THE MEANING AND APPLICATION OF THE CONCEPT OF POTENTIAL EXPOSURE

A Report from the CRPPH/CSNI/CNRA/RWMC Expert Group (December 1995)

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ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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THE MEANING AND APPLICATION OF THE CONCEPT OF POTENTIAL EXPOSURE

1. INTRODUCTION

The publication of ICRP Recommendations on potential exposure, in 1991 and 1993, has stimulated a number of meetings and discussions, sometimes heated, among groups of technical specialists; particularly between the specialists in the fields of radiation protection and nuclear safety, but also including waste management experts.

The term "potential exposure" is used to describe a radiation exposure that is not certain to occur or, more specifically, an exposure whose probability of occurrence, while not being negligible, is significantly less than one. Potential exposure reflects the combination of the probability of occurrence of potential events and the chance that such events will result in a radiation dose to individuals. The concept of potential exposure is complementary to that of normal exposure, whose probability of occurrence is not significantly less than one, thus encompassing exposure resulting from normal operations including minor mishaps.

The issues concerning implementation of potential exposure recommendations mainly involve matters such as scope, methodologies for implementation in general and as applied to specific practices, and how they might be treated in a regulatory context. Differences in use of terminology employed by different organizations and specialists have sometimes inhibited mutual understanding of potential exposure issues and how to resolve them.

Although substantial progress has been made in coming to grips with potential exposure issues since the publication of the relevant ICRP recommendations, discussions about them still suffer from a lack of clearly defined issues and a mutual understanding of the terminology being employed. These problems become exacerbated as the number and kinds of specialists engaging in such deliberations expand.

The NEA, therefore, formed in 1993 an Expert Group consisting of representatives from its Committees on Radiation Protection and Public Health (CRPPH), Safety of Nuclear Installations (CSNI), Nuclear Regulatory Activities (CNRA) and Radioactive Waste Management (RWMC), as well as representatives from ICRP and IAEA, to examine problems associated with the application of potential exposure concepts, to frame precise statements about the issues and to clarify some terminology which has caused confusion. It is believed that representation on the Expert Group constitutes a good cross section of specialists concerned with potential exposure.

The Expert Group held two meetings in which a large number of issues, both of a substantial nature and concerning problems of interpretation and terminology were discussed. These discussions were carried out taking fully into account not only the relevant ICRP Publications but also the recent IAEA work and the current thinking in Member countries. The Expert Group was chaired by Mr. Richard Cunningham (United States), who was also the principal editor of the document.

The principal issues considered by the Group included the meaning and the scope of application of the concept of potential exposure as defined by the ICRP, the establishment of a common understanding and of agreed definitions concerning a number of terms used by the different communities sometimes with different meanings (i.e., risk, probability vs frequency, limits vs constraints, etc.), the use and practical limitations of Probabilistic Safety Assessment (PSA) techniques in safety assessment and regulatory decision making, the concept of safety goals, how to deal with low probability/high consequence events, the time aspects of potential exposure particularly in radioactive waste management, etc. In each of these areas, the Group clarified definitions, identified issues and in some cases attempted to reach consensus positions.

This report from the Expert Group is published as a contribution to the international debate, as a basis to stimulate reflection on this question within the NEA relevant Committees and, possibly, to offer a common ground for future exchanges of views between these Committees.

2. BACKGROUND: DEVELOPMENT OF THE POTENTIAL EXPOSURE CONCEPT

The developments of radiation protection and of nuclear safety concepts have been somewhat separate. Traditionally, radiation protection has mainly focused on the protection of workers and members of the public from exposures during normal operations and from the radiological consequences of accidents. At the same time, nuclear safety has developped throughout the years a complex set of approaches and methods for the prevention and mitigation of accidents in nuclear installations. The introduction of the concept of potential exposure as is now defined can provide a bridge between these two complementary aspects of the science of prevention.

Discussion of what is now termed "potential exposure" first appeared in the NEA Report "Long-Term Radiation Protection Objectives for Radioactive Waste Disposal" (NE84) and in ICRP Publication 46 (IC85). Those reports, which focused upon the management of solid radioactive wastes, included a brief discussion of the ways in which event scenarios and probabilities could be treated.

The IAEA's Safety Series report No. 104 (IA90) provided a more elaborate discussion of the concept of potential exposure. That report provided an outline of a conceptual treatment for potential exposures, and followed closely the principles of radiation protection recommended by ICRP for normal operation of a radiation source. The conceptual framework was based upon the transformation of the limitation of individual doses in a relatively straightforward manner into the limitation of the probability of harm to an individual. The report recommended that potential exposures be limited to an individual risk approximately equivalent to the risk implied by the dose limits for normal operation, but also recommended that potential exposures be limited separately from normal exposures. The report concluded that the procedure for translating the ICRP principles of justification of individual risk, and did not provide any specific recommendations in those areas. The report, written from a radiation protection standpoint, clearly reflected a radiation protection type of approach to the treatment of potential exposures. The approaches of the nuclear safety community, namely the establishment of design criteria and determination of whether an appropriate safety goal has been achieved, are not present in the discussion, and no particular attempt was made to integrate or discuss either the conceptual or linguistic differences.

The ICRP, in Publication 60 (IC91), expressed the conceptual basis for potential exposures in terms similar to the principles for normal exposures and noted the interrelationship between potential exposure and normal exposure in many decisions regarding a radiation source. The Commission's recommendations indicated that potential exposures should be treated separately from normal exposures in terms of limitation of risk. The objectives of any treatment for potential exposure were stated to be the prevention of accidents and the mitigation of their consequences, since these were the areas which are amenable to further design, construction, procedural, and other activities. It was noted in Publication 60 that the specification of collective detriment from potential exposures is difficult and controversial, even if the consideration of detriment is limited to attributable deaths. Thus, the report stated that it is not appropriate to depend on the use of the product of the probability of an event and the number of attributable deaths should it occur -- the expectation value of the number of deaths -- because this conceals the fact that the outcome will be either no consequences if the event does not occur, or the full consequences if it does. Instead, multi-attribute analysis was suggested as an appropriate approach. The effective use of multi-attribute analysis, however, requires broad agreement on the attributes to be considered, how they are to be weighted and the comparisons made with alternatives. Broad agreement is often difficult to achieve.

Publication 60 was clearly seen by the ICRP as a first step in the development of a conceptual framework for protection from potential exposure. In fact, work by an ICRP task group to further elaborate the framework was underway prior to the publication of the document. The result of this work was ICRP Publication 64 (IC93), which was developed to provide an extension of the basic principles of potential exposure contained in Publication 60. Publication 64 thus devotes considerable discussion to the concept of risk and probability, and notes the complications of accounting for both stochastic and deterministic effects. Within the discussion of basic principles, the report includes, for the first time in an ICRP document, the "ethical and managerial principles of the nuclear safety community, and particularly that of "defense-in-depth". The discussion also includes reference to "safety culture" as an important component in dealing with potential exposures.

Publication 64, in dealing with the concept of individual risk, focuses upon the use of a constraint on the annual probability for consequences that can be grouped together or on specific scenarios. The publication includes a table of ranges of probabilities in a year as an example from which a constraint might be selected. The publication also briefly discusses the assessment techniques that are available for deciding that an adequate level of protection has been achieved, and describes both the deterministic approach and the probabilistic approach. The limitations and uncertainties inherent in assessments, such as incompleteness in selection of initiating events, incompleteness in modelling, interdependencies of complex systems, uncertainties in data and uncertainties in human reliability analysis are described, although no specific approaches to overcome those difficulties are discussed.

While Publication 64 provides a significant elaboration of the basic framework for treating potential exposures, it represents a development path which is clearly linked to the assumption that quantitative tools are available for determining probabilities and risks. The suggestion of constraints for probability sequences also presupposes that the quantitative tools have been developed with sufficient rigour to allow some measure of absolute comparison with a given standard of acceptability. What is lacking in such a treatment is the recognition of the practical state of development and of the problems of application of probabilistic risk or safety assessments.

The International Nuclear Safety Advisory Group (INSAG) of the IAEA has recently devoted some efforts to exploring the issue of potential exposure in relation to nuclear power plants. A final report has been published as Report INSAG-9 (IA95). This report is not dissimilar in scope and discussion to the ICRP documents in its treatment of the concepts of risk and probability. The INSAG report also provides

more detailed treatment of the status and use of probabilistic safety assessments and explores the relationship between the concept of a safety goal and the use of PSA's. The report provides for the first time some consideration of the relationship of a safety goal to the general conceptual framework of constraints and limits. Differences between the typical radiation protection approach of optimisation and the safety goal approach depend on how safety goals are applied. The purpose and application of safety goals vary among countries.

The International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources (BSS) (IA96) are indicative of the current status of development of the concept of potential exposure. The BSS provide for the first time a clear linkage between the application of radiation protection concepts and the application to sources of safety concepts which have traditionally been applied only to large installations such as nuclear power plants. During the development of the BSS, considerable controversy developed over whether techniques were sufficiently developed to allow a standard for individual risk limitation or constraint to be used. The BSS, while describing approaches for ensuring safety of sources, stops short of specifying numerical criteria for risk. In the view of the majority of Member countries, the state-of-the-art for application of probabilistic risk assessments to a broad range of practices and sources is insufficient to warrant the inclusion of such criteria in the BSS. A second somewhat controversial issue was whether a single set of risk values could be specified which would be considered acceptable for the wide range of sources and practices from nuclear reactors to the use of sealed radioisotope sources.

3. COMMON GROUNDS FOR FURTHER DISCUSSION

As a foundation for its further discussions, it was generally agreed within the Expert Group that the concept of potential exposure:

- applies to all types of sources.
- appears as a natural extension of normal exposure (i.e. exposure within limits which is anticipated to occur with a probability approaching one), since experience has shown that situations arise in most practices that may result in exposure limits being exceeded. The unreasonable alternative would be to prohibit the use of any source where such a potential exposure situation could be envisioned. As a practical matter, a large portion of a safety evaluation effort, often the largest portion, is the identification of potential exposure situations and the development of preventive or mitigative measures.
- is concerned with radiation health impacts and, therefore, is simply one component of accident consequences. Potential exposure recommendations do not address other social and economic impacts that might be associated with an accident. For accidents involving one or a few individuals, which is typically the case with small, simple sources, potential exposure might be the dominant concern. For postulated accidents which could result in large consequences, including social and economic, potential exposure may be a relatively small component of the total concern. Therefore, potential exposure recommendations concerning radiation health impacts would encompass some, but not all, of the safety related considerations that enter into the regulatory process.

is generally similar in the fields of radiation protection, nuclear safety and radioactive waste management as applied to the objective of protection against radiation harm. To the extent that differences exist, they relate mainly to the way protection and safety objectives are defined, to how they are assessed, and to how they are applied to practical situations.

On these bases, the Expert Group has identified the topics which it believes encompass the main conceptual and practical issues concerning potential exposures. They are terminology, the role of deterministic safety assessment and probabilistic safety assessment (PSA), treatment of uncertainties, treatment of low probability events, treatment of consequences, safety goals, the long-term aspects of waste management, including treatment of uncertainties, as well as regulation of potential exposure and indicators of risk.

4. TERMINOLOGY

Similar terms used in different contexts or with different meanings among specialists have resulted in poor communication about potential exposure concepts and issues. Some terms employed in one speciality are not commonly used in others. Such terms and their underlying concepts also have inhibited clear communication. Key terms of particular concern are as follows:

4.1 RISK

The word "risk" can be used in a variety of ways and be given several meanings. In the common loose meaning of everyday language it is the threat of an undesirable outcome, e.g., death or adverse economic consequences. Two common definitions of risk used in technical work are: a) the probability of a defined unwanted consequence, and b) the mathematical expectation of consequences, i.e. the annual probability of an accident multiplied by a measure of the consequences if the accident occurs.

4.2 SAFETY

Safety is a quality to which a low level of risk can be assigned. It is possible to quantify risk but not safety except in terms of the absence of a quantified risk. Therefore, the term "safety" should be used only in a general way, for example, to express a judgement about acceptability of risk, with risk being employed when quantification is necessary. From a practical operational standpoint, the achievement of safety can be considered as the practice of avoiding harm and is assessed through performance indicators, design verification, incident analysis, use of reliability data, etc.

4.3 **PROSPECTIVE/RETROSPECTIVE**

There seems to be some confusion created by how the terms 'prospective' and 'retrospective' are used. Potential exposure is prospective, because it is a consideration of the prospect of exposure that might occur with a probability less than unity. If exposure actually occurs, it is no longer potential. Efforts to determine why it occurred are therefore retrospective. A safety assessment, whether applied to a new plant or an existing plant, is prospective in that conclusions about future performance related to safety or risk are prospective.

In nuclear safety the terms, "prospective" and "retrospective" are often applied to safety assessments depending on whether the plant under consideration is in the planning stage or already exists.

4.4 **PROBABILITY/FREQUENCY**

Since probabilities are often assessed on the basis of observed frequencies, there is sometimes confusion between the two concepts. In general, <u>probability</u> is an expression of the degree of belief in something, for example that a specified event will occur. It is prospective and it is based on previous experience and information, logic, intuition, etc. <u>Frequency</u> is the occurrence of a specified event per unit of something, e.g., time or procedures conducted. The frequency with which specified events in the past have occurred often forms part of the basis for estimating the probability of an outcome.

The seemingly simple concept of probability is complex in its application and, if care is not exercised, it will be used incorrectly. Problems with the correct application or use of probabilities are compounded with the complex concept of 'uncertainties' about information or models used to arrive at probabilities.

There does not appear to be an interdisciplinary issue associated with the concept of probability nor with the use of probability and frequency. Incorrect use of probabilities and frequencies, confusing the two, or drawing unjustified conclusions from assessments based on probabilities, frequencies, etc., is a problem in all disciplines. These difficulties suggest the need for continuing attention to achieve better understanding.

4.5 EVENT/SEQUENCE/SCENARIO/CONSEQUENCE

For purposes related to potential exposure, an <u>event</u> is a failure in performance. A <u>sequence</u> is a chain of events leading to a consequence. A <u>scenario</u> is a defined sequence of events, or grouping of sequences with similar starting and/or end-points. Initiating events can lead to multiple scenarios, depending on the path of the sequence. The <u>consequence</u> is the end-point of interest, preferably expressed quantitatively.

Probabilities can be assigned to events, sequences, scenarios and consequences. To avoid confusion, it is important to identify to which any specified probability is assigned.

For potential exposure purposes, the consequence is radiation injury. It is also noted that, from a nuclear safety perspective, the end-point of interest may also be the damage state of the installation, e.g., core melt. Therefore, it is also important to be specific about end-points.

4.6 LIMITS AND CONSTRAINTS

The ICRP uses limits and constraints in very specific ways. A <u>dose limit</u> applies to the total dose to an individual from all relevant sources. A <u>dose constraint</u> is a value of individual dose from a specific source. It is used in the optimisation of protection to restrict the choice of options to those in which the individual doses from the source are less than the constraint. It is not a supplementary dose limit.

In order to limit dose or risk to members of the public, it is practical to apply controls only to the source rather than placing broad dose or risk restrictions on individual members of the public. A dose limit as such is not applicable to potential exposure. Although a risk limit for an individual can be defined by analogy with a dose limit, there is a conceptual problem with a risk limit stemming from the fact that risk includes two components; the probability of a consequence to the individual and the consequence itself. It is possible to have the same numerical risk value assigned to low probability, high consequence accidents and high probability, low consequence accidents. The conceptual problem, therefore, is that a risk limit might imply that the probability of an accident and the magnitude of its consequences are interchangeable. Applying a risk limit to an individual with reference to all relevant sources of potential exposure also involves practical problems, including determination of regulatory compliance and the feasibility of appropriate enforcement actions. However, individual and collective risk from a specific source can be restrained by various approaches, such as application of the principle of "defense in depth" and restrictions on operating parameters. How this is done depends on the type and complexity of the source.

4.7 UNACCEPTABLE/ACCEPTABLE/FULLY ADEQUATE

The distinction between the unacceptable, acceptable and fully adequate regions of risk is usually not a clearly drawn boundary line. The <u>unacceptable</u> region is where the risk cannot be justified in normal situations, although it might be justified in extraordinary circumstances. The <u>fully adequate</u> region is where the risk is sufficiently low that further efforts to optimise protection are not worthwhile. It constitutes an ideal situation that is rarely achieved in complex industrial activities. The region of <u>acceptable</u> risk, between the unacceptable and fully adequate regions, is employed in many fields of safety to accommodate the fact that something can be acceptable under certain conditions and not others. This is the region where the risk is accepted for a desired benefit, and is acceptable only if the overall cost of reducing the risk exceeds the improvement gained. It is the region in which optimization takes place. As safety has not a static character but, rather, implies a permanent search for improvement, optimisation does not stop after the initial assessment. It is a continuing process, particularly in large complex facilities.

The sequence of terms Unacceptable/Tolerable/<u>Acceptable</u> has been used in some documents, particularly those of radiation protection, in conceptually similar ways as the sequence Unacceptable/<u>Acceptable/Fully</u> Adequate. There is some potential, therefore, for misunderstanding what is meant when the term 'acceptable' is used. The term 'tolerable' also seems particularly susceptible to being misunderstood or used out of context.

5. SAFETY ASSESSMENT AND UNCERTAINTIES

Quantification of potential exposure involves safety assessments which may be performed with deterministic or probabilistic (or a combination of both) methods, depending on the characteristics of the individual case considered. The term "deterministic" implies that an event and its consequences are assumed to occur.¹ The term "probabilistic" implies that an event and its consequences, given the event, have a probability but no certainty of occurring.

¹ Similarly, in the field of radiation protection the term 'deterministic' is used in connection with a level of radiation dose from which health effects or consequences are assumed to occur, i.e., deterministic effects (previously called non-stochastic effects).

Safety assessments generally consist of scenario analysis as a first step and dose calculation (consequence analysis) as a second step. Analysis of potential exposure scenarios is intrinsically probabilistic; their probability of occurrence, being significantly less than one by definition, has to be determined. It should be noted that a deterministic scenario analysis has a probabilistic component in the selection of scenarios to be analyzed since some scenarios may be considered as being too improbable to be included in the assessment.

Both deterministic and probabilistic safety assessment methodologies must be employed with caution because of sources of uncertainty. Basically, the assessment methodology does not introduce sources of uncertainty; they already exist. Uncertainties include questions of completeness, lack of information on reliability and long-term performance of equipment, common cause failures and interactions between humans and machines. Modelling human failure is a particularly confounding problem. Because of these uncertainties, expert judgement is required to varying degrees and this may introduce substantial differences in quantitative results when assessments are performed by various experts, even if based on the same fundamental data.

In the frame of deterministic consequence analyses, an attempt is usually made to overcome the uncertainties by use of bounding assumptions, models and data. Due to this process, deterministic analyses sometimes mask the uncertainties. In the frame of probabilistic consequence analyses the uncertainties can be explicitly considered as probability distribution functions entering into the calculation.

There seems to be a consensus, as reflected in ICRP Publication 64, the INSAG-9 report and the NEA/CSNI Working Group No. 5 statement of 1992 on the role of PSA results (NE92), that PSA is a valuable methodology which can be employed to better ensure safety. PSA's primary benefits are the improved insights into the safety aspects of design and operation, because it can reveal vulnerabilities not contemplated in a deterministic safety assessment. Also, the use of PSA in the "relative" sense to identify dominant contributions to risk often is more useful than absolute results in terms of probability of consequences.

While there is general agreement that both deterministic and PSA methods have an important contribution to make to the assessment and demonstration of safety, they have limitations which have to be understood, particularly in relation to their utility as absolute measures of safety. Their application to specific practices is in various stages of evolution. The main issues and concerns regarding deterministic and probabilistics assessments seem to be the level of skill with which they are conducted and the results interpreted, the lack of harmonized treatment of uncertainties and models employed within a practice, and their role in the regulation of safety. (cf. section 10). A particularly confounding issue is the decision whether, for a specific practice, deterministic consequence calculations are sufficient or whether probabilistic calculations are needed instead or in addition.

One of the more valuable international efforts in this regard could be to assist in adapting PSA methodology to practices other than nuclear power plants and radioactive waste repositories and in using this experience to overcome some of the problems that will be encountered. It is noted that both the ICRP and the IAEA have initiatives in this area. Substantial work is being carried out by the NEA in the area of application of PSA to radioactive waste disposal.

6. LOW PROBABILITY EVENTS AND MAGNITUDE OF DOSE

It is sometimes suggested that small potential exposures might be neglected when reaching decisions about the acceptability of radiation sources. To some extent, this is already done in the application of safety assessments. It is a common practice in nuclear safety to consider only the individuals at highest risk, on the basis that other individuals at lower risk are thereby adequately protected. This policy is not quantitatively related to the magnitude of potential exposures.

If there is a need to define a negligible magnitude of potential exposure, the logic must be clearly set out. The numerical expression of a potential exposure involves two components: the probability that an individual will receive a dose and the magnitude of that dose. If the magnitude of the dose, if it should occur, is no more than a few millisieverts, it is legitimate to combine these components by first replacing the dose by the probability of a defined biological effect, usually death attributable to the exposure, and then multiplying this conditional probability by the probability of incurring the dose. This product is then the unconditional probability of death attributable to the potential exposure. However, at doses higher than a few millisieverts, an individual is unlikely to regard changes in the probability of receiving the dose and the probability of subsequent biological effects as being interchangeable.

It follows that the aggregation of the two components of potential exposure into a single value of unconditional probability of death should be used with care and the logic clearly set out. For many situations, it may not be appropriate to define a single value of the aggregated quantity below which the potential exposure can be regarded as negligible.

7. CONSEQUENCES

There are two categories of consequences related to potential exposure: the radiation health detriment to an individual and the total radiation health detriment to the exposed populations, i.e., the collective detriment.

The health detriment associated with the potential exposure of an individual can be calculated directly. Potential exposure is expressed as two quantities; the dose and the probability of its occurrence. The detriment probability coefficient for stochastic effects given by the ICRP (IC91) converts the dose into the conditional probability, given the dose, of the resulting harm to the individual and the individual's progeny. Multiplying this conditional probability by the probability of receiving the dose gives the detriment associated with the potential exposure.

As stated earlier, quantified detriment associated with potential exposure must be used with care. It presumes that changes in the probability of receiving the dose and in the probability of health effects are of equal importance to the individual. This will be true only at low doses. It also ignores other consequences of the originating event. This is appropriate only at low doses.

Thus, at low doses, say a few millisieverts, the health detriment associated with a potential exposure can be a useful quantity. It can be extended to give the collective detriment in the same way as individual dose can be extended to collective dose. At higher individual doses, the detriment from a potential exposure is inadequate. The unaggregate values of probability and dose need to be presented. At these higher doses, the potential exposure may not be the limiting feature of the initiating event, especially if that event is one which stimulates public concerns.

There are difficulties in characterizing consequences in terms of collective detriment. These difficulties are mainly that:

- radiation health detriment to the exposed population is only one component of the societal impact in the event of a major accident, including the impact associated with land contamination, and might not be the dominant one;
- if potential exposure could result in doses above the threshold for deterministic effects, it is not clear how this component can be included in the assessment of the collective detriment recognizing that the total detriment is not correctly reflected by the product of the average dose and the number of people exposed, i.e., the collective dose.
- deaths are sometimes treated differently; particularly, individually identifiable deaths which occur soon after exposure above a deterministic threshold as compared to deaths resulting from exposure in the stochastic range, which have a long latency period and are not easily attributable to a particular source of radiation, or in many instances, to radiation at all.
- the mathematical expectation of deaths per unit time is sometimes used in safety assessments to compare the relative risk associated with different accident scenarios. However, even in this application, it must be used with care, because the results of this kind of calculation can be very misleading. For example, a probability rate of 10⁻³ per year for a consequence of 10³ deaths produces an expectation of one death per year. It does not reflect the fact that in reality there may be either no deaths or as much as a catastrophic one thousand deaths.

Furthermore, "Radiation Protection" seeks to protect humans from radiation health detriment through application of the principles of justification, optimisation and dose limits. "Nuclear Safety" is mainly concerned with accident prevention and mitigation. "Management of solid radioactive waste", particularly disposal of high level waste, is specifically concerned with isolation of hazardous wastes from the biosphere in a manner that protects health now and in the future without imposing undue burdens on future generations. Although there are similarities, there are also some differences among these disciplines on how best to distinguish in quantitative terms between levels of risk to individuals and society which are acceptable and those which are unacceptable given the benefits of a particular technology. Also, there is not good agreement about the relative roles of individual and collective health risk to distinguish between the acceptable and the unacceptable. These too are important issues related to seeking policy consensus on how to characterize consequences.

It follows that presentation of risk and consequences is complex. Risk involves sets of probabilities, each with a range of consequences. Therefore, risk should not be represented by a single number, except perhaps for very simple sources. A full presentation of potential events with respective probabilities and consequences is needed.

The non-linearity of risk due to doses in the deterministic range as well as other types of consequences makes it seem likely that complex presentations will be needed with judgements of acceptability aided by non-linear functions. Complementary cumulative distribution functions (CCDF's) or f-N curves, or clusters of such curves, have been used in the past to aid in judgements about acceptability of potential exposures and other types of consequences. However, the use of such curves for comparison with other types of accidents or in a more absolute sense can be controversial, particularly with respect to societal risk, because of the subjective factors involved in establishing their profiles.

How best to present a clear exposition of potential health detriment as well as other accident consequences is a subject of continuing deliberation. The INSAG-9 report addresses issues related to individual risk and societal risk in some detail. However, there is ample room for both NEA and IAEA to pursue this matter to achieve broad policy consensus as well as providing guidelines for application to specific practices.

8. SAFETY GOALS

Safety goals have been used for a number of years in nuclear reactor safety as probabilistic criteria against which the safety of a nuclear power plant can be judged. They are usually expressed as a limitation on the annual probability of some specified adverse event, such as severe damage to a reactor or exposure to members of the public.

Up to this point, safety goals have mainly been applied to analysis of existing power plants to determine how they might relate to a specific level of safety. As such, the numerical value of the goal has usually been taken to be the average level of safety achieved in the group of facilities under consideration rather than a mandatory limit for all plants. There might be great difficulty in providing convincing demonstration of compliance for any single plant, and it might not be possible to make an existing plant comply with a safety goal for a new plant. The continued operation of an old plant may still be acceptable, but the safety of the plant would need to be examined on a basis different from that of a new plant, particularly with regard to factors such as need for power, cost of replacement power, remaining life of plant and history of performance.

One problem with safety goals is that exactly what they are, and the function they serve, vary from country to country. Thus far, safety goals and how they are used have been driven by national safety policy. For some, a safety goal is a level of probability set in the acceptable range but not so low as to remove the requirement to make further improvements where reasonably practical. With this approach, some countries, e.g., the UK, apply a "limit" to be met and strive for improvements below the limit. For others, a safety goal is an "aspirational target" (see NE92). In the US, "safety goals" represent a general statement about levels of safety considered to be acceptable for an "average" plant in a population of plants.

There is no clear international agreement on safety goals for the annual individual risk to the public from nuclear accidents nor for the collective risk of radiation health detriment to the population, which is a much more complex problem. A universal safety goal covering all practices would not be reasonable, nor would it be reasonable in many instances to have a single safety goal apply to all sources within a practice. If it is worthwhile to pursue international agreement on numerical values for safety goals, then it is also necessary, in parallel, to pursue consensus on what they mean or how they are to be used. If safety goals are a good way to judge the acceptability of risk from potential exposure, then much further effort to achieve international consensus on the subject is warranted.

9. TIME ASPECTS OF POTENTIAL EXPOSURE

Adequate treatment of the long time scales in the safety assessment of waste disposal systems is a challenging problem. There currently is no international agreement about the exact performance criteria (sometimes termed "indicators" by waste management specialists) to be met or the time scale selected. These are largely driven by national policies, which vary among countries. Weighting of the social and environmental impacts of a repository, rather than consideration of dose alone, can bear an important influence on performance criteria. Regardless of the specifics of the performance criteria adopted by individual countries, there seems to be a common policy that people in the future should not be subjected to a risk that is greater than society is willing to accept now. In this respect, and in the absence of formal international agreement on performance criteria for waste disposal, it can be said that safety levels formulated in most national regulations are essentially equivalent.

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Both deterministic and probabilistic assessment methods can play an important role in making the case that performance criteria are likely to be met. PSA requires careful treatment of probabilities over long time scales, an assessment of the risk to individuals in any given period within the long time scale, how risk changes with time, and how risk might change with an "altered" evolution of the isolation system over time compared with the expected, or "normal" evolution, of the system.

Performance of a full PSA, i.e., a probabilistic scenario analysis and a probabilistic consequence analysis, in the field of radioactive waste disposal poses considerable difficulties. These are essentially difficulties in assigning probabilities of occurrence for scenarios and for barrier failures. Although some countries, e.g., the UK, make serious attempts to perform full PSAs for radioactive waste disposal systems, many others resolve the issue by definition of a few enveloping scenarios and corresponding boundary conditions based on a systematic scenario analysis. Consequences of these scenarios are then evaluated through application of probabilistic methods with uncertainties being taken into account. Calculated frequency distributions of results are thus conditional on the given scenario and the boundary conditions and assumptions under which the analysis is performed. Although probabilistic tools, including expert judgement, probability distributions for necessary parameters, etc., are employed, this type of analysis, i.e. calculation of the consequences for a given scenario with probabilistic tools, might more appropriately be called <u>uncertainty analysis</u> in order to point out the difference to a full PSA.

Basic treatment of waste disposal issues as they relate to potential exposure is covered in ICRP Publication 46 (IC85), although it is currently recognised that this publication needs some revision to be brought fully up to date with subsequent ICRP recommendations. The structured approach to PSA for a waste disposal system is similar to that for a nuclear power plant. However, the safety assessment for a nuclear power plant with proper care and maintenance, probabilities and consequences should remain relatively constant over its comparatively short life. For waste disposal, even with "normal evolution" of the system, both probabilities and consequences change over time due to factors such as barrier deterioration, geological changes and radioactive decay, thus complicating the presentation of safety assessment results. The main difficulties in providing a robust safety assessment for disposal are a lack of feedback from operating experience and design evaluation, lack of environmental models for the future, etc. These problems seem to be well recognized, although their resolution is not easy.

Independent from assessment of potential exposure, the PSA methodology, or "uncertainty analysis", is a useful tool for establishing a robust safety analysis to satisfy regulatory requirements for waste disposal. Given the initiatives in this area, it is questionable whether or not all that can be reasonably done at the international level to aid the process is being done. This is a matter that might be explored further. It is to be noted, however, that NEA, IAEA and others have substantial programmes in the assessment of the safety of waste disposal.

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10. REGULATION OF POTENTIAL EXPOSURE AND INDICATORS OF RISK

The regulation of potential exposure is controversial and has been debated in a number of fora. One of the main issues is whether or not risk limits and risk constraints should be established in regulations to serve in a manner analogous to dose limits and dose constraints. Some argue that regulatory limits and constraints on risk are the best way to ensure the application of potential exposure concepts in practice. For example, there is a stream of opinion that placing limits on estimated risk represents the most useful approach to the regulation of certain aspects of long term regulatory safety, such as in radioactive waste disposal, and such limits are being applied to some extent by some countries.

Radiation protection, waste management and nuclear safety specialists, recognize, however, that there are difficult problems with incorporating quantitative risk requirements in rules or regulations. To do so requires the use of PSA. The availability of data, the degree to which systems and components are modelled, and the understanding of the accident progression are examples of the uncertainties influencing the accuracy of PSA. The regulator would need to specify how it will judge PSA methods used to evaluate practices against quantitative criteria. Event initiators, and component and reliability data have to be verified as valid on a case-by-case basis. Assumptions, modelling details and assessment decisions need to be identified in a way which would allow them to be defended against legal challenges. These are some, but not all, of the difficulties associated with the inclusion of quantitative risk limits and constraints in regulations at this time. However, as PSA techniques and data bases develop, regulators are increasing the use of PSA to assist in decision making in identifying vulnerabilities which can be addressed through application of engineering standards or by placing limiting conditions on operations. Employed in this manner, some regulatory authorities use PSA as an adjunct to, but not as an integral part of, the approval procedure.

The alternative to applying limits in terms of risk is to develop limits in terms of other quantities, i.e, some quantitative measures which reflect the risk. In this regard, there is not much difference between the approaches used in radiation protection and nuclear safety. For example, authorized effluent release limits are indicators used to control dose to members of the public. Dose is not measured directly. Similarly, risk indicators involve things that can be tested or measured, e.g., equipment reliability. A key issue is how to aggregate indicators of risk to reflect the overall status of risk. Aggregation of risk, although useful for certain purposes, can result in a serious loss of information and aggregated risk cannot be measured directly. There is not a one to one relationship between risk and a series of engineering requirements based on the indicators, nor can there always be a trade-off between probabilities and consequences. Therefore, it will often be necessary to retain unaggregated risk to gain a comprehensive picture of system safety..

Potential exposure concepts and the methodologies used to implement them are just beginning to be applied to some practices. The transition for regulatory purposes from a purely deterministic approach to a mixed deterministic/probabilistic approach is an evolutionary process which is expected to continue. Both the extent to which a mixed approach is used and how it is incorporated in regulatory processes depends on international and national improvements in consistency of models, collection of reliability data, treatment of human errors, etc., much of which tends to be practice specific. Regardless of progress made in the development of probabilistic methodologies for the regulation of potential exposure, setting limits on quantitative measures which reflect risk will continue to be a practical regulatory technique to control many aspects of potential exposure. General guidance on how to aggregate risk indicators and how they should be employed would be a useful contribution to dealing with potential exposure.

11. GENERAL CONCLUSIONS

11.1 Potential exposure is concerned with radiation health impacts and, as such, is a component of the potential consequences of an accident or other situations that are not considered as 'normal'. Except for accidents involving the kinds of sources which are likely to expose only a few people, it may not be a major feature of the accident consequences. Actual consequences resulting from a significant reactor accident, for example, are likely to have social and economic implications that are much more significant than the radiation exposure.

11.2 The magnitude of potential exposure involves two components; the probability of an individual receiving a dose and the magnitude of that dose. At doses higher than a few millisieverts, an individual is unlikely to regard changes in the probability of receiving the dose and the probability of subsequent biological effects due to that dose as being interchangeable. Therefore, the aggregation of the two components of potential exposure into a single value of unconditional probability of harm should be used with care and the logic clearly set out. For many situations, it may not be appropriate to define a single value of the aggregated quantity below which potential exposure can be regarded as negligible.

11.3 Terminology used to address potential exposure issues will continue to be a communication barrier. There are several reasons for this. Some terms have underlying concepts that are complex and not well understood by all those involved. In some instances, the meaning of the same or similar terms differ among disciplines. In other instances, and regardless of the discipline, terms are misused or not used with sufficient rigour to prevent misunderstanding. These problems should diminish as the interdisciplinary initiatives of the NEA, IAEA and ICRP begin to have a broad impact.

11.4 A recurrent issue in the Expert Group discussions about potential exposure was how to characterize and treat collective risk. It appeared in the discussions about consequences, treatment of low probability events, safety goals and the long-term aspects of waste disposal. Reasons for difficulties in solving this problem are described in some detail in the INSAG-9 report. In addition, however, there was some indication, although no clear conclusion in the Expert Group discussions, that there may also be fundamental differences among disciplines on the relationship of potential exposure to the collective detriment and how each should be considered in reaching safety decisions.

11.5 The manner in which risk is regulated remains controversial. The main issue being if and when quantitative risk requirements should be incorporated in regulations and standards. Such requirements are being applied to some extent by some countries in the regulation of the long-term disposal of radioactive waste. For the present, however, it appears that the most feasible and straightforward approach to the regulation of risk in most practices is through the judicious use of indicators of risk and related engineering standards with the use of PSA where practical as an adjunct to, but not as an integral part of the approval procedure. Establishing numerical values for risk is a practice-specific evolutionary process. The extent to which quantitative risk limits can be, and are desirable to be, incorporated in regulations will depend on matters such as the quality of data bases and assessment models, and the utility of alternative approaches.

11.6 Differences between the typical radiation protection approach to optimisation and the application of safety goals depend on how safety goals are used. The approach to safety goals as described in the INSAG-9 report is very similar to the radiation protection approach. However, it should be recognized that, at least for the present, the purpose and application of safety goals vary among countries.

11.7 Although assessment methodologies exist, the difficulties in applying them, with uncertainties being taken into account, over long time scales for radioactive waste disposal are well recognized. Resolving these problems in a way which provides a robust safety analysis for regulatory purposes is a challenge. Both NEA and IAEA have substantial programmes in this area.

11.8 While there is general agreement that both deterministic methods and PSA have an important contribution to make to the assessment and demonstration of safety, they have limitations which have to be understood, particularly in relation to their utility as absolute measures of safety. One method of assessment supplements the other and aspects of both methods are used in many safety assessments. There are valuable international efforts under way at NEA, IAEA and ICRP to assist in adapting PSA methodology to practices other than nuclear power plants and waste repositories.

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ANNEX I

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