting research to trace the movement of water, and is comparing geohydrologic environments for radioactive waste disposal.

The Bureau of Land Management, as custodian of federal lands, reviews proposals involving federally controlled land (*e.g.* waste disposal).

f) Department of State (DOS)

The DOE and the NRC negotiate international accords in concert with the Department of State (DOS). The DOS negotiates agreements for co-operation and evaluates political, military and legal ramifications of export agreements. Pursuant to the Nuclear Non-Proliferation Act of 1978, the DOS plays an active role, screening agreements and contracts for compliance with United States nuclear law and policy.

Within the State Department, the Bureau of Oceans and International Environmental and Scientific Affairs is responsible for formulation and implementation of policies and proposals concerning nuclear non-proliferation, nuclear exports, and other aspects of nuclear policy in relation to other nations and international organisations. The Bureau assists the DOE in negotiating contracts for technology transfers.

B. Other Federal Agencies and Offices

a) Federal Emergency Management Agency (FEMA)

This Agency (FEMA) assumes lead responsibility for all offsite nuclear emergency planning and response. With the DOE and the NRC, it co-ordinates federal, state and local efforts to develop and evaluate radiological emergency response plans and warning systems, with particular emphasis on the adequacy of state and local plans.

b) National Aeronautics and Space Administration (NASA)

This Agency (NASA), concerned with civilian and military aspects of space exploration, operates the Lewis Research Center. The Center conducts projects in life sciences, nuclear medicine, and radiobiology. It has also studied the impact of radiation damage emanating from nuclear activities in space.

c) Tennessee Valley Authority (TVA)

This federal Agency (TVA) conducts a co-ordinated resource conservation, development, and land use programme in the Tennessee River Valley Region. It also produces and markets various types of power, including nuclear. The TVA investigates options for waste disposal and nuclear safeguards.

d) White House Offices

Two offices attached directly to the White House help decide priorities.

The Office of Management and Budget (OMB) develops the Administration's budget proposals each year. With authority to review individual federal agency requests subject to congressional approval, the OMB can influence which aspects of nuclear energy receive emphasis.

The Office of Science and Technology Policy co-ordinates research developments undertaken by various agencies, especially interdisciplinary approaches to waste disposal.

C. Semi-Public Agencies

a) American National Standards Institute (ANSI)

This organisation (ANSI) acts as a clearing-house to co-ordinate standards development. It consists of several management boards, one of which is the Nuclear Standard Board. Both NRC and DOE participate in that Board as voting members. The Board reviews standards developed by other organisations, such as the American Society of Mechanical Engineers and the American Society for Testing and Materials. The Institute deals with, among others, utilisation or measurement of ionising radiation, nuclear energy, fissionable materials, and chemical processing of nuclear materials. The ANSI represents the United States in the International Standards Organisation (ISO) and the International Electrotechnical Commission.

b) National Academy of Sciences (NAS)

The National Academy of Sciences (NAS) is an umbrella group which conducts research in all areas of science and engineering, including the physical and social sciences. It publishes a report on the Biological Effects of Ionising Radiation, and has set up a standing board dealing with radioactive waste management.

c) National Council on Radiation Protection and Measurement

This group studies nuclear physics, nuclear medicine and waste disposal as they relate to radiation protection. The Council formulates recommendations on radiation protection and measurement by compiling available scientific information from many disciplines. The Scientific Committee of the Council drafts recommendations which are in turn adopted by the Council. The recommendations cover consumer protection, occupational health, environmental protection, and nuclear waste disposal.

d) National Nuclear Data Center

The Center, a part of Brookhaven National Laboratory, co-operates with the OECD, the IAEA and focuses on continuing relationships with the former Soviet Union States in publishing the Computer Index of Nuclear Data (CINDA). The Center assists in computer data retrievals and evaluates a broad range of technical multidisciplinary data.

c) Atomic Energy of Canada Ltd. (AECL)

i) Legal Status

Atomic Energy of Canada Limited (AECL) was incorporated under powers granted to the Minister under Section 10(2) of the Atomic Energy Control Act [RSC 1970, c.A-19]. Formal incorporation as a company under the Companies Act (1934) was by way of letters patent dated 14 February 1952. The Company applied for, and was granted, continuance under the Canada Business Corporations Act on 8 July 1977.

The AECL is a commercial limited liability corporation acting on behalf of the Crown within the limits of the powers conferred on it by the Minister of Natural Resources, with the approval of the Governor in Council. Its share capital is held by the Minister in the name of the Crown.

ii) Responsibilities

The AECL is a decentralised corporation consisting of a Corporate Office plus two operating companies, each of which specialises in different areas of nuclear development. AECL Research provides the scientific and technical base for Canada's nuclear programme. AECL CANDU designs and markets the CANDU reactor system, components and related technologies in Canada and abroad. AECL Technologies Inc. is a wholly-owned subsidiary of the AECL incorporated in 1988. Its principal office and place of business is Rockville, Maryland.

iii) Structure

The Corporate Head Office is the central administrative body of the AECL. It comprises a president and chief executive officer and three vice-presidents.

The board of directors has thirteen members (including the chairperson of the board and president). Board members are appointed by the Governor in Council for a three year term that is renewable. The appointment of subordinate officers (including the Presidents of AECL Research and AECL CANDU) is the prerogative of the board of directors.

iv) Financing

The shares of AECL, a federal Crown Corporation, are held by the Minister of Natural Resources on behalf of the Crown. The financial resources of AECL CANDU come from revenues from supplies and services it provides to Canadian and foreign utilities and firms. AECL Research generates some of its own funds by undertaking commercial research and development work. The remainder of its funds come from money voted to it by the federal Parliament and from cost-sharing agreements with provincial utilities.

AECL's annual financial statements are audited by the Auditor General of Canada and approved by the Shareholder at the Annual Meeting of Shareholders. The financial statements of the corporation and the Auditor General's report are submitted to Parliament by the Minister of Natural Resources.

While AECL is incorporated as a private Canadian Company, its research and development expenditures, capital expenditures, loans and major transactions or undertakings are subject ultimately to parliamentary, government or Governor in Council approval.