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Managing Information and Requirements in Geological Disposal Programmes







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Table of abbreviations and acronyms

AERES	Agence d'évaluation de la recherche et de l'enseignement supérieur (Agency for the evaluation of research and higher education, France)
ALARA	As low as reasonably achievable
ANCCLI	Association nationale des comités et commissions locales d'information (National association of local information committees and commissions, France)
APM	Adaptive phased management
ASN	Autorité de sûreté nucléaire (Nuclear safety authority, France)
BfS	Bundesamt fur Strahlenschutz (Federal Office for Radiation Protection, Germany)
CBFO	Carlsbad Field Office of the Department of Energy (United States)
CCST	IRSN project on capitalising on scientific and technical knowledge (France)
CCWG	Change Control Working Group
CLIS	Local Information and Oversight Committee of the Bure Underground Research Laboratory (France)
CNE	Commission nationale d'évaluation (National Review Board, France)
CNSC	Canadian Nuclear Safety Commission
CoRWM	Committee on Radioactive Waste Management (United Kingdom)
CSM	Centre de stockage de la Manche (Radioactive waste storage centre, France)
DGR	Deep geological repository
DI	Derived inventory
DOE	Department of Energy (United States)
DOORS	Dynamic object oriented requirements system
DSDC	Disposal System Development Committee
DSFS	Disposal system functional specification
DSS	Disposal system specification
DSTS	Disposal system technical specification
EBS	Engineered barrier system
EC	European Commission
EDM	Electronic document management

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EDRMS	Electronic document and records management system
EGOS	Expert Group on Operational Safety (NEA)
EIA	Environmental impact assessment
EPA	Environmental Protection Agency
ERAM	Endlager für radioaktive Abfälle Morsleben (Morsleben radioactive waste repository, Germany)
ES	Expert system
FEP	Features, events and processes
GDF	Geological disposal facility
HLW	High-level waste
HQ	Hydro-Québec (Canada)
IAEA	International Atomic Energy Agency
IGSC	Integration Group for the Safety Case (NEA)
ILLW	Intermediate level long-lived waste
IMS	Information management system
IRRS	Integrated regulatory review service
IRSN	Institut de radioprotection et de sûreté nucléaire (Institute for Radiological Protection and Nuclear Safety, France)
ISIS	Integrated scientific information system
JAEA	Japan Atomic Energy Agency
KMS	Knowledge management system
LILW	Low- and intermediate-level waste
M&O	Management and operations
MoM	Minutes of meetings
MTP	Mean term planification
NDA	Nuclear Decommissioning Authority (United Kingdom)
NEA	Nuclear Energy Agency
NPP	Nuclear power plant
NSCA	Nuclear Safety and Control Act (Canada)
NUMO	Nuclear Waste Management Organisation of Japan
NWMO	Nuclear Waste Management Organization (Canada)
NWP	Nuclear Waste Partnership
OCR	Optical character recognition
OPECST	Parliamentary Office for Scientific and Technological Assessment (France)
PA	Performance assessments

PARS	Phenomenological assessment of repository situations
PCR	Planned change request
PIC	Passive institutional controls
PMR	Permit modification request
QSA	Qualitative safety assessment
R&D	Research and development
RD&D	Research, development and demonstration
RES	Regulatory environmental services
RK&M	Records, knowledge and memory
RM	Requirements management
RMS	Requirements management system
RSC	Rock suitability classification
RWI	Radioactive waste inventory
RWM	Radioactive Waste Management Limited (United Kingdom)
RWMC	Radioactive Waste Management Committee (NEA)
SAGD	Steam assisted gravity drainage
SCR	Selective catalytic reduction
SFR	Final repository for short-lived radioactive waste (Forsmark, Sweden)
SIAF	Interministerial Department of the Archives of France
SKB	Swedish Nuclear Fuel and Waste Management Company
SNF	Spent nuclear fuel
SRL	Scientific readiness level
SRTG	Service de recherche sur les transferts dans la géosphère (Biosphere transfers research department, ASN, France)
SSM	Swedish Radiation Safety Authority
STUK	Radiation and Nuclear Safety Authority (Finland)
TSO	Technical support organisation
URL	Underground research laboratory
WENRA	Western European Nuclear Regulators Association
WIPP	Waste Isolation Pilot Plant (United States)
WPS	Waste package specification
ZIRA	Zone d'intérêt pour la reconnaissance approfondie (restricted interest area)

1. Introduction

At the 16th meeting of the Integration Group for the Safety Case (IGSC), it was agreed to initiate a study dedicated to information and requirements management [NEA, 2014].

Generally, a requirement is a characteristic to which a material, product, process or system shall conform. Product requirements might be expressed for physical, mechanical, or chemical properties and safety, quality or performance criteria. A requirement exists either because the type of product demands certain functions or qualities or because the client, user or stakeholder wants that requirement to be part of the delivered product. Typically, there are two types of requirements: the "product requirements" prescribing properties of a product and "process requirements" prescribing activities, methodologies that must be followed in the framework of a specific process. The term "specification" means a collection of requirements. "Constraints" or "boundary conditions" are seen as global issues. They are constraints or restrictions on the project, present inherently, imposed by the stakeholder itself or by the project context. These constraints shape the requirements [ASTM, 2016; Robertson and Robertson, 2006].

This paper focuses on the information and requirements management for the disposal of the radioactive waste and spent nuclear fuel (SNF). Thus, the product of the requirements is the deep geological repository (DGR) whereas the process is the implementation programme for the DGR realisation. The fundamental objective of a radioactive waste disposal facility is to protect people and the environment from harmful effects of ionising radiation [IAEA, 2006]. To these ends, guidance and recommendations have been set over the safety requirements that geological disposal facilities should satisfy (e.g. safety functions, siting criteria) and over the process requirements to achieve this objective (e.g. elements of a stepwise approach, planning) [IAEA, 2011].

Requirements related to radioactive waste disposal projects arise from various fields of activity and from a range of different actors. For example, the regulator will typically define requirements on the performance of a disposal system that must be met if a site and design are to be deemed adequate for licensing. The implementer, on its part, will typically define requirements on the site and on the components of the engineered barrier system (EBS) that favour, for example, engineering feasibility and both operational and long-term safety. Requirements management may be defined as the process whereby, i) requirements are kept comprehensive, up-to-date, organised and accessible to all relevant parties, and ii) information is collated to show that the requirements are met. Information management, on the other hand, may be defined broadly as the activity by which all information relevant to a project (or its regulation) can be processed in an organised manner. Information management includes various activities such as reviewing, archiving, planning, structuring, updating and disseminating to all relevant parties. The formulation of requirements and their management in the field of safety case development for radioactive waste disposal has been the object of IAEA guides such as IAEA, 2008 and IAEA, 2012. IAEA, 2008 states that "a management system shall be established, implemented, assessed and continually improved". It shall be aligned with the goals of the organisation and that people and the environment are protected both now and in the future shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:

- bringing together in a coherent manner all the requirements for managing the organisation;
- describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;
- ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety."

The term "information" is defined by the [NEA, 2014], as organised data that may or may not be recorded on a medium. In the context of this study, we will focus on recorded information. It can take the form of data as measurement, calculation, signal, construction plans or texts. Information management and requirements management are closely related, which is why they are treated as a single topic in the present IGSC study.

In recent years, many organisations have developed systematic methods and tools for information and requirements management. This is sometimes driven by the need on the part of the implementer to meet regulatory expectations, e.g. regarding the traceability and quality of the information presented in safety cases. In addition, there is a need to organise the huge volume of information that is produced during the programme implementation; this remarkable information production is due to:

- a) the complex and multidisciplinary nature of repository projects;
- b) the long duration of these projects, which generally extend over several decades, during which programme boundary conditions (e.g. the legal and regulatory framework) might change;
- c) the iterative, evolving nature of site selection and characterisation (and associated requirements on the site and design) and the safety case; and
- d) the extensive relevant information that is available from other fields and from other national programmes, as well as from international organisations such as the Nuclear Energy Agency (NEA), the International Atomic Energy Agency (IAEA) and the European Commission (EC).

Furthermore, there is often a need to integrate new and historical decisions, and to link these to the safety case, bearing in mind that relevant information may be documented in a variety of different ways (in electronic and paper reports, meeting minutes, press releases, etc.) and that undocumented comments, decisions and opinions may sometimes be relevant [NEA, 2010].

Looking at the terminology introduced above-, we can infer that at in a generic stage, a safety case is a collection of requirements expressed by a variety of stakeholders, i.e. a "specification" over a future disposal system. Throughout the disposal program, these requirements are increasingly satisfied based on a structured set of knowledge and evidence based on acquired information. Making a robust safety case is to ensure that the requirements will be satisfied regardless of the uncertainties associated with the supporting knowledge.

The main goal of this IGSC study is to examine how information and requirements management is implemented and executed in the various member organisations, including similarities and differences and to identify potential areas of collaboration. The present document reports some first observations on the topic, based mainly on the responses to a questionnaire prepared by JAEA and ONDRAF/NIRAS. The organisations responding to the questionnaire and their respective countries and roles are listed in Table 1.1.

Organisation	Country	Role
ONDRAF/NIRAS	Belgium	Implementer
Nuclear Waste Management Organization (NWMO)	Canada	Implementer
Radioactive waste repository authority (SÚRAO)	Czech Republic	Implementer
Posiva	Finland	Implementer
Andra	France	Implementer
Institute for Radiological Protection and Nuclear Safety (IRSN)	France	Technical support organisation (TSO)
Japan Atomic Energy Agency (JAEA)	Japan	Research and Development (R&D) institute
Federal Office for Radiation Protection (BfS)	Germany	Implementer
Radioactive Waste Management (RWM) Ltd	UK	Implementer
Department of Energy (DOE)	US	Implementer
Swedish Radiation Safety Authority (SSM)	Sweden	Regulator

Table 1.1. Organisations responding to the NEA questionnaire on information and requirements management, their respective countries and roles

The questionnaire is available in Appendix A, responses to the questionnaire are compiled in Appendix B, and in Appendix C, some key statements from these responses have been extracted that highlight specific points. These statements are the principal source of information for the following sections of the main text.

2. Main principles underlying information and requirements management

Based on the responses to the NEA questionnaire, the main principles underlying information and requirements management may be summarised as follows.

2.1. Traceability

In the framework of any repository project, there is a recognised need for clear records to be kept of all relevant requirements, of siting and design decisions and, in relation to the safety case, of all decisions regarding scenario selection, model assumptions and parameter values, ranges or probability density functions (PDFs), as well as other numerical and non-numerical data, etc.

These requirements, decisions and data need to be readily traceable to their various sources, and it should ideally be possible to identify or trace the rationale behind the various requirements and decisions without undue difficulty.

2.2. Comprehensiveness/completeness

To compile a safety case (and during the review of a safety case), it needs to be shown that there are no critical gaps in the requirements, decisions, data and other information that support the case, or in the rationale behind these requirements and decisions. A reason to structure information and requirements within information and requirements management systems is to identify and/or eliminate any such gaps.

2.3. Consistency/quality

An aim of information and requirements management is to ensure that the same, qualitycontrolled data are used consistently by all relevant parties at a given stage of a project, and that their work is informed by the same key decisions and a consistent set of requirements. Data quality can mean, for example, that data comes from peer-reviewed literature sources and/or from carefully conducted, repeatable experiments.

2.4. Openness/ease of access

Requirements, decisions and data relevant to a project need to be readily available to all stakeholders and at an appropriate level of detail.

2.5. Flexibility

In the course of a project, an organisation (implementer or regulator) needs to have the capacity to assimilate large amounts of new information as it becomes available, and also to accommodate new or modified decisions, requirements etc. that affect its work.

2.6. Long-term preservation of key information

Requirements, decisions and data relevant to a project need finally to be archived for as long as they might reasonably be needed. For some critical decisions and data, archiving may extent over several generations. Safety cases in support to licence application and the related regulatory review falls in this category (see for example the case of SSM in the questionnaire answers).

3. Structuring of information and requirements

Most organisations adopt hierarchical systems of documentation to record information pertaining to a project. High-level documents may include, for example:

- RD&D plans;
- Safety (case) reports; and
- Site descriptions or geo-syntheses.

Requirements are often also described, along with their rationale, in high-level reports, such as design basis [Posiva, 2012] of the Finnish Posiva and the Disposal System Specification and Waste Package Specification of the British Radioactive Waste Management Organisation (RWM) Ltd. [NDA, 2010 and 2012] and various national regulatory documents. These reports, periodically updated, generally give an overview of their respective subject matter, and, where necessary, are underpinned by lower-level reports and external references that provide more details.

Requirements themselves may also be arranged hierarchically, with the more general requirements at the top of the hierarchy and more detailed or specific requirements at lower levels.

For example, Posiva developed a requirements management system called VAHA. VAHA includes five hierarchical levels of requirements:

- Legal and stakeholders' requirements (level 1);
- Requirements applying to the whole disposal system and safety functions for the barriers (level 2);
- Barrier-specific long-term performance targets and target properties (level 3);
- Barrier-specific design requirements (level 4); and
- Barrier-specific design specifications (level 5).

VAHA level 5 (design specifications) is the most detailed and generally the most quantitative of the entire VAHA structure requirements. These lower requirements give the actual specifications for manufacturing and implementing the engineered barriers, and for constructing the underground openings, in order that both the EBS and the host rock fulfil the requirements presented on higher levels.

Requirements applying to the whole disposal system and safety functions for the barriers appear at a higher level (level 2) in Posiva VAHA. The structuring of requirements and information based on high-level safety functions is also a feature of the argumentation approach followed by some organisations.

ONDRAF/NIRAS, for example, has developed a hierarchy of safety statements that allows scientific and technical information to be structured in a manner that supports the development of the safety case [ONDRAF/NIRAS, 2013]. General statements concerning the safety concept and safety functions, at the highest levels, are underpinned with more detailed and specific lower-level statements. The highest-level statements in the hierarchy

are shown in Figure 3.1. Statements, such as that the safety functions (isolation, engineered containment, delay and attenuation of releases) can be relied upon, are claims or requirements, that clearly require substantiation. Note that the "requirements" referred to explicitly in the figure are external (regulatory and other stakeholder) requirements and the statement that these requirements are met also requires substantiation. These high-level statements are deemed to be substantiated if the lower-level statements that underpin them are themselves substantiated. Lowest-level statements include statements of phenomenological understanding derived directly from the information base (assessment basis), as well as from the results of safety analyses.

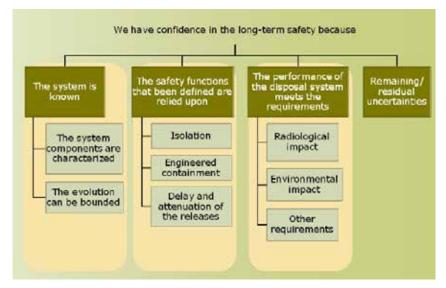
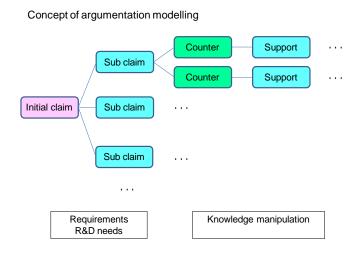


Figure 3.1. Highest-level safety statements in the ONDRAF/NIRAS statement hierarchy

The approach adopted by JAEA [Makino et al., 2012] illustrated in Figure 3.2. is conceptually very similar to that of ONDRAF/NIRAS. JAEA has developed a series of initial claims (purple box) and sub-claims (left-most blue boxes) in support of the safety case, analogous to the hierarchy of safety statements developed by ONDRAF/NIRAS.

Figure 3.2. Argumentation modelling approach developed by JAEA



At the lowest level of sub-claims, features, events and processes (FEPs; green boxes) support the validity of the sub-claims. They form different lines of argumentation that demonstrate that the sub-claims are fulfilled. This argumentation modelling tool can also be used to classify and perform a high-level uncertainty analysis. Should an uncertainty associated to an evidence be so large that the sub-claim and therefore the initial claim are affected upstream, then this uncertainty is classified as a high priority of the research programme. A concrete illustration of this approach can be found in the Appendix A including the answers to the questionnaire given by JAEA.

This type of structuring highlights the linkage between requirements management and information management, since information/knowledge management provides the means to test whether or not requirements are met. Structuring requirements in a systematic manner and then considering whether the information/knowledge base is sufficient to assess these requirements can highlight any gaps in the information/knowledge base that the R&D programme can then aim to fill.

Although the hierarchical structuring appears very useful, especially in the development of safety cases, there are other equally valid and useful ways of structuring information. They could be used instead of, or also in addition to the hierarchical structuring way.

As an example, Andra developed a different approach, termed Phenomenological Assessment of Repository Situations (PARS). PARS identifies a series of time frames and repository situations, dividing repository evolution into intervals in space and time based on the phenomena that may occur and the associated uncertainties in each time frame and situation. The discretisation scheme is based on expert judgement as informed by evidence from laboratory and underground research laboratory (URL) experiments, natural analogues, scoping calculations, modelling studies and performance assessments. Qualitative Safety Assessment (QSA) is then used to explore possible malfunctions of the repository components and examine if these can affect the capacity of a component to fulfil its safety functions, in each time frame and repository situation. The general scheme of the PARS approach is discussed in the appendix including the questionnaire answers given by Andra and detailed in Andra (2005a) and (2005b).

One more structuring way is the use of "storyboards", which are diagrammatic illustrations of the FEPs and their interactions in a given scenario and/or time frame. Storyboards have been found useful as a means to promote discussions between experts in the course of interaction meetings and other exchanges, and can help, for example, in the identification of uncertainties [ONDRAF/NIRAS, 2008]. An example of a storyboard from the Belgian programme is shown in Figure 3.3.

A last example is the use of FEP charts or diagrams to show how FEPs are related to system evolution and to illustrate their influence upon each other. Figure 3.4 shows an example of a FEP chart presented in the IGSC Scenario Development Workshop (WS) in 2015 from the Japanese programme [NEA, 2016].

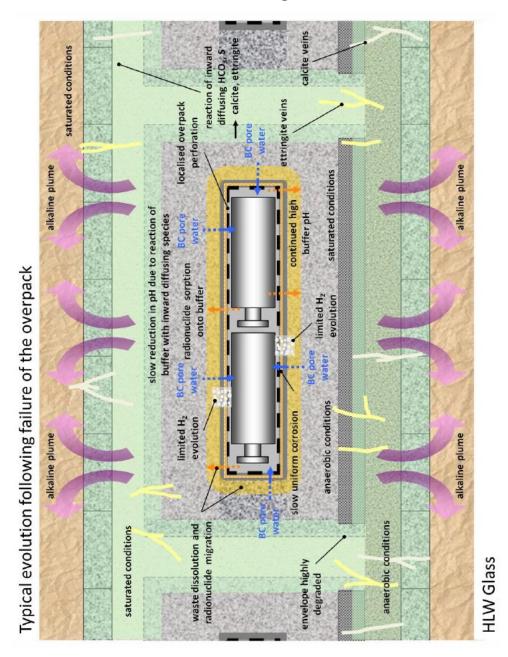


Figure 3.3. ONDRAF/NIRAS storyboard for the high-level waste HLW and the surrounding near field

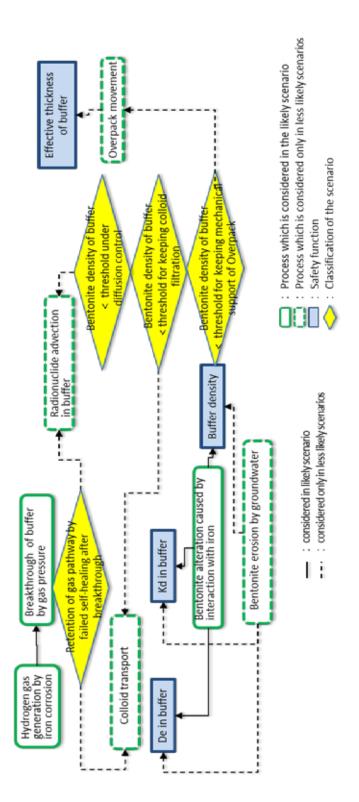


Figure 3.4. Examples of a FEP chart from the Japanese programme

4. Software tools and formal procedures to support information and requirements management

A number of software tools and formal procedures have been developed to support information and requirements management. Examples of relevant types of software tools are given in Table 4.1.

Туре	Examples/details
Commercial requirements management tools	Commercial software or an electronic documentation system to scrutinise requirements and their fulfilment.
	E.g. the Dynamic Object Oriented Requirements System (DOORS) in NEA [2004] and in the BfS questionnaire.
Databases	Requirements databases (implementers and regulators) with hierarchical organisation.
	E.g. Posiva's VAHA system (see Section 3).
	Document databases, which may directly store documents and/or identify (e.g. via hyperlinks) where documents are stored.
	E.g. <i>Doris</i> used by BfS, <i>EDM</i> used by IRSN.
	Databases of raw data (e.g. from site characterisation) or data used in modelling, e.g. in the context of safety assessments [see questionnaire answers given by Andra and the related report on ISIS methodology (Andra, 2015)].
Expert systems (systems that emulate the decision-making ability of a human expert)	Tools to capture "tacit" knowledge (e.g. developments by JAEA to capture otherwise undocumented expert knowledge).
Intranet systems	To allow access to databases and also to facilitate informal information exchange (e.g. working drafts) within an organisation.
Internet systems	Public websites to allow public access e.g. to R&D results and scientific publications, review reports, opinions and decisions, and hence facilitate openness(there may be legal obligations to the free access to information that need to be respected).
	Web-based (wiki-type) reporting software.
	E.g. the <i>CoolRep</i> and <i>Twiki</i> system developed by JAEA and IRSN, respectively (see questionnaire answers for further details).
Templates	Templates to promote structured documentation of e.g. specific decisions or the outcome of R&D projects.
Metadata	Metadata, "data about data", structure and organise the raw data in the data management system.

Table 4.1. Examples of relevant types of software tools for information and requirements management

As indicated in Table 4.1, software includes databases of various types. Key features of such databases are often the capability to manage and make changes to data, maintain histories of such changes and also search facilities that allow the data of interest to be

readily available. Such databases may be available within an organisation through intranet systems and externally, via the Internet.

The modern data management systems support the use of metadata, "data about data" in their classic definition. Metadata allows context, background and changes to be stored with data, allowing the information to be located, used and re-used on long term. As the other tool identified in Table 4.1, metadata play a fundamental tool for the implementers to demonstrate that their repository programmes are appropriately driven.

Regarding procedures, quality management, which includes quality planning, quality control, quality assurance and quality improvement, is typically applied to all types of information underpinning key decisions by the regulator and implementer. Quality management documents generally describe, for example, the internal processes that are necessary before documents of various types are issued or models, computer codes and data are cleared for use in a safety case.

Other procedures to support information and requirements management include, on the part of the regulator:

- Formal procedures for issuing or updating regulatory requirements and guidelines; and
- Formal regulatory process or plan for the review of key documents submitted to the regulator by the implementer.

A review plan may specify, for example, the objectives of the review, which legal and regulatory requirements are the basis for the review, how the review is organised, which competences are needed, as well as a time and work plan. A review process may include, for example, national consultation to gather information from a wide range of stakeholders.

Procedures undertaken by the implementer may include, for example:

- **Configuration (change) management**, which is a process facilitating the orderly management of system information and system changes. Configuration management implements the policies, procedures, techniques, and tools that are required to manage and evaluate proposed changes to the system and to track and record the status of changes. The process is important in the context of repository programmes e.g. to ensure that subtle changes that might have an impact on safety or feasibility are identified (e.g. NWMO, Posiva).
- **Interdisciplinary meetings (also called integration or interaction meetings)**, which are intended ensure that information e.g. from engineering and geoscience is integrated appropriately into the safety case as the project evolves (e.g. ONDRAF/NIRAS).
- **Data freezing/Data cut-off**, whereby data required (e.g. to support a safety assessment) are fixed for the duration of that assessment. Data freezing may be seen as an aspect of quality management, in that it is undertaken to ensure consistency in the data used for different modelling activities within the safety assessment. Data freezing early in the course of a safety assessment is important given that a major assessment may typically take 2-3 years to carry out, during which time new data is likely to be acquired. Generally, new data acquired after the data freeze will only be taken into account in setting model parameter values if they result in major changes, reflecting actual errors in the original data.

5. Interaction between information and requirements management, safety assessment and design development

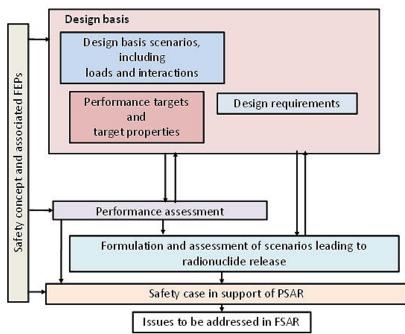
The discussion so far has indicated a number of ways in which information and requirements management interact with safety assessment and design development. This interaction is iterative in nature and is illustrated, for example, in Figure 5.1, which is from Posiva's design basis report for the TURVA-2012¹ safety case. The continuous iteration between long-term safety requirements formulation, design and implementation is necessary yet challenging as design development often occurs at the same time as requirements development. Ideally, the requirements should be defined first and the design then developed accordingly. However, these activities proceed in parallel in practice and, in some cases, design requirements are even set prior to long-term safety requirements.

A particular challenge in assembling systems of requirements is to trace the requirements or rationale that motivated design decisions, when in practice these may date back several decades, and might not have been fully documented at the time. For this circumstance, Posiva presents an interesting example. The design requirement for the thickness of the buffer rings around the SNF canisters in the KBS-3 disposal system was defined around 1983. This requirement was defined based on the canister diameter (assumed at that time) and on the diameter of a deposition hole that was considered feasible to construct using the methods of boring available in 1978 (i.e. when the 1.5 m deposition hole diameter was first proposed). Subsequent safety analyses have shown that this thickness is adequate and it has remained the same for over 30 years. Clearly, that would not be the case if the thickness had been found unsuitable for long-term safety.

As illustrated by this example, if the design is developed before the final long-term safety requirements are available, this introduces the risk that an established design will not fulfil these requirements. There is a trend towards promoting closer co-operation between long-term safety, design and implementation to avoid such conflicts. Furthermore, a close co-operation among barrier-specific experts is also increasingly sought since setting requirements on a given barrier has implications on other barriers.

^{1.} TURVA-2012 is the safety case that Posiva developed in support of the Preliminary Safety Analysis Report (PSAR) for the construction licence of the Finnish DGR.

Figure 5.1. The development of the repository system as iteration between requirements, designs and safety assessments



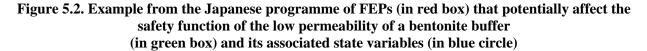
PSAR = Preliminary Safety Analysis Report (for construction licence application); FSAR = Final Safety Analysis Report (for operating licence application – the main safety documents required by the Finnish authorities).

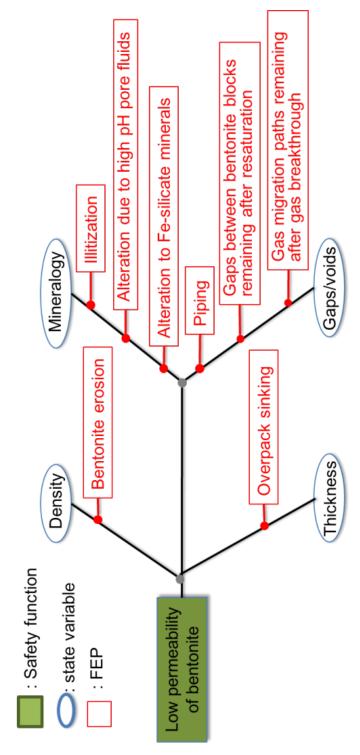
Source: Figure from Posiva's TURVA-2012 safety case.

A specific way in which information and requirements management interacts with safety assessment concerns the development of long-term safety scenarios. As described in Section 3, in the argumentation approach developed by ONDRAF/NIRAS and JAEA, FEPs that could (e.g. if their impact on the system is sufficiently important) compromise the validity of the lowest-level safety statements or sub-claims, are identified. Similarly, in Posiva's safety assessment approach, they identified the FEPs that could potentially lead to performance targets and target properties² (level 3 requirements in the Posiva's VAHA requirements management system) not being fulfilled. Figure 5.2 shows an example presented in the Scenario WS in 2015 [NEA, 2016] from the Japanese programme where a sub-claim regarding a safety function (low permeability of bentonite) is challenged by numerous FEPs (e.g. bentonite erosion, illitisation, etc.).

Information is then compiled that enables the actual impact of these FEPs on the lowlevel statements/sub-claims/targets, and hence on the high-level statements/initial claims/safety functions, to be assessed.

^{2.} In Sweden, SKB's indicator criteria for safety function have a similar role to Posiva's performance targets and target properties.





6. Key challenges of evolving requirements and information management

Requirements management is closely related to information management and shares the same underlying principles. Requirements are generally structured in a hierarchical fashion. Experience gained by advanced programmes indicates that requirement management should be planned in a holistic way from the start of a programme. Requirements themselves inevitably evolve as a programme proceeds, typically being rather general or generic at early stages and increasingly specific and well-defined at later stages. This can lead to an increase in the numbers of levels in requirements management hierarchies. Adherence to some requirements can be assessed quantitatively; for example, it may be achieved if requirements are expressed in terms of quantitative indicators. In programmes that are still in an early (i.e. pre-site selection) stage, it may be deemed more important to show adherence to some requirements more than others, with the focus generally being on long-term safety requirements. As the program proceeds, adherence to other requirements typically gains more weight, e.g. requirements on engineering feasibility and operational safety, affordability and other stakeholder requirements. However, in accordance with the above-mentioned holistic planning, it is important that all types of requirements are represented in requirements management systems throughout the course of a programme, even if some types of requirements are initially only high-level and general in nature, so as not to lose sight of the importance of each type.

Programmes at an early phase tend to be RD&D oriented. As mentioned above, the requirements guiding such programmes tend to be rather general and generic. They start out as fairly vague ideas, relatively few in number, as the analysts and stakeholders explore the RD&D areas. Furthermore, separate requirements often apply to each individual feature; thus, they may be used to frame individual RD&D topics on those features. At later stages, when programmes become more "project-oriented", requirements become more precise and stable. Their number increases, particularly those on operational safety and engineering feasibility. Some may be set by regulation bodies or other stakeholders, while others may be set by the implementer in response e.g. to (limitations in) available scientific knowledge. At these stages, multiple requirements will generally apply to each feature and, at the same time, individual requirements may affect multiple features. As a result, a potentially problematic issue are the trade-offs that may need to be made between conflicting requirements that can arise e.g. from operational safety vs. long-term safety considerations or from different stakeholders who may each have their own specific concerns and priorities. Requirement management also becomes particularly important when optimising a specific aspect of the RWM programmes (e.g. engineering feasibility, financial sustainability). Posiva's comments over the challenges of a requirement management system illustrate this discussion. This aspect was also discussed in NEA (NEA, 2014b). This requirement evolution is actually not specific to RWM but is usual in engineering processes [Robertson, S. and Robertson, 2006].

Experience from a range of implementers and regulators indicates that a prerequisite for successfully developing and implementing information and requirements management in repository programmes is strong leadership and commitment from top management, including the allocation of necessary resources. Furthermore, to promote understanding, good will and active involvements from the various actors that need to be engaged in information and requirements management (including developers and users of information and requirements), the right balance needs to be struck between promoting the use of standardised and structured tools and procedures and avoiding placing undue burdens on these actors. There is a need to set on the one hand fundamental rules on which a management system should be based and that each user should follow and, on the other hand, "nice-to-use" functionalities or "nice-to-do" practices. A too strongly prescriptive and controlling management system would result in an undue burden on maintenance, updating and training, considerably affecting its efficiency. A well-balanced and flexible management system goes thus hand in hand with a strong safety culture enabling the traceability, transparency and comprehensiveness of the records.

As noted above, a key challenge affecting both information and requirements management is how to put in place an effective notification system that can inform all relevant actors of changes to information and/or requirements that may affect their work, and how to ensure that the actors respond appropriately to these changes. More advanced, project-oriented programmes require increasingly fast reaction to changes, and hence the development of appropriate notification and change procedures become even more challenging.

Regarding information management, an ongoing challenge is to ensure that organisations maintain the necessary competence to understand, use and draw conclusions from the various types of information that are available as the needs of a programme evolve e.g. from more research and planning-oriented activities towards implementation. This is issue of particular concern given that the waste management programmes are in all cases longer than a working life and certainly longer than most employment periods. Furthermore, given the long duration of repository programmes, information acquired early in the programme (or by another programme) can easily be forgotten or overlooked, resulting in the duplication of a piece of research. Many important choices are often taken at the early stages of a programme. These choices may well determine the focus of RD&D activities over the following decades, possibly long after those individuals responsible for the choices have left the programme. Hence, it is crucial to record clearly the rationale for these choices, to allow them to be understood, reviewed and revised if necessary as the programme proceeds.

Finally, in spite of the increasing application of sophisticated electronic systems with advanced search facilities, it can still be difficult and time consuming to find a certain piece of information if it is not known in which part of the system the information is located.

7. Conclusions and ways forward

Implementing a safe disposal system for radioactive waste is a complex project stretching over decades. Since geological disposal is a first-of-a-kind project, there is a lack of operational experience in general, as well as a lack of information on requirements setting and management process. Important challenges include the following:

- The amount of information and data that must be managed by disposal programmes increases over time as the programmes proceed.
- The information and data that must be managed is highly diverse. Some raw data are difficult to collect in databases. Also, they might require a large amount of specifications and metadata to understand them.
- The information and data is used and managed by a variety of different actors over several generations.
- The data changes must be properly managed, including by recording and maintaining the history of such changes.

To deal with this complexity, a range of tools has been developed, such as (electronic) document templates, editorial procedures to facilitate efficient reporting and tools for efficient archiving and traceability. Many of these tools and processes are tailored to a specific project. There are also tools that have been developed to support the structuring of information for specific uses or to highlight specific features, such as:

- Storyboards that give an integrated picture of the system evolution; and
- FEP charts to analyse the interdependences between system features and the events and processes that affect them.

According to their intended use, these structuring tools may focus on:

- · Comprehensiveness, e.g. if they are intended for use in scenario analysis; or
- Transparency, e.g. if they are intended to support communication with stakeholders or between experts.

As discussed in this document, information management and requirements management are closely related. Requirement management systems in particular have been identified as essential tools in the development of geological disposal systems and their safety cases. Such systems may be used to:

- Ensure all relevant requirements are addressed;
- Structure safety cases in such a way as to show how requirements are met and to highlight any remaining open issues;
- Prioritise future work to address such issues;
- Facilitate the optimisation of disposal systems, taking all relevant requirements into account; and
- Guide the development of monitoring programmes e.g. to identify any nonconformities or deviation of a measurable parameter with respect to preestablished requirements.

Thus, requirements management is likely to become a prominent feature in future safety cases. Recently, many advanced programmes, such as those in the Nordic countries, have been carrying out important work on the topic. Requirements management is also being addressed in international fora, such as the IAEA GEOSAF project and the NEA Expert Group on Operational Safety (EGOS), with specific focus on operational safety or design requirements. Regulatory bodies are involved in this field, alongside the implementers. It is recommended that, perhaps in a few years' time, the IGSC should consider making a synthesis of these developments, bringing together material from future safety cases and from these international fora. In this respect, requirements management relevant to the construction and operation phase may deserve particular focus.

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Appendix A. Questionnaire

Question 1: General & context

Please state your name, contact details and the name and main roles of the organisation you represent (e.g. implementer, licensing authority, decision maker, regulatory TSO, research organisation, etc.). Describe briefly the current status of your national programme and the future major objectives

Question 2: Information management

A. Given the substantial amount of information that will be generated during the course of an R&D programme, what management tools have been developed and implemented to:

- Collect and structure the information in order to promote consistency and to contribute to the objectives of the safety case.
- Organise information in such a way that it provides guidance and a framework for decision making.
- Manage the information so that past decisions and the context in which they were made are traceable.
- · Facilitate access and transparency to involved audiences.

Consider the following elements when responding to the question (non-exhaustive and possibly redundant):

- Are there specific regulatory requirements regarding the structuring of the information in the safety case (e.g. requirements regarding key reports and their organisation) as well as the traceability and transparency of the information.
- What tools are implemented so that salient, safety-relevant information is not lost in the mass of other information generated?
- What tools are implemented to ensure a complete and integrated view of the information relevant to the safety case at hand (e.g. safety functions, FEP structure), in particular to provide support for programme steering and the traceability of decisions.
- How, and to what extent, are records preserved so that they are available for future programme stages? Preservation of a selected record may, for example, be required for monitoring purposes or to confirm the rationale for past decisions. Is there a procedure to decide what information should be kept and when it can be discarded?
- Are there any plans to account for the possibility that technological tools (e.g. media for data storage) will become obsolete?
- Are there contingency plans regarding record preservation in the event the project is put on hold or terminated.

B. Have you experienced any difficulties in the management of information or in the development and/or implementation of adequate management tools in the course of the programme?

What are the future challenges regarding this management?

Question 3: Requirements management

A. To implementers:

What tools/processes have been implemented to ensure that the geological disposal programme proceeds in a manner that complies with the requirements imposed e.g. by the legal and regulatory framework and by other interested stakeholders, as well as the more technical requirements that may emerge in the course of the programme, e.g. from design development and associated research activities?

To regulators:

What tools and processes ensure the development of a structured and comprehensive set of regulations and guidance?

How do you check that regulations and guidance are complied with when reviewing a safety case?

Consider the following elements when responding to the question:

- How do you identify and structure requirements, and identify any possible interdependencies and conflicts (e.g. operational vs. longterm safety requirements, multiple design constraints on components)?
 - Possible elements in responses include:
 - Organisation of multidisciplinary teams/meetings.
 - Departmental structuring of the organisation.
 - Introduction of a "requirements management system" (methodological and/or IT) tool.
 - Develop human resources with multidisciplinary profiles and competence maintenance.
 - External audits.
- B. Have you experienced any difficulties in developing and/or implementing requirements management tools/processes (e.g. complexity of the task as soon as you try to take the entire system into account) in the course of the programme?

What are the future challenges regarding this management system?

Appendix B. Questionnaire responses

The organisations responding to the questionnaire and their respective counties and roles are listed in Table B.1.

Table B.1. Organisations responding to the NEA questionnaire on information and
requirements management, their respective counties and roles

Organisation	Country	Role
ONDRAF/NIRAS	Belgium	Implementer
Nuclear Waste Management Organization (NWMO)	Canada	Implementer
Radioactive waste repository authority (SÚRAO)	Czech Republic	Implementer
Posiva	Finland	Implementer
Andra	France	Implementer
Federal Office for Radiation Protection (BfS)	Germany	Implementer
Radioactive Waste Management Limited (RWM)	UK	Implementer
Department of Energy (DOE)	US	Implementer
Institute for Radiological Protection and Nuclear Safety (IRSN)	France	TSO
Japan Atomic Energy Agency (JAEA)	Japan	RD&D
Swedish Radiation Safety Authority (SSM)	Sweden	Regulator

Responses to the questionnaire are compiled in the following sections.

Note: The questionnaires were compiled in 2015 and reflect the situation within responding organisations at this date. Developments since 2015 are not reflected in the responses presented within this report.

ONDRAF/NIRAS, Belgium

Question 1 General & context

Manuel CAPOUET Safety Assessment Group Implementer m.capouet@nirond.be

Currently there is still no national policy for the long-term management of high-level and/or long-lived waste in Belgium. This lack of political implication has delayed the elaboration of a safety case with a clear conditional decision. In the meantime ONDRAF/NIRAS has issued the so-called "waste plan" (2011) detailing the challenge regarding the long-term management of radioactive waste to the government and other interested stakeholders. This waste plan compares different options among which the geological disposal proposed by ONDRAF/NIRAS based on the return of experience of studies on clay.

With the "waste plan", ONDRAF/NIRAS has submitted all necessary documents to the government to allow him to make a fully informed decision in principle. This decision causes currently the main delay in the Belgian programme. This is the first and next step needed within the Belgian programme. Once this is obtained, ONDRAF/NIRAS will be in state to set the objectives of the first Belgian safety and feasibility case (SFC1). If the government follows the proposal of ONDRAF/NIRAS which is geological disposal in poorly indurated clays (Boom Clay or Ypresian clays), the next phase will be to start to look for possible sites within the Boom Clay and/or Ypresian clay. A next decision would then be to choose a site and to launch the integrated project to prepare the licensing application.

Question 2: Information management

Question 2 A

In a geological disposal programme, many studies stretch out over several years. They require regularly a redefinition of the objectives in function of the increasing body of knowledge and the modification of the boundary conditions on which they rest. In order to manage this complex programme ONDRAF/NIRAS has developed a knowledge management system (KMS) to record any studies within its context (data, reports, meeting, decisions, links with other studies) and ensure its traceability. This KMS is structured around three tools described here after.

The first primary tool to structure the knowledge in preparation to the first Belgian safety case is the set of safety and feasibility statements [ONDRAF/NIRAS, The Long-Term Safety Strategy for the Geological Disposal of Radioactive Waste – SFC1 level 4 report: second full draft, ONDRAF/NIRAS report NIROND-TR 2009-12E, 2009; ONDRAF/NIRAS, Research, Development and Demonstration (RD&D) Plan for the geological disposal of high-level and/or long-lived radioactive waste, State-of-the-art report as of December 2012, ONDRAF/NIRAS report NIROND-TR 2013-12 E, 2013]. These consist of claims regarding what the disposal system does, and the properties that it has, relevant to the safety or feasibility of the system. Safety and feasibility statements are often expressions of the requirements on the disposal system as a whole, the various

subsystems and the individual components. The statements are organised in a structured, hierarchical set or tree, with lower-level claims underpinning higher-level claims as shown in figure here below.

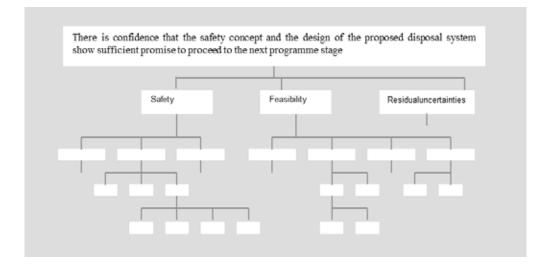


Figure B.1. Hierarchical structure of the safety and feasibility statements

In the hierarchical structure, the top (high-level) statements are the most general ones and as the substantiation progresses, the statements are increasingly becoming more specific. For example a lower-level statement can be that the metallic overpack for category C waste has no perforations. In totality these statements should at the end substantiate the pivotal claim of SFC1 that 'there is confidence that the safety concept and the design of the proposed system show sufficient promise to proceed to the next programme stage'.

The structure of the safety branch shown in Figure B.2. is supported by the following three branches:

"the system is known" – the associated statements concern the characterisation and evolution of the system and its components.

"the safety functions that have been defined are relied upon" - the associated statements aim to show that the proposed disposal system will provide defence in depth over the long term.

"the performance of the disposal system meets the requirements" - the associated statements aim to show this on the basis of performance calculations and safety indicators, assessment of environmental impacts of chemically-toxic contaminants and comparison of these with nuclear and environmental regulatory requirements and other stakeholder requirements.

The feasibility branch aims to show that the proposed disposal system can be constructed, operated and progressively closed in a manner that is operationally safe and meets relevant technical requirements, and that its costs can be covered with the current funding mechanism. They comprise statements concerning (i) engineering practicality, (ii) operational safety, (iii) costs and (iv) quality assurance.

The "residual uncertainties" statements aim to show that uncertainties related to the proposed disposal system that remain at a given programme stage do not undermine the

goals of the present stage and can be dealt with to the degree necessary for each future stage. As soon as this aim is met, the programme can proceed from one stage to the next. They comprise statements to the effect that (i), there are no uncertainties that call into question the capacity of the system to fulfil the requirements and (ii), there are good prospects that future R&D will enable safety-relevant uncertainties to be reduced or even avoided.

For the implementation phase, all the branches (long-term safety, feasibility, and residual uncertainties) must have reached an adequate and equal attention and development.

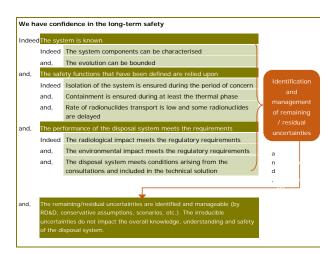
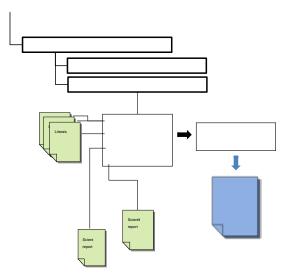


Figure B.2. Detailed structure of the safety branch (version 2013)

The substantiation of the lower-level 'leaf' statements is based on technical documents, and the argumentations resulting from it (Figure B.3.). The evaluation of these arguments identifies open issues that may need to be addressed through RD&D to strengthen an underpinning argument, since an open issue that has a direct effect on the lowest-level leaf statements will affect the ones above. The relevance and significance of any open issues pertaining to the statements can be evaluated quantitatively by means of a RD&D plan consisting of experimental or desk studies, exploratory or safety calculations or an analysis to capture expert judgement.

The safety and feasibility statements are therefore a tool providing a way to structure the documentation of the safety case. The link with the safety statements ensures that all activities are properly framed, consistent with the objectives of the safety case and safety oriented.





Complementary to these statements is the so-called "SCR environment". The SCR environment has been developed in the ONDRAF/NIRAS KM system with its own metadata and objects. The SCR environment supports the reporting of a particular study–which can spread over a long time. It guarantees in particular (Figure B.4.):

- The traceability of all decisions taken in meetings for the study under concern.
- The link between the study and the objective of the safety case (though the customised folder "integration module").
- The data used, though a customised folder containing an excerpt of the data used for the particular study and selected from a database stored also in the KM system.

Email c	ontent to: 1.11.33432@nirc	ond-km.be			View as Web Fold	
Phase 1 - Initiate	Phase 2 - Research, Report & Review	Phase 3 - Integration	Phase 4 - Closure	Phase 5 - Release	Your role in this phase: All Users Administrators KM Project Developers	
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Figure B.4. The SCR structure

The SCR environment has 4 phases:

- Phase 1: Initiation.
- Phase 2: Research, Report and Review.
- Phase 3: Integration.
- Phase 4: Closure and Release.

Each of these phases defines the roles of everyone. In phase 1, the task manager initiates the study by motivating the objective of the study, the resources involved and the responsibilities. In phase 2, the expert in charge of the study makes the reporting. After back and forth reviewing and adaptation the document is finally accepted and the SCR environment is shifted in phase 3, where the results of the study are contextualised with respect to the overall objective of the safety case. The document is issued in phase 4.

All information and knowledge generated is stored on discs, with a rotation cycle of 1, 2, 3, and 4 weeks whereby the discs that are not in use are safely stored outside with a company that has archiving and safely storage of data as its core business. In the period 2004-2008 all relevant scientific and engineering reports of the previous RD&D programmes (1978-2000) deemed valuable were digitised and 2 paper copies were made to create an overall project library. These are the current formal measures regarding the preservations of records for future programme stage (e.g. for monitoring purpose or project shut down). Usually all formal documents are kept without distinction.

The ONDRAF/NIRAS KMS has been developed by a contractor. There is no plan to account for the obsolescence of technological tools.

A third tool implemented in the ONDRAF/NIRAS KM system allowing traceability of the records is the Minutes of Meetings (MoM) environment. The MoM template allows a meeting secretary to identify each discussion point with a unique ID allowing to trace and filter actions related to a particular issue, or assigned to a specific expert. Similarly to the "SCR", the MoM environment can be linked with the safety statements. A formal reviewing process is also implemented.

Two additional tools, not used for RD&D steering but for completeness checking are the FEP lists and the storyboards. Storyboards illustrate the phenomena – thermal, hydraulic, mechanical and chemical – occurring within specific compartments of the disposal system under consideration, for specific scenarios. An example of a storyboard is shown in the figure here below. The figure shows a transverse cross section through a disposal gallery containing vitrified HLW and illustrates the key processes expected to occur during the thermal phase, when the temperature in the EBS is at its highest. Like the safety statements, storyboards can be checked for completeness, since these provide a comprehensive overview of all the processes and events that may occur in a disposal.

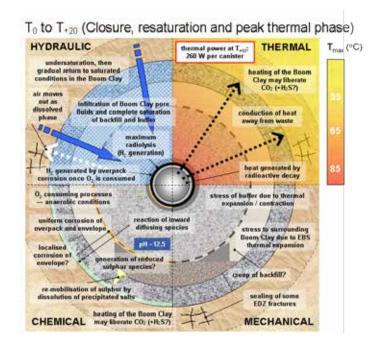


Figure B.5. Storyboard illustrating THMC processes

Question 2 B

Defining the requirements that a KMS should have was a challenging task at the beginning of the SFC1 project. This task requires a holistic view of the geological disposal programme as well as a clear definition of its short and long terms objectives. Without clear national policy and in absence of regulatory requirements, the KMS programme revealed sometimes too ambitious with respect to the resources of the organisation. The desire of a full and integrated traceability resulted in the development, the maintenance and the use of a sophisticated KMS that takes a lot of resources, daily involvement and good will of each user. Despite this high level of sophistication, the lack of clear rules resulted in some traceability issues (as for example since all the anterior versions of a document are kept available in the system, this can sometimes lead to a scattering of versions for the same document). Managing traceability is part of a safety culture that an organisation needs to develop and maintain.

In the future, the objective of the geological disposal programme of ONDRAF/NIRAS is to find a balance between the flexibility of use and the rigidity of standardised and structured processes & activities by setting on the one hand what are the fundamental rules on which a KMS should be based and that each user should follow and, on the other hand, what are the "nice-to-use" functionalities of a KMS or "nice-to-do" practices. These non-binding processes give the possibility to test possible measures that could reinforce the QA aspects of knowledge management.

Ad hoc KMS have been developed within ONDRAF/NIRAS in function of the requirements of the different departments. Knowledge management being part of the IMS, consistency between the various KMS should be improved.

Question 3: Requirement management

Question 3 A

Several tools have been developed for the management of the requirements.

The development of the safety case SFC1 and the definition of the related RD&D activities need to consider requirements of different types: For example, the requirements arising from the long term or operational safety, from the nuclear and mining regulations, those arising from the design specifications as well as requirements expressed by different groups of stakeholders. These requirements are often interdependent, may on occasion also compete, and evolve as the SFC1 develops. They must be adequately identified and integrated in the management system.

The safety and feasibility statements presented in the answer to question 3A allow to formulate and organise these requirements as clearly as possible, and ensure they are met.

The requirements, expressed in the Belgian legislation or by the IAEA on the elements of the safety case that substantiate the safety and the feasibility of the disposal system, can be adequately translated in the safety and feasibility statements. As for example, we find statements such as:

-The evolution of the disposal system and of its environment can be bounded: This statement is supported by series of sub statements about the adequate knowledge of the expected evolution of the system as well as the potential internal and external perturbing events and the associated uncertainties.

- The long-term safety of the disposal system can be assessed is supported by sub statements that illustrate the defence in depth and the robustness of the system.
- The radiological and non-radiological risks associated with accident scenarios and external events during the operational period touches to the operational safety.

Also, requirements expressed by the stakeholders such as the retrievability aspects are translated in the safety statements.

In the current situations the safety statements express only high-level regulatory requirements. Our KMS is not yet designed to manage detailed regulatory requirements or (internal) technical requirements emerging from other fields of activities. The management of these specific requirements is carried out through dedicated interaction meetings. It takes place as follows: The SFC1 project is part of the department "LTRD&D". Its activities are structured around three distinct groups of expertise, with clear defined responsibilities and roles: the Phenomenology group, the Safety group and the Technology group.

The Phenomenology group is responsible for the development of the scientific basis required for the long-term management of the radioactive waste. It concerns the identification and the characterisation of processes potentially relevant for the long-term safety that take place in the natural or engineered components of the disposal system.

The Technology group is responsible for the development of the repository design and assessing the means for its implementation, including the development and the demonstration of prototypes, cost evaluations and operational safety assessments. It provides design specifications, and thus defines the engineered system to be investigated.

The Safety group is responsible for the analyses of the proposed disposal system related to long-term safety, both radiological and non-radiological. These analyses provide focus

to the work of phenomenology pole on one hand by identifying the key safety-relevant phenomena and can lead to formulation of safety requirements on key components which the feasibility group should target.

The studies conducted by these three task groups aim at substantiating specific branches of the safety statement tree, and therefore to meet the requirements imposed by the boundary conditions. At regular intervals, interdisciplinary meeting are organised between the different groups. These meetings serve a role of integration. They allow to analyse the results of a study on the other dimensions of the project, as for example, to assess the influence of a natural process on the design or on the long-term safety. These meetings can take the form of meetings between a couple of collaborators from two different groups up to internal interdisciplinary meetings of several days. These interactions are a crucial moment to analyse the impact of requirements defined for one "FEP" or a set of "FEPs" in a particular field on other areas of the programme. These interactions lead to the identification of cross-cutting issues and decisions that can be of importance for the continuity of the programme. For these reasons, specific QA measures are attached to the MoM to ensure traceability of each action identified in these meetings.

Question 3 B

The set of safety and feasibility statements has required more resources than initially evaluated from the point of view of the conceptual development as well as the implementation and maintenance in the KMS.

Requirements issued by the stakeholders (including the regulators) involved in the setting of the boundary conditions remain essentially conceptual and defined at a high level. These requirements are compartmentalised and targeted to a certain area of activity. At the onset of a geological program, each involved group will work with the objective of filling these boundary requirements and will tend to stay within this compartmentalisation. With the knowledge increasing in each area of activity so emerge specifications impacting other components of the disposal system. These specifications are transversal requirements that have to be considered along with the boundary conditions. Typical example of this transversality is the impact of the requirements emerging from the long-term safety on the operational safety or the feasibility aspects. Implementing this transversal management is a future challenging task for Ondraf/Niras.

Nuclear Waste Management Organization (NWMO), Canada

Question 1: General & context

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Current status:

In 2002, the Government of Canada passed the Nuclear Fuel Waste Act, resulting in the creation of the Nuclear Waste Management Organization (NWMO) to develop and implement a plan for the long-term care of the nation's used nuclear fuel.

The Nuclear Fuel Waste Act requires the nuclear fuel waste owners – Ontario Power Generation, New Brunswick Power Corporation, Hydro-Québec (HQ), and Atomic Energy of Canada Limited – to establish segregated trust funds to finance the NWMO's operations and the long-term management of used fuel. The NWMO operates on a not-for-profit basis.

Within three years of the legislation coming into force, the NWMO was required to submit to the Minister of Natural Resources proposals for the management of used nuclear fuel and a recommended approach. The NWMO completed its study in November 2005, with the input of over 18 000 Canadians, and recommended the Adaptive Phased Management (APM) approach which consists of both a technical method and management system.

In June 2007, the Government of Canada supported the APM approach for the long-term management of used nuclear fuel. Technically, APM has as its end point the containment and isolation of used nuclear fuel in a DGR constructed in an appropriate rock formation where the used fuel will be safely and securely contained by engineered barriers and the surrounding geology. The NWMO is now responsible for implementing APM, subject to all the necessary regulatory approvals³.

An early milestone in implementing APM was the collaborative design of a process to select a site for Canada's used nuclear fuel repository and Centre of Expertise. This was finalised in 2010, after extensive input from Canadians, and in May of the same year, the NWMO proceeded to the first step in implementing it by initiating a broad programme to provide information, answer questions and build awareness among Canadians about APM and the siting process itself. The NWMO then began the process to identify an informed and willing host for Canada's repository, and opened it to all interested communities. Twenty-two communities in Saskatchewan and Ontario expressed an interest in learning more about the project.

Twenty-one communities successfully passed an initial screening and elected to advance to preliminary assessments, initiating Step 3, Phase 1 of the site-selection process.

^{3.} NWMO. 2010. Regulatory Oversight of Adaptive Phased Management. Nuclear Waste Management Organization Backgrounder.

Future major objectives:

The NWMO is now in the fifth year of implementing the siting process. A narrowing down process has begun, as the NWMO and an early group of communities considered findings from the first phase of preliminary assessments. As of March 2015, 11 communities continue to explore their interest in hosting APM, and Aboriginal peoples and communities in the surrounding area are progressively being engaged in learning and decision making. The NWMO expects that the advancement of preliminary assessments (Step 3, Phase 2) over the next five years will build information to guide a future decision on selection of the one or possibly two areas to proceed to detailed site characterisation (Step 4).

Another focus of the next five years will be to conduct testing to demonstrate that engineered barriers meet all safety requirements and can be produced effectively and efficiently. Over the planning period, the NWMO will complete design, fabrication and testing of the prototype repository containers, buffer system and placement system, and will establish a prototype test facility for engineered barrier evaluations.

The NWMO will continue to refine conceptual designs and post-closure safety assessments for a repository in both crystalline and sedimentary rock formations, and keep the Canadian Nuclear Safety Commission informed on our work. Throughout the planning period, engagement and social research will continue. Attention to sound governance and assurances around programme funding will be maintained. Investing in people and the skills key to programme success and continuity will remain a priority.

Key milestones for the next five year planning period include:

- Advance preliminary field studies and assessments (Step 3, Phase 2) to support future identification of one or two communities to progress to the detailed site characterisation phase of work;
- Conduct this work collaboratively with the communities involved, First Nations and Métis peoples and surrounding communities in order to establish a foundation to proceed in partnership to implement the project;
- Design and manufacture physical prototypes of the used nuclear fuel container;
- Establish a container, engineering, and test facility for both the repository and transportation containers;
- Complete an integrated review of microbiological processes that could occur within the repository environment;
- Advance transportation plans through container design, testing and through engagement of citizens to inform the development of a planning framework;
- Work with waste owners in planning for future transport of used nuclear fuel from the interim storage facilities where it is currently stored; and
- Complete an update to the conceptual design and cost estimate for APM.

Question 2: Information management

Question 2 A

Safety assessments must address the expectations of the Canadian Nuclear Safety Commission (CNSC), as outlined in CNSC Guide G-320, Assessing the Long Term

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Safety of Radioactive Waste Management.⁴ Consistent with Sections 5 and 7 of G-320, safety assessments are expected to demonstrate the understanding of the system through a well-structured, transparent and traceable methodology. Specifically, the assessment documentation should provide a clear and complete record of the decisions made and the assumptions adopted in developing the model of the waste management system. The parameters and variables used to run the model and to arrive at a given set of results should be reported and justified.

This is consistent with international guidance. The IAEA Guide SSG-23, The Safety Case and Safety Assessment for the Disposal of Radioactive Waste,⁵ advises that the safety case and supporting safety assessment should be reviewed and updated as necessary prior to each major decision point, as well as periodically, to reflect increasing knowledge and experience. The evolution of the safety case should be documented so that it is transparent to interested parties. It is important that the safety case prepared for each step of the facility lifetime should provide sufficient depth of information and assessment to support the decisions required. At the end of the facility lifetime, the safety case should contain all of the information that needs to be passed on to future generations: for example, the basis for institutional controls.

The NWMO follows an internal Safety Assessment Procedure that establishes responsibilities and expectations for the performance of safety assessments, the results of which are usually part of a safety case. This procedure defines the requirements for safety assessments, including planning, scenarios, criteria, data collection, reviews and documentation of the results.

The procedure also requires periodic review of safety assessments, whether due to updated regulations, or significant changes in design, operating conditions, effects of ageing, or knowledge of key processes or hazards.

Upon completion of the assessment, sufficient information is archived to ensure an independent specialist, competent in the field concerned, could reconstruct the assessment and duplicate the results without undue difficulty. This includes computer model runs.

The structure of safety assessments, the main component of the safety case, is largely aligned with analyses of relevant Features, Events, and Processes (FEPs). Specifically, assessment scenarios of interest are identified through consideration of the various FEPs that could affect the repository system and its evolution.^{6,7} In this way, assessments are developed in a systematic, transparent and traceable manner, using FEPs to ensure comprehensive consideration of site characteristics, waste properties and receptor characteristics and their lifestyles.

- 6. NWMO. 2012. Fourth Case Study: Features, Events and Processes. Nuclear Waste Management Organization Technical Report NWMO TR-2012-14.
- 7. NWMO. 2013. Fifth Case Study: Features, Events and Processes. Nuclear Waste Management Organization Technical Report NWMO TR-2013-06.

^{4.} CNSC. 2006. Regulatory Guide G-320: Assessing the Long Term Safety of Radioactive Waste Management. Canadian Nuclear Safety Commission. Ottawa, Canada.

^{5.} IAEA. 2012. IAEA Safety Standards: The Safety Case and Safety Assessment for the Disposal of Radioactive Waste. International Atomic Energy Agency. Specific Safety Guide IAEA SSG-23. Vienna, Austria.

Much of the data used to define the various models of the repository system are determined by the Geoscience and Engineering groups within the NWMO. These data are provided, reviewed, and approved through a Data Clearance Instruction, ensuring data tracking, consistency in data presentation and quality control in data usage. This procedure confirms safety assessments are based on the correct engineering and geoscience data. In parallel, Safety Assessment personnel meet regularly with their engineering and geoscience colleagues to ensure their components are combined appropriately as the project evolves. This process establishes an integrated view of the information relevant to the safety case.

The NWMO requires that its records be managed in an approved Record Management System for storing physical and electronic records, having index, search and reporting capabilities. Currently, the official Records Management System for the NWMO is SharePoint.⁸

The analytical, scientific and design software as well as related software tools and datasets are stored and backed up as per the NWMO Information Technology Standard.

On an annual basis, records are assessed to verify they are correctly indexed, attached and filed to ensure preservation and protection from loss or deterioration.

Reports and files prepared in support of a licence are stored permanently; reports and files prepared for other purposes are retained for a minimum of 7 years.

NWMO Records kept in electronic form are regularly backed up in accordance the NWMO Information Technology Standard. Paper records are filed in file cabinets.

Currently, succession planning for information technology is not explicitly defined; however, the maintenance of appropriate and reliable data storage systems is considered within the NWMO Quality Assurance program.

The NWMO Records Management System allows for records to be sent to off-site storage.

^{8.} Londer, O. and Coventry, P. 2013. Microsoft SharePoint 2013 Step by Step. Pearson Education.

Question 2 B

In support of developing the safety case, the NWMO has recently prepared two preproject reports to illustrate its approach to conducting safety assessments for conceptual used fuel repositories: the first within a hypothetical crystalline rock setting in the Canadian Shield⁹; the second within the sedimentary rock of the Michigan Basin.¹⁰

NWMO's current Record Management System cannot accommodate the 3D design and structure drawings that define the conceptual systems considered within these assessments. Consequently, these drawings exist as multiple copies on shared drives. Version control and revision locks are partly dependent on staff discipline. The NWMO is now implementing a Product Lifecycle Management system (Teamcenter, Siemens) to ensure data such as these are controlled, readily available and traceable; this is discussed further under Section Q3.

Similarly, NWMO's current Record Management System cannot accommodate the model simulation results for these two geospheres, primarily due to the quantity of data and their configuration. These data are now stored separately with limited, offline accessibility.

Construction and excavation of the repository will yield a variety of new site information. When applying for an operating licence, the safety case will require review and possible revision to align with the new information. Revision of geosphere models will depend on earlier versions remaining functional; otherwise, models may have to be rebuilt. The NWMO is investigating data management systems for spatially organised geosphere information, including metadata for traceability (one example is the Geosoft Data Access Protocol, widely used by public- and private-sector resource companies around the world; the acQuire module allows integration with geochemical and borehole data).

The NEA Radioactive Waste Management Committee (RWMC) initiative on the Preservation of Records, Knowledge and Memory (RK&M) across Generations¹¹ was launched to minimise the risk of losing records, knowledge and memory, with a focus on the period of time after repository closure. The Repository Metadata (RepMet) Management Project¹², which will have a strong connection to the RK&M project and be affiliated to the IGSC, is aiming to create sets of metadata that can be used by national programmes to manage their repository data, information and records in a way that is harmonised internationally and suitable for long-term management; RepMet deals with the period before closure. The NWMO is participating in both programmes.

- 10. NWMO. 2013. Postclosure Safety Assessment of a Used Fuel Repository in Sedimentary Rock. Nuclear Waste Management Organization Technical Report NWMO TR-2013-07.
- 11. NEA RWMC. 2015. Preservation of Records, Knowledge and Memory Across Generations (RK&M): Phase-II Vision Document. Nuclear Energy Agency. Radioactive Waste Management Committee.
- 12. NEA RWMC. 2014. Vision Document for the Radioactive Waste Repository Metadata Management (RepMet) Project. Nuclear Energy Agency. Radioactive Waste Management Committee.

NWMO. 2012. Used Fuel Repository Conceptual Design and Postclosure Safety Assessment in Crystalline Rock. Nuclear Waste Management Organization Technical Report NWMO TR-2012-16.

Question 3: Requirements management

Question 3 A

Implementation of a DGR under APM falls within federal jurisdiction and will be regulated under the Nuclear Safety and Control Act (NSCA) and its associated regulations. Under Section 26 of the NSCA, activities associated with a nuclear facility can occur only in accordance with a licence issued by the CNSC. The regulations require that applicants and licensees employ configuration management; this requirement is applied through facility-specific licences.

Configuration management is the systematic approach for ensuring that the physical configuration of a facility is understood in relation to the design requirements, and that the facility is operated within the Licensing Basis. This is especially important for repository facilities, which have lifecycles spanning many decades.

To meet this requirement, the NWMO is now implementing a Product Lifecycle Management system (Teamcenter, Siemens). The key objective is to ensure data and their associated hierarchy (i.e. assumptions, decisions, revisions etc.) developed during conceptual design, preliminary design, detail design, construction/installation and commissioning phases are controlled, readily available and traceable. This will ensure that:

- The repository design is fully documented and traceable, so that the rationales for the future design basis and Licensing Basis are understood;
- The repository system and equipment, their physical and functional characteristics, match the design basis, Licensing Basis and repository documentation; also, that they continue to match as modifications are made;
- Operation and maintenance conform with the design basis and Licensing Basis; and
- Operating, training, modification, and maintenance processes are consistent within the design basis and Licensing Basis conditions, and that the rationale is understood.

The NWMO configuration management procedure currently focusses on repository design, a primary input to the safety case. Given the long duration and iterative approach, conceptual and preliminary designs require a traceable history of key changes to the design and its requirements to facilitate licensing and knowledge management. As the NWMO progresses through the lifecycle of its repository programme, our configuration management procedure will be expanded to include construction, operation and decommissioning.

Question 3 B

The existing Records Management System at the NWMO is document-based and continues to include some manual record-keeping systems. Printed materials have to be analysed (and occasionally, revised) for configuration management to include indexing, cross-referencing and retrieval capability.

Improved management of knowledge and requirements often requires additional restrictions on how activities are planned, performed and documented. The existing culture at the NWMO carries the momentum of all progress achieved to date, adding to the challenge of implementing new policies and procedures.

Adopting the new configuration management system across the NWMO will require training and skill maintenance.

During transition to the new system, some departments within the NWMO will continue to maintain their own knowledge management and requirements management systems. For information supporting the safety case, these systems will be integrated and crossreferenced to ensure alignment of any overlapping information.

Any changes in the repository system, whether in concept, design or in the development process, will impact configuration management.

Radioactive waste repository authority (SÚRAO), Czech Republic

Question 1: General & context

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The Ministry of Industry and Trade established the Radioactive Waste Repository Authority (RAWRA – SÚRAO), a state organisation concerned with radioactive waste disposal on the basis of relevant SÚJB licences.

SÚRAO is responsible for the following:

- preparation, construction, commissioning, operation and closure of radioactive waste repositories and monitoring of their impact on the environment;
- radioactive waste management;
- conditioning of spent or irradiated nuclear fuel into a form suitable for its disposal or further utilisation;
- keeping records of radioactive waste receipts and their generators;
- administration of payments;
- drafting of proposals for determination of payments to the nuclear account;
- provision for and co-ordination of research and development in the field of RWM;
- monitoring of reserves of licensees for decommissioning of their installations and approval of drawing on funds in the reserves;
- provision of services in the field of RWM;
- provision of contributions to municipalities.

RAW in gaseous, liquid and solid form is generated during the operation and decommissioning of nuclear reactors and when dealing with ionising radiation sources. A smaller proportion of RAW is made up of transient waste the radioactivity level of which, following short-term storage, is lower than clearance levels; such waste can safely be returned to the environment. Low and intermediate-level waste makes up the largest category of radioactive waste in terms of volume. The technology for the processing and conditioning of such radioactive waste prior to its disposal is well-established and is implemented by RAW producers in the Czech Republic. LILW ceases to be radioactive after a few hundred years and, therefore, can be disposed of in near-surface repositories.

LILW generated at nuclear power plants is disposed of in a surface disposal facility located within the Dukovany NPP complex. The facility's total disposal capacity is able to accommodate all the waste generated by the operation and decommissioning of the Dukovany and Temelín NPPs, provided that the waste meets acceptability criteria, even if the lifetime of these power plants is extended to 60 years.

LILW generated by the industrial, research and medical sectors is disposed of at the Richard (near Litoměřice) and Bratrství (near Jáchymov) repositories; the Dukovany repository is also partly utilised for this purpose.

The system which governs the centralised processing and treatment of RAW generated by producers outside the nuclear energy sector is managed on a commercial basis by ÚJV

Řež which possess the relevant technology and is a holder of the licenses required by legislation.

The operation of all Czech repositories, including the monitoring of the now-closed Hostim repository, is managed by SÚRAO in compliance with the relevant licences granted by the SÚJB and, in the case of mined cavities, in compliance with permits and licences issued in accordance with mining regulations.

A certain amount of RAW does not meet acceptability criteria for disposal at existing repositories. Relevant requirements have been defined concerning the method and quality of treatment and conditioning which allow for the storage of such waste both by producers and at SÚRAO's facilities prior to its subsequent disposal in a DGR.

The Concept of RAW and SNF in the Czech Republic of 2002 requires that two candidate sites for the construction of a DGR be included in land use development plans by 2015. Following a survey of the whole of the geographical area of the Czech Republic, six sites were identified and subjected to characterisation studies. However, the general public in the sites concerned opposed plans for the construction of a DGR and further geological exploration work was suspended until 2009. Meanwhile, the Czech Land Use Development Plan for 2008, which was approved by Government Decision No. 929 of 20 July 2009, Article (169), charged the Ministry of Industry and Trade and SÚRAO with specifying the surface area of the sites concerned and with determining conditions for the legal protection of land at sites with conditions suitable for the construction of a DGR; legal protection status will apply to these sites up to the time that the two most suitable sites are selected. In addition, the investigation of former military areas was launched by SÚRAO at the end of 2008 in compliance with its plan of activities which was approved by the government (Government Decision No. 1315 of 20 October 2008). A further site, situated close to a uranium mine in operation at Dolní Rožínka, was added to the list of candidate sites; sites in the vicinity of nuclear power plants have been also under consideration. Geological investigation work must be preceded by a Ministry of the Environment Decision on the identification of investigation areas.

The capacity of the Bratrství repository will soon be exhausted; it is expected that the disposal of RAW at the facility will end around 2020. The disposal of waste containing natural radionuclides which, according to current Limits and Conditions, cannot be placed in the Dukovany or Richard repositories must therefore be ensured after this time. Two options concerning the disposal of such waste are available: storage until the commissioning of the planned DGR or the utilisation of the Richard repository should safety analysis prove that it can also be used for the disposal of this category of RAW.

It is envisaged that the current free capacity of the Richard repository available for RAW disposal will be exhausted by 2025, depending on the actual volume of waste produced as a result of the repair of environmental damage at ÚJV Řež. It is possible, however, that further disposal capacity at the Richard repository will be made available by means of the adaptation of access tunnels and other unused space within the repository. In recent years, SÚRAO has adapted a number of excavated spaces at the Richard repository and, based on this experience, assumes that the relevant adaptations will be made within two years of the issuance of the relevant SÚJB licence.

The systematic development of a DGR programme in the Czech Republic began following the termination of a contract which provided for the transportation without charge of SNF to the former Soviet Union in 1989. In 1992 the Czech Geological Institute selected 27 sites deemed potentially eligible for DGR siting. A comprehensive

review of available geological data on the selected sites was conducted and eight of the sites were recommended for further research. Subsequently, a summary was made of information available at the time on the expected amount of SNF and other radioactive waste which would have to be disposed of in the future DGR and an analysis was made of basic information concerning waste characteristics, the engineered barriers that would be required and the characteristics of various rock environments. SNF disposal casks were designed based on carbon steel and basic design projects conducted concerning both the underground and above-surface parts of the future DGR. The first reference project for a DGR at a hypothetical locality within the Czech Republic was developed in 1999 and updated in 2011.

The updated reference project for a DGR of 2011 envisages the disposal of SNF from NPPs presently under operation, i.e. 4 generating units at the Dukovany NPP and 2 units at the Temelín NPP as well as planned new nuclear units (2 at Temelín and 1 at Dukovany). It is envisaged that SNF produced as a result of the decommissioning of current NPPs and planned NJZ as well as other RAW which cannot be disposed of in near-surface repositories will be disposed of in the DGR.

Following a critical evaluation of the candidate sites in terms of meeting the necessary criteria for the siting of nuclear installations in compliance with SÚJB Regulation No. 215/1997 and possible conflicts with the protection of the environment (under Act No. 114/1992), 11 candidate sites were selected in 2002 in three different rock types. Subsequently, SÚRAO prioritised 6 of the 11 selected sites, all in granitic rock.

Evaluations were conducted of transport accessibility, population density and the advantages and disadvantages of siting at all of the six prioritised sites and in 2004 - 2005 geophysical research work was performed in order to reduce the spatial extent of the areas of interest.

In 2004 the government accepted, by means of Decision No. 550/2004, the suspension until 2009 of all geological work at the six sites under investigation with a view to DGR siting. The reason for the suspension consisted of the negative attitude of the communities concerned with regard to activities relating to DGR construction. In 2009 the national Land-Use Development Plan, prepared by the Ministry for Regional Development, was approved by Government Decision No. 929 of 20 July 2009 in which (Article 169) the Ministry of Industry and Trade, in co-operation with SÚRAO, was charged with selecting the two most suitable sites for DGR construction by 2015 with the involvement of the communities concerned (this date was originally specified in the Concept of RAW and SNF management in the Czech Republic of 2002).

Following the suspension of work on site selection in the period 2005–2009 and the rescheduling of the approval of the amended Atomic Act (2001), which contains a proposal for the provision of incentives for communities involved in the DGR siting process, it was necessary to amend the completion date for site selection. Consequently, the postponement of the identification of two candidate sites to 2018 was suggested in SÚRAO's Plan of Activities for 2012. The date was subsequently approved by Government Decision No. 955 of 20 December 2012 which charged the Minister of Industry and Trade with selecting two candidate sites for DGR construction by 31 December 2018 and with submitting the respective proposal accompanied by a summary of the positions of the communities concerned to the government for approval.

The status of preparation as at the date of the Concept update allows for the selection of the final site in 2025 and the commencement of DGR operation in 2065. The former of

the two dates, however, does not include a time reserve and will be met only if geological investigation works progress smoothly.

Obtaining the consent of communities to their involvement in the DGR site-selection process is, despite the offer of financial incentives from the nuclear account, far from certain. For this reason and since DGR sites must satisfy a range of demanding criteria, primarily concerning the high level of safety essential for the operation of the future DGR and the stringent requirements involved in determining a technically, economically and sociably acceptable solution, other potential sites are currently being considered. Following an examination of archive geological data, the Kraví hora site in the Vysočina region was added to the list of potential sites; a more positive public attitude concerning DGR investigation work can be expected at this site due to local experience with uranium mining.

In accordance with Government Decision No. 1315 of 2 October 2008 geological research studies were conducted in the Boletice former military area which resulted in the identification of a potential site at Chlum in the northern part of the Boletice area. Options for the siting of the DGR in sites which were excluded in 2002 will be revised and research will continue with regard to the identification of other areas in the Czech Republic which might be eligible for DGR siting. The study of the Boletice area and the revision of previous research studies are intended as backup solutions to be considered in the event that none of the current candidate sites are deemed eligible.

Site selection will be carried out in several stages during which the number of sites and the surface areas thereof will be gradually reduced. The first stage will involve the revision of available data and the performance of surface geological surveys without encroachment into the Earth's crust. It is expected that this stage will result in a reduction in the number of potentially eligible sites to be subjected to further detailed geophysical, geochemical, hydrogeological and geotechnical research activities involving the drilling of boreholes (2–4 boreholes to a depth of 500 metres and 1–2 boreholes to a depth of 1000 metres). The suitability of selected sites will be summarised in the form of detailed safety reports, which will confirm the operational and long-term safety of the repository at the conceptual level, feasibility studies, which will provide an evaluation of both the suitability of the DGR technical solution and the costs of construction at given sites, and studies of both the impact of the DGR on the environment and the anticipated social and economic impacts on local communities and microregions.

Question 2: Information management

Question 2 A

Structuring of the information in the safety case, in all stages of licensing, is prescribed a list of documents which have to be provided, namely

- safety report
- plan of monitoring
- quality assurance programme
- proposal of closure,

and in relevant cases

- emergency plan
- limits and conditions of operation and
- acceptance criteria.

All these documents are considered to be the components of the safety case. In addition, regulatory body has special requirements for the content of the safety report, which are outlined in a methodical directive of SÚJB.

Input data used in the presentation of the safety case, i.e. safety report and other documents; have to be referred to and the references can be checked by SÚJB.

R&D work in the field of RAW and SNF management has been carried out to date in the Czech Republic, in most cases closely connected with wider EU research programmes. Such R&D activities, which are aimed at providing scientific and technical information concerning the deep disposal of RAW and SNF, improving public awareness of RAW issues and supporting the acceptance of the RAW and SNF deep disposal concept make up important elements of the overall DGR development programme.

In2014, there was started a project of R&D for a support of safety, the parts of the project being

- RAW and SNF
- Container
- Disposal shafts
- Buffer, backfill and sealing materials
- Transport of radionuclides
- Host structure performance
- Methods for host rock characterisation

The project has to be revised in the period of five years. Presently, the objective is to provide data necessary for siting period.

In fact, there still exist no imperative set by the regulatory body that would organise the data from R&D which would map the decision-making process.

SÚRAO has developed a system of criteria / indicators that shall be met in the geological repository siting process. These criteria are divided into following principal fields: project issues, long-term safety, operational safety, environmental requirements and socioeconomical aspects. This criterial system will serve as a support of the decision-making process, but real procedure has not yet been stated.

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Criterial system has been developed with the intention to respect safety functions and related FEPs. The structure of criteria / indicators formalises FEPs relevant for the siting period.

Archiving input data is presently assured just by archiving R&D reports, in hard copies and electronic form.

Record management and discarding plan is obligatory by law and defines categorisation of the records in the "subject groups and subgroups", e.g.: waste management (disposal, storage) repository operation and maintenance, monitoring (radiation and non-radiation, personal dosimetry), RAWRA management and decision making. The plan does not yet contain any specific approach to the geological repository records selection and classification. In fact, it is prepared the GIS system archiving procedure and hydrogeological data database is under development. Safety case related data are to be structured and recorded with respect to their origin, relevance and decision process for their use in safety assessment is to me traced. The process is under development as well.

Safety related calculations have to be performed by a standardised toll / software approved by a SÚJB committee. Calculations in standardized software are in possession of SÚRAO and can be checked for data tracing purpose.

R&D as a support of safety will provide a range of data that shall be used in safety case. The evidence of data, their sorting and assessing their relevance should be solved as a part of quality assurance programme.

The regulation on quality assurance issued by SÚJB provides guidance on data evidence, monitoring and checking, but the compulsory evidence is related just to "special equipment". In geological repository these will probably be container, backfill and sealing, as safety related components. The data will be obligatorily followed in construction, operational and closure phases.

In the stage of siting, regulatory body will follow the decision process and traceability of decisions on the basis of memorandum on partnership between SÚRAO and SÚJB. Furthermore, SÚJB is supported by a supervision group formed in Research Centre Řež. In fact, there exists no legislative support for direct participation of regulatory body in the siting process before SÚRAO applies for land protection at the selected site.

The right to free access to information in the Czech Republic is codified in Act No. 106/1999 which establishes rules for the provision of information and free access to information in compliance with the relevant regulation of the European Community (Directive 2003/98/EC of the European Parliament and of the Council on the re-use of public sector information). The right to information on the environment was established by Act No. 123/1999 in compliance with European Community legislation (Directive 2003/4/EC of the European Parliament an of the Council on public access to environmental information) which sets out rules concerning the right both of access to information on the environment and that in a full and timely manner, the creation of conditions for the exercise of these rights and full support for the active disclosure of information on the environment by those obliged to do so.

Availability of information on the back end of the nuclear fuel cycle and RAW and SNF management forms the primary prerequisite for discussion between all interested parties on solutions to such issues. The principal objectives in terms of communication for all parties responsible for RAW and SNF management consist of continuity, transparency and openness of information. Facilitate access and transparency to involved audiences.

By the Concept of RAW and SNF management, the public will be kept informed on various activities relating to RAW and SNF management, and suitable conditions for the exchange of information and public participation will be created.

The involvement of affected communities and other stakeholders in the decision-making process is an important element in achieving progress in the preparation of any major project. Such an approach to public participation was applied in the Czech Republic for the first time in connection with the EU ARGONA project (the 6th Euratom Framework Programme for Research and Technological Development) as part of which the so-called Reference Group for DGR Site Selection was established consisting of representatives of the state and selected sites and non-governmental organisations. The task of the Reference Group was primarily to open discussions on issues and problems, however minor or non-relevant they might seem, raised by those living in candidate sites. The Reference Group was subsequently succeeded by the working group for Dialogue on the DGR which is made up of, in addition to representatives of the state, representatives from both chambers of parliament, candidate sites and non-governmental organisations. The objective is to design a long-term partnership programme between SÚRAO and the communities affected by the development and subsequent operation of the planned DGR. SÚRAO plans to draft a partnership memorandum the aim of which will be to specify the rights and responsibilities of all the parties involved in the various stages of repository development and operation, to identify the instruments and means of mutual communication and to establish principles governing the financial compensation process.

It will be important to ensure into the future that the working group is able to conduct its activities independently of the state, to clarify the mechanism governing the processing of the results obtained and to discuss the gradual extension of the range of activities undertaken – it is planned that local working groups will be established at individual sites under the umbrella of the current working group.

Full transparency and the active involvement of the communities concerned and the general public in compliance with Council Directive 2011/70/Euratom and recommendations made by European Nuclear Energy Forum working groups make up essential preconditions for a successful and sustainable final decision regarding site selection.

Question 2 B

Missing issues are the source of difficulties in using the results of R&D programme. For safety case, it is necessary to collect and justify input data relevant to evaluated scenarios. R&D presently provides extended information, not fully directly usable in calculation. Specific approach to the geological repository records selection, structuring, justifying and classification, would be helpful. The activities started recently as a support of R&D programme related to safety of geological repository.

Question 3: Requirements management

Question 3 A

To implementers:

The process of geological repository development is fulfilled in more phase, each of them has to be licensed by regulatory body in accordance with Atomic Act. These phases are land use plan development, construction, operation (the license is usually provided for the

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period of five years), and closure. In the process of land use plan development and repository closure, Ministry of Environment controls the EIA process, Mine Authorities are involved in all phases and Ministry of Industry is involved in the activities that are pursued by Construction Act.

Siting, as a phase now realised in the Czech Republic, is not included as a special licensed step. On the other hand, Ministry of Environment has to issue permission on geological research on candidate sites.

Research activities are the basis for safety assessment, submitted to regulatory body and other stakeholders. Safety assessment is the principal tool for optimisation of the repository design. Optimisation is an inevitable condition of project submission.

Technical requirements have to meet the criteria derived from safety constraints. Technical requirements will be formulated as project criteria or indicators using the results of safety analysis, uncertainty and sensitivity analysis, with respect to ALARA principle.

Question 3 B

As it was preceded, the siting process has been interrupted for many years by government decision. All assumptions on project solution of the repository were made using reference values for the repository host structure.

At present, it is necessary to collect real data from real candidate sites which would lead to better experience with the management system, including participation of regulatory body and other stakeholders.

Posiva, Finland

Question 1: General & context

Barbara Pastina Posiva Oy (implementer) Long-term safety manager

In 2012, Posiva Oy submitted a construction licence application for a SNF disposal facility to be constructed at Olkiluoto, Finland. A safety case (TURVA-2012) was compiled to support the licence application. The disposal concept is based on the KBS-3 method. The reference design is the KBS-3V design, where the SNF canisters are emplaced individually in vertical deposition holes positioned along deposition tunnels.

In February 2015, the regulatory agency STUK, submitted to the Ministry of Economy and Employment (who is responsible for granting the construction licence) a favourable statement with respect to the construction licence application. The licensing process is still ongoing as of June 2015.

The future main objective is to receive the licence to construct the repository, which is expected by the end of the year. STUK has formulated a few requirements that need to be fulfilled before the construction starts so they need to be addressed in the next months following the licence.

The next main licensing step is the operation licence application, planned for 2020. Work for the new safety case has started.

Question 2: Information management

Question 2 A

The main information management systems in Posiva are Posidoc and Kronodoc. They are both storage servers, Posidoc is for Posiva staff only while Kronodoc can be access (via a secure code) to key consultants outside Posiva.

Kronodoc and Posidoc are used to store reports, meeting minutes, presentations, correspondence with STUK, working material.

Recently an intranet service has been introduced (TiimiNet) to facilitate the information exchange, such as report working drafts so that multiple people can work on a file at the same time. This is a more informal tool compared with Posidoc and Kronodoc.

Concerning information in the sense of data, the safety case team is developing the "safety assessment database". The purpose of this database is to record the data that are used in the performance assessment and analysis of scenarios (i.e. radionuclide transport models) and to identify how the data are used in the modelling chains. This database is also used as a tool to manage changes in data (for example proposed by the design group). The challenge is to put in place an efficient notification process that can give a quick feedback on the impact of a given change in a parameter and notifies the persons using the parameter so they can provide feedback on the impact of the change in their work.

Question 2 B

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Question 3: Requirements management

Question 3 A

The VAHA ('Vaatimusten Hallinta', i.e. 'Requirements Management' in Finnish) system was officially launched in 2007 to develop the requirements database (Posiva 2012-03). Requirements in VAHA are hierarchically organised according to five levels:

- legal and stakeholders' requirements (level 1),
- requirements applying to the whole disposal system and safety functions for the barriers (level 2),
- barrier-specific long-term performance targets and target properties (level 3),
- barrier-specific design requirements (level 4) and
- barrier-specific design specifications (level 5).

The level 1 requirements arise from laws, decrees, decisions-in-principle and other highlevel stakeholder requirements. Level 2 consists of system requirements as defined by Posiva on the basis of the requirements from Posiva's owners and the regulatory requirements listed on level 1. The level 2 requirements define the EBS components and the functions of the EBS and host rock. The system requirements also define, for example, the maximum quantity of SNF to be deposited.

Safety functions (L2) are high-level descriptions of the role of each barrier in providing long-term safety. Performance targets (L3) for the engineered barriers and target properties for the host rock are derived from each safety function, as required in the

Finnish regulations (STUK YVL D.5, paragraph 407). For the rock barrier, the target properties set the starting point for the definition of the Rock Suitability Classification system (RSC) developed by Posiva. The classification system includes both the updated rock suitability criteria as well as the procedure for the suitability classification during the construction of the repository. The RSC is used to identify suitable rock volumes for repository panels and to assess the suitability of deposition tunnels for locating deposition holes and to accept deposition holes for disposal.

The performance targets have been set to provide the link between the initial state and long-term safety. The performance targets form the basis for the definition of design requirements and the latter define the design specifications, which enable the fulfilment of the performance targets during the long-term evolution of the disposal system. Design requirements and design specifications have to be defined in a way that can be easily verified and controlled in production mode. Performance targets can only be verified through modelling in the performance assessment.

All requirements have to be linked to a higher and lower level requirement to ensure that there are no "orphan" requirements for which the traceability to long-term safety would be lost. The initial state of the disposal system can be affected through the design requirements and system implementation practices (up to the closing and sealing of each deposition hole or tunnel); the degree to which the performance targets are met is evaluated through performance assessment (Posiva 2017-02). In this sense, VAHA is a tool to translate high-level, long-term safety related requirements into design specifications to follow during design, construction and operation of the disposal facility. Therefore, it is also a way to manage the information.

The design basis refers to the current and future environmentally induced loads and interactions that are taken into account in the design of the disposal system, and, ultimately, to the requirements that the planned disposal system must fulfil in order to achieve the objectives set for long-term safety. The design basis report (Posiva 2012-03), which is part of the safety case, documents the safety bases of the requirements at levels 3 and 4 in VAHA.

In defining the design basis, Posiva must, by regulation, on the one hand assess the likelihood of different scenarios and, on the other hand, identify those deemed reasonable and assess those that may be possible but are considered highly unlikely. Although only scenarios deemed reasonable are used as design basis scenarios, scenarios that are deemed unlikely also need to be assessed in the safety case. The performance assessment evaluates the fulfilment of the performance targets by the proposed design. Uncertainties identified in the performance assessment drive the formulation and assessment of scenarios potentially leading to radionuclide releases.

VAHA is organised as a database and it is an internal tool, not accessible by others. One version of VAHA was published for STUK in the design basis reports [Posiva 2012-03] to give a snapshot of the requirements in 2012. Requirements are continuously and iteratively updated due to additional progress in system understanding or feedback from the authorities. It is expected that many updates will happen with the actual construction of the repository and production of the barriers, as operational experience is gathered. Requirements formulation is still ongoing 8 years after the VAHA project started.

Changes are managed through the configuration management system. The configuration management system takes care that any change (in design or requirement) is managed in a systematic way and it is assessed for its impact on the overall configuration. The

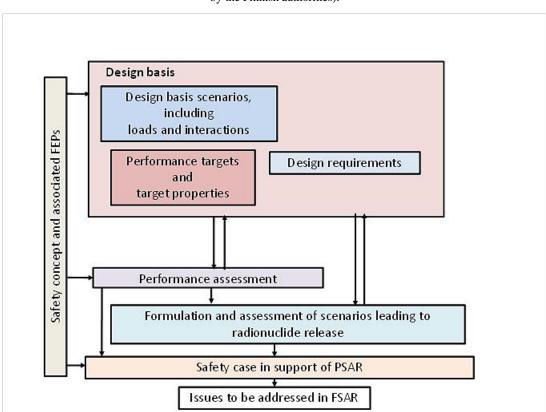
changes are classified into change categories (A, B, C, D) depending on their impact on the configuration (hence on safety). The larger the impact the higher up in Posiva's hierarchy the change will be assessed. The challenge is to ensure that the changes are correctly classified and that subtle changes that might have an impact on safety are identified. This has to be the work of a group that has a holistic view of the system and knows how the design data are used in the safety case.

Iteration between requirements formulation, safety assessment and design

The development of a hierarchical and comprehensive system of long-term safety requirements for a disposal alternative that has been innovated and refined for more than a decade unavoidably entails significant iteration between requirements formulation, safety assessment and design development. A similar iterative process was also identified in the development of the TURVA-2012 safety case, which fed into the Preliminary Safety Analysis Report compiled for the construction licence application (Figure 1).

The continuous iteration between long-term safety requirements formulation, design and implementation is necessary yet challenging as design development often occurs at the same time as requirements development. Ideally, the requirements should come first and the design develops later but, in practice, it is done in parallel and even design requirements may be set prior to long-term safety requirements. This was noticed, for example, already at the time the VAHA requirements management system was established. One key task at the beginning of the VAHA work was to collect requirements of various types from various sources and to develop the five-level structure for requirements that were at least partly formulated long before the VAHA project started. Some design requirements and specifications were developed from earlier iteration loops of long-term safety, design and production that were only partially reported. For example, the thickness of the buffer rings around the canister was defined around 1983 based on the canister diameter assumed at that time and on the diameter of a deposition hole that was considered feasible to construct using the boring methods available in 1978, i.e. when the 1.5 m deposition hole diameter was first proposed. Subsequent safety analyses have shown that this thickness is adequate and it has remained the same for over 30 years. Clearly, that would not be the case if the thickness had been found unsuitable for longterm safety. It is also important to acknowledge that the KBS-3 method, with its barriers and their specifications, aims specifically at providing long-term protection from the hazards of the SNF. All design work, therefore, has its basis on long-term safety requirements, even if these requirements have been considered implicitly in some stages, only to be explicitly tested in safety assessments. Furthermore, the regulatory requirements are themselves evolving along the development of the repository programme and this introduces additional hurdles to requirements management and design development work. If the design is developed before the final long-term safety requirements are available, this introduces the risk of developing a design that no longer fulfils these requirements. A close co-operation between long-term safety, design and implementation is to be encouraged to avoid such risk. Furthermore, a close co-operation among barrier-specific experts is also to be sought since setting requirements on a given barrier has implications on other barriers. In Posiva's case, the VAHA system can be conceived as a tool to manage the requirements and provide traceability and as a communication tool between long-term safety and design and development work.

Figure B.6. The development of the repository system as an iteration between requirements, designs and safety assessments



PSAR = Preliminary Safety Analysis Report for construction licence application and FSAR = Final Safety Analysis Report for operating licence application (the main safety documents required by the Finnish authorities).

Question 2 B

Some of the design requirements and design specifications were developed since the 80s, well before the introduction of terminology such as safety function and performance targets. Some requirements on the barriers were driven by long-term safety while others were driven by operational safety or practical considerations (e.g. there has to be a handle on the canister to allow retrieval, if necessary). Therefore, there was a need to develop a requirements management system. The VAHA project was started in 2007 to establish the requirements data base. The regulatory agency STUK has its own requirements management database to check that all the requirements in its regulations are fulfilled and to facilitate the licensing review process.

The VAHA work turned out to be much more demanding than it had been expected as there were many requirements that had different purposes, some did not have any clear rationale, some were very details and others very general, many were poorly formulated (see challenges below). Nonetheless work started and developed iteratively along with design and safety case.

When STUK required in 2010 that Posiva should not only report the performance targets (linked to the safety functions) but also show how these were fulfilled, that also led to

significant changes both in the structure of the SAFCA portfolio and in the priority of the VAHA work. From that time on Posiva had to work on the VAHA contents while checking that the requirements formulated would also be feasible for implementation. The addition of the design basis report, documenting the safety bases of the requirements at level L3 and L4 in VAHA to the SAFCA report portfolio greatly helped clarifying some of the requirements bases and improving them. However, the reasoning behind some requirements still remained rather vague because they were introduced before the implementation of the VAHA system and traceability was lost.

The shift to requirements-based work at Posiva brought about an important improvement in the integration of the R&D with the safety case at Posiva. However, several important requirements still need clarification, in particular as regards the criteria for the requirements verification.

Since geologic disposal is a first-of-a-kind project there is lack of operational experience in general and also in requirements setting and management process. A further challenge is that quality standards for requirements verification are often missing or have to be modified from other applications (e.g. nuclear power plants).

Furthermore, requirements formulation and requirements management is a specialised field of project engineering. The lack of experience in requirements formulation, verification and requirements management in general became quickly apparent in the first versions of VAHA. For example, the initial formulation of requirement was often unclear, more than one requirement were lumped together and the requirement hierarchy (high-level requirements all the way to design specification) was not sufficiently established. This caused several problems for the requirements interpretation, verification and implementation level. STUK commented that the link between long-term safety and design requirement was not visible. Furthermore, requirement formulation and management require effective co-operation between long-term safety, design and production/construction in order to achieve the desired level of specificity, clarity and effectiveness of requirements. Furthermore, requirements also require collaboration among different barriers as the requirements on one barrier affect those on others.

There are many other requirements than long-term safety requirements to be managed, for example operational safety requirements and "functional" requirements (e.g. make sure that the equipment can fit in the tunnels). The plan is to merge all these requirements into one database but this has not yet happened.

There will be situations in which different requirements might be in conflict. For example, operational safety related requirements might be in conflict with long-term safety related requirements with respect to rock support (through bolting or netting or shotcreting).

Question3: Requirements management

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Andra, France

Question 1: General & context

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Jean-Noël Dumont Special Advisor, Programmes Division jean-noel.dumont@andra.fr

Andra is recognised today in France and worldwide for its expertise and advice in the field of management, design and disposal of radioactive waste.

Andra (National radioactive waste management Agency) is responsible for:

- Producing and publishing the inventory and the locations of radioactive materials and waste in France,
- · Steering research and studies on storage and deep geological disposal,
- Designing, installing and managing storage facilities or disposal facilities for radioactive waste taking account of long-term prospects for production and management of this waste and to carry out all the studies necessary for this purpose,
- · RWM and remediation of orphan radioactively polluted sites,
- Providing the public with information about the management of radioactive waste.

The future major objectives of Andra are:

- Continue to develop the Cigéo Project for the disposal of High Level Waste (HLW) and Intermediate Level Long-lived waste (ILLW) that has gone from demonstration of feasibility in 2005, based on the URL, to the Cigéo Project, now in the industrial design phase.
- Continue to develop the FAVL project (disposal of Low-Level and Long-Lived waste).
- Develop the pre-disposal activities for the Agency such as storage, sorting and treatment and control of waste, including the construction of new facilities and an R&D programme that now covers all actions linked to the optimized management of radioactive waste.
- Maintain the dissemination of the Agency's know-how internationally both from an institutional and scientific stand point and from a commercial one to promote in all countries a safe and responsible management of radioactive waste.

Question 2: Information management

Question 2 A

The approach to the project for a future geological repository led by Andra includes the overall elements that are advocated today for the success of such an undertaking. The system is based on a few simple principles, as follows:

- a clear description of responsibilities, duties and functions of every organisation involved in RWM;
- a stepwise decision-making process: the project was marked by periodic milestones in order to take stock of the progress achieved through the research, studies and investigations, before proceeding forward to the next step;
- information and transparency, notably through the implementation of appropriate authorities, both at the national level, pursuant to the "Act on Transparency and Security in the Nuclear Field" (Loi sur la transparence et la sûreté nucléaire) [30], and at the local level, via the CLIS (Local Information & Oversight Committee of the Bure URL);
- control systems, whether scientific and technical or safety related in nature;
- the development of host territories and the financing of research and activities with the securing of appropriate funds to build and operate the repository.

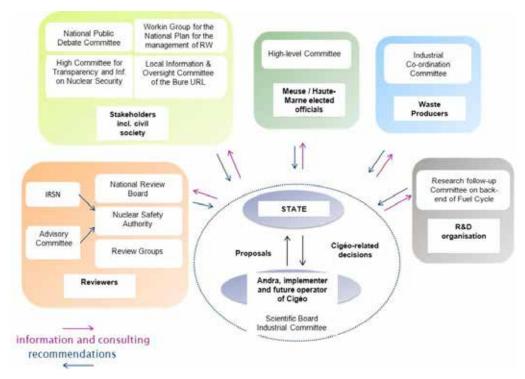


Figure B.7. Framework of French organisations involved in the DGR development

Scientific knowledge and phenomenological assessment

Since 1991, Andra has operated a major research programme on the study of geological disposal. This is in addition to the work aimed at characterising the geological medium of the Meuse/Haute Marne site. Studies and research are also carried out on data acquisition on the waste packages and repository construction materials, on their behaviour in the repository and their evolution under the effect of interaction between components.

Over the last 20 years, Andra's R&D work programme has substantially called on the French and international scientific community. Many scientific collaborations with French and international scientific partners, as well as exchanges with foreign counterpart agencies or organisations were developed (some hundred laboratories are regularly

associated with the research programme, laboratory consortiums exist for dedicated topics, Andra actively takes part in the several EC programmes in the field, etc.).

In addition, a support policy for doctorate and post-doctorate theses has been implemented. In 2012, evaluation of Andra's research work by the French Evaluation Agency for Research and Higher education (AERES) underlined Andra's research strategy efficiency and dynamism; among others integration of multidisciplinary scientific expertise and exceptional technical control were highlighted as Andra's R&D work strong points.

More generally, Andra's scientific activities are followed up by a Scientific Board (created by the 1991 Law) whose members are designated by a ministerial decree for a five year period. To accompany more specifically the scientific programme established in the Meuse/Haute-Marne site and URL, Andra created an orientation and monitoring committee (COS – Comité d'Orientation et de Suivi) consisting of ten French and foreign members, originating from the academic world and well-known research establishments.

To assess the safety of a repository, it is necessary to thoroughly understand the properties and evolutions of the repository's various components up to very long time scales. Such knowledge allows the assessment of the repository safety on a sound scientific basis. Andra's scientific knowledge and know-how for phenomenological assessment is briefly presented below.

Phenomenological Analysis of Repository Situations (PARS)

As a first step towards safety assessment, Andra's approach is based on a description of phenomenological evolution of the repository, based on current scientific and technological knowledge and taking into account all kinds of associated uncertainties. Describing the phenomenological evolution of a set of engineered and natural components means an overall knowledge of all the processes governing the evolution of the repository and their coupling (in space and in time).

The main phenomena affecting the repository must therefore be successively dealt with while focusing on their implications on other processes. For this reason, the thermal, hydraulic, chemical and mechanical phenomena processes are dealt with before those associated with radionuclide release and transfer.

In order to appraise the repository complexity, Andra developed a specific methodology, called PARS, for complete and continuous analysis of phenomenological evolution of repository situations.

PARS provides a consistent basic representation of the repository and its expected geological environments ("most probable" or "normal") thermo-hydro-mechanicalchemical evolution; it also deals with knowledge uncertainties (on processes, models or parameters).

PARS is based on a breakdown of the evolution of the repository in different situations: each of these situations corresponds to the phenomenological state of part of the repository or its environment at a given period in the repository lifetime and reflects the thermal, hydraulic, chemical and mechanical phenomena involved with their chronology and coupling (coupled or independent phenomena, concomitant or sequenced phenomena). This multi-discipline assessment takes into account different kinds of consistent arguments (scientific knowledge, in situ experiments, numerical modelling...).

The PARS analysis provides:

- results that can be used directly for design studies of the repository and its engineered structures;
- elements of analysis on the influence of the operations and reversibility duration with regard to the different phenomena;
- input data for modelling and digital simulation of the phenomena and their interaction, in view of safety analysis in particular.

Two principles underline PARS:

- a need for completeness in order to meet the safety analysis requirements,
- a need for the traceability of the hypotheses and choices made during the research process in order to update the analysis as new knowledge is acquired and the project develops.

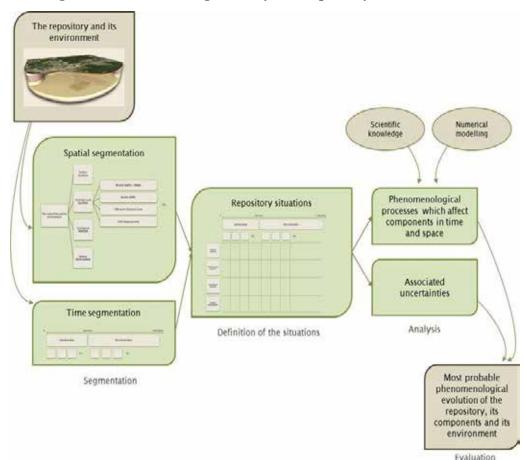


Figure B.8. Phenomenological analysis of repository situations (PARS)

Knowledge reference documents (input for PARS)

PARS input data, beyond repository general architecture and definition of components is Andra's acquired scientific knowledge. This knowledge acquisition is documented in the four following references:

"Materials of a waste repository reference document", grouping the data related to the behaviour of the materials used for the construction of the repository (3 volumes: steel, concrete, clay and backfill materials) in expected repository conditions;

- "Radionuclides and toxico-chemical elements behaviour reference document", which covers the data related to the physical and chemical behaviour of the radionuclides in expected repository environments (2 volumes: intrinsic behaviour in repository conditions and thermodynamic & kinetic parameters);
- "Source term modelling of waste packages reference document", which summarises the knowledge and models of waste behaviour in the repository environment (4 volumes: HLW, LL-ILW, SF and graphite waste);
- "Meuse-Haute-Marne Site reference document", which covers the data related to the geological medium and the biosphere.

Andra's scientific knowledge documentation

These reference documents are regularly updated since their first edition in 2005; currently, a new version is ongoing as support documents for the preparation of the licence application.

At this point, it should be noted that except for the "Meuse/Haute-Marne site reference document" and the "Radionuclides and toxico-chemical elements behaviour reference document", these reference documents are geological setting independent and are therefore of value for a repository in any geological setting.

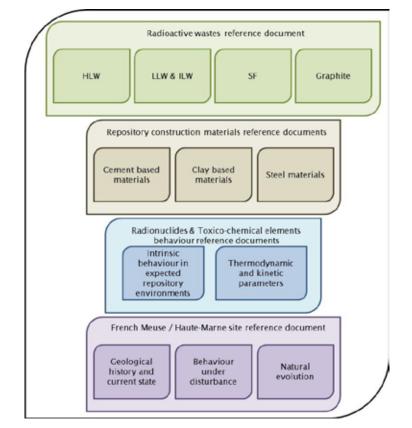


Figure B.9. Reference documents about Andra scientific knowledge for DGR development

Scientific knowledge management

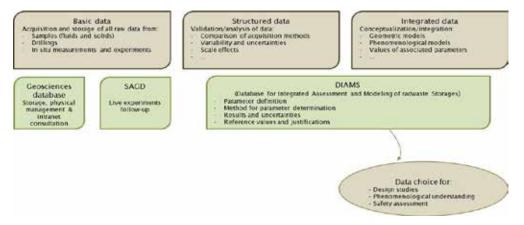
Andra's scientific knowledge is built on the basis of a huge amount of data acquired through numerous investigations, experiments, works and studies. As an illustration, over the last 20 years, more than 600 drill holes were implemented, about 45'000 solid samples and 13'000 liquid samples were analysed and around 15'000 files of in situ measurements and 30'000 pictures were registered. Managing, structuring and integrating all these data is essential for traceability and justification of the data chosen in the different applications such as phenomenological evaluations, design studies or safety calculations.

To this end, Andra developed specific data management tools:

- GEO and SAGD databases which are dedicated to raw data acquisition, storage and consultation;
- DIAMS (Database for Integrated Assessment and Modelling of radioactive waste Storages) in which raw data are analysed, structured and integrated in a way that it helps for choosing the model or the value of a parameter to retain for phenomenological assessment, design studies or safety assessments ant that the choice is traceable and justified.

articulation Andra currently pursues the formal of the whole acquisition/structuring/integrating/tracing/justifying/using ISIS called process, methodology (Integration and Structuring of Scientific data), in particular through a review process of data and models by internal experts of the different "information users" (i.e. design studies, phenomenological evaluation, safety assessments) at the different stages. Reviewers have stressed the importance of ensuring such an integrated, traceable and consistent knowledge management approach. Indeed, it is crucial to put in place early in the process such an integrated traceable scientific knowledge management adapted to the specificities of a geological repository (e.g. numerous various data acquired progressively, input data for safety assessment and with the duty to ensure long-term memory).

Figure B.10. Scientific knowledge management according to Andra ISIS methodology: from acquisition to utilisation



As already explained, sound scientific knowledge and know-how for phenomenological assessment, constitute an essential input data for design studies and safety assessment. A major part of Andra's technology in this field, which can be qualified as "generic", constitutes a valuable basis for a disposal facility project, and is applicable to any geological setting and/or the type of waste.

B. Have you experienced any difficulties in the management of information or in the development and/or implementation of adequate management tools in the course of the programme?

What are the future challenges regarding this management?

Andra has developed two main projects regarding challenges for management of information:

- 1. ISIS project : to ensure a rigorous management and use of scientific data
- 2. Memory project : to perpetuate memory of knowledge and information over several centuries

ISIS Project: This project has been developed to improve traceability and justification of data taken into account in conceptual models, design studies, safety calculations,

Andra's scientific knowledge is built on the basis of a huge amount of data acquired through numerous investigations, experiments, works and studies. As an illustration, over the last 20 years, more than 600 drill holes were implemented, about 45'000 solid samples and 13'000 liquid samples were analysed and around 15'000 files of in situ measurements and 30'000 pictures were registered.

The known difficulties were:

collecting all raw data in the databases is not easy for some of them (data partnerships, theses, etc. ...),

• the level information for reading and understanding the raw data files and getting the traceability of the processing and analysis was often limited, requiring return to the technical reports or specifications

To ensure a rigorous management and use of scientific data and to justify the selection of the data to be used in various calculations (e.g. calculation of performance, safety assessment of the repository...), Andra has developed a quality method of traceability of its scientific data and knowledge.

This approach is called ISIS and aims to

- Trace the different stages in data processing from the acquisition of data to the use of data in various applications (models, analyses);
- Trace the analyses (including methods, critical analysis of data, uncertainties) which lead to information and scientific knowledge;
- · Provide a smart and easy access to all data through ad hoc data bases; and
- Ensure the consistency between data bases and knowledge bases and between data users and data bases managers.

ISIS mainly concerns the data characterising the geological environment, the EBS and the initial state of the environment:

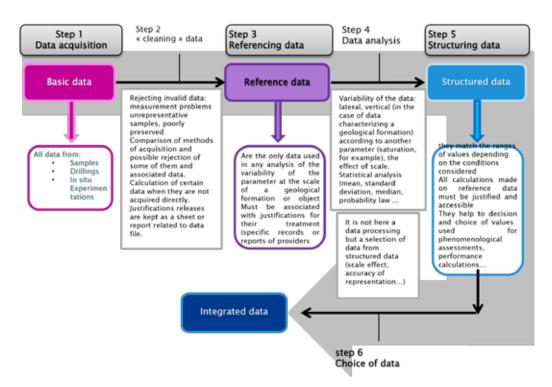


Figure B.11. Data flow in the Andra ISIS methodology

Memory project:

Andra need to develop solutions for memory requirements of the repositories, these requirements include information and knowledge keeping during some centuries:

For the French surface repositories (CSM and CSA), Andra need to provide information over at least 3 centuries after closure: existence and content of the repository and knowledge in order to: understand, correct, transform.

For a future DGR in France, Andra need to provide information and knowledge for over at least 5 centuries (Safety Guide).

The Andra reference solution for surface repositories is organised with six mechanisms:

Three "passive-memory" mechanisms on permanent paper:

- Detailed memory : Hundreds of volumes
- Summary memory : 1 volume (decision-makers/public)
- Easements (land registry) : above- and below-ground use Three active memory" mechanisms (oral transmission):
- Informing the public
- Roles of the LICs (Local Information Committee)
- A 10-yearly evaluation: meeting the needs of future generations

One of the difficulties for this solution was to select and organise all the information (hundreds of volumes) needed for a sufficient knowledge during the next three centuries. A first selection has been done for CSM and a first review was performed in 2012.

The next challenge is to consolidate the reference solution for the CSM repository, according to the results of the last review:

- Select and add new documents (historical context, pictures ...)
- Improve the search methodology into the Detailed Memory
- Development of a Key Information File, on an international basis

Future challenges

One of the main future challenges (regarding the management of knowledge and information) is the management of rapid increase of information in projects:

The project for the future DGR in France (Cigéo) produce during one year more data and documents than the production of all the pre-operational and operational phase (30 years) of the first surface repository (CSM).

The management of all the data (and knowledge) including acquisition, traceability, use, long-term conservation... become more and more complex and requirements are also steadily increasing during the same time.

Q3 Requirements management

A. What tools/processes have been implemented to ensure that the geological disposal programme proceeds in a manner that complies with the requirements imposed e.g. by the legal and regulatory framework and by other interested stakeholders, as well as the more technical requirements that may emerge in the course of the programme, e.g. from design development and associated research activities?

The requirements of the geological disposal programme are established from various sources:

• The legal and regulatory framework, which concerns mainly safety but also reversibility (see below).

- The local stakeholders framework: siting of the underground and surface facilities, access to information (namely on environment impact, nature and quantity of waste to be disposed of), participation in decisions (namely on the definition of the siting zone), economic impact for the territory
- The waste producers framework: nature, quantity and fluxes of waste packages to be disposed of, cost management.

Concerning safety:

Andra's overall safety approach is schematically presented on next figure. This safety approach is common to the various types of disposal facilities Andra is in charge of¹³.

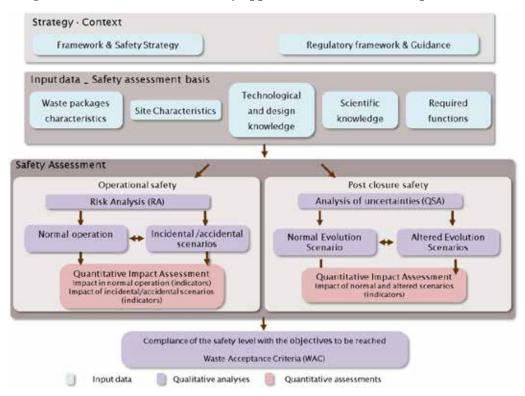


Figure B.12. Andra's overall safety approach for radioactive disposal facilities

This approach is implemented iteratively at each step of the development of the program, according to a loop as presented:

^{13.} Apart from the Cigéo project, the existing disposal facilities of very low, low and intermediate-level short-lived waste disposal facility (i) CSM located in the Manche district near the AREVA La Hague reprocessing facility, now in the post-closure monitoring phase, (ii) CSA, located in the Aube district, under operation and (iii) Cires, also located in the Aube district and under operation and disposal facilities under study of low level and long lived waste.

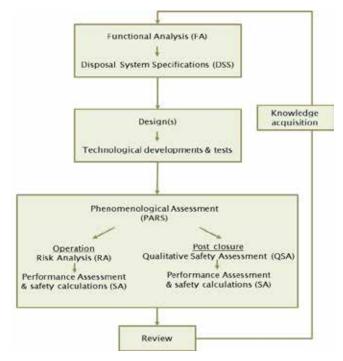


Figure B.13. Andra's iterative development process

Concerning reversibility:

The 28th June 2006 Act requires that the disposal be "reversible", for a duration "not less than 100 years". More detailed requirements for reversibility are due to be fixed by a future act, before the licence for construction. In the meantime, Andra has established a set of proposals for reversibility, taking account of the results of exchanges with the various stakeholders since the 28th June 2006 Act, including the public debate held in 2013. The corresponding reversibility requirements have been integrated in the disposal system specifications.

Overall:

The safety approach, applied and developed by Andra for more than 20 years, was submitted at different stages of the Cigéo Project to evaluation by the Nuclear Safety Authority, ASN and its technical support organisation, IRSN and twice to international peer reviews which accorded its strong endorsement. More recently, in connection with the industrial phase, three project reviews, involving outside experts from the industrial realm, have been held. The steps already achieved are recapped in next table.

Cigéo Project's iterative development process: chronological milestones already achieved regarding requirements compliance:

Table B.2. Chronological milestones of the Cigéo project regarding requirements compliance

1996	Application submitted to the government in order to build an Underground Research Laboratory (URL) on the 3 initially studied sites, presenting initial design options taking into account the configuration of the potential sites, the compliance of these host sites with the safety requirements and a preliminary long-term post-closure safety evaluation In 1998, Government selected the Meuse/Haute-Marne site for implementation of an URL.
2001	Publishing of the "Dossiers 2001" [generic granitic site and Meuse/Haute-Marne (clay) site], presenting the acquired knowledge and providing a preliminary long-term post- closure safety assessment of the preliminary repository concepts
	Detailed review by the French Nuclear Safety Authority (ASN), the French National Review Board (CNE) and an international peer review conducted under the aegis of OECD/NEA.
2005	In accordance with the "1991 Law", issue of the "Dossiers 2005", on feasibility of a geological disposal facility (GDF) for the Meuse/Haute-Marne (clay) site and for a generic granitic site,
	 Reviews of the "Dossiers 2005" by the French Nuclear Safety Authority (ASN), by the French National Review Board (CNE), the Parliamentary Office for Scientific and Technological Options (OPECST) and an international peer review conducted under the aegis of OECD/NEA
	Public debate on waste management policy in 2006
	Publishing of the resulting Planning Act in June 2006
2009	Proposal for a suitable restricted interest zone (ZIRA) for the geological disposal facility (GDF) implementation on the Meuse/Haute-Marne site, including operational safety analysis of surface and underground facilities and post-closure safety assessment for zone selection.
	March 2010, approval by the government after consultation with the different assessors and local elected officials, launching the industrial project Cigéo.
2011	Reference safety guidelines (including fire rules) within the disposal system specifications for the industrial design phase. First project review (20 experts), before launching the invitation to tender for prime contractor.
2012- 2013	 Outline phase reviews: Review of the operational safety analysis by the French Nuclear Safety Authority (ASN). Detailed reference safety guidelines (including fire rules) for operation, as an input for the next industrial design phase, were drawn up by Andra in 2013. Second project review, for validation of the design options resulting from the outline phase, before launching the preliminary design.
2013- 2014	Public debate on Cigéo.
2015	Completion of the preliminary design phase Third project review (30 experts), for validation of the results of the preliminary phase

and definition of the input data for the detailed design phase.

Question 2 B

A first challenge for Andra during the course of the programme has been incorporating new knowledge in the design studies. Along the development of the project, knowledge increases and the design evolves, as a result from studies and research. This requires taking into account the necessary modifications while keeping a stable set of input data for the studies still running. Added to the technical consequences of design input modifications are contractual and financial consequences. The reviews before launching each phase of the industrial design (outline, preliminary design, detailed design) aim at addressing this issue, fixing as far as possible the input data for the duration of the next phase. Nevertheless, adjustments have to be performed during the course of each phase.

A second challenge is the large variety of stakeholders behind the requirements. Design implies setting trade-offs, between requirements of different nature (operational/long-term safety, reversibility, operational cost, investment cost, environment impact, etc.). A role of Andra is to create the conditions for the best trade-offs, by meeting regularly the various stakeholders (local, waste producers, regulators...), in order to achieve a shared view of the requirements to be written in the disposal system specifications, and avoid as much as possible later changes. This applies, for example, to interpretation of the safety regulation.

A third challenge is the size of the project, which increases in the course of the programme, and for which the necessary qualifications move. At the early hours of the program, research and feasibility design, co-ordinated within a project of moderate size, constituted the major qualifications required, directly managed within Andra. Since the industrial project Cigéo was launched, the manpower and qualifications within the company are not sufficient, despite an intense recruitment effort. Therefore it was decided to contract with companies for the design of the repository. However, specific parts of the design studies cannot be contracted, for example post-closure safety, for reasons both of expertise and of responsibility (nobody can bear responsibility over centuries and millennia, this has to be kept within the state responsibilities, borne by the state-owned company Andra). This has introduced a new challenge, which is to manage teams of different cultures within and outside Andra, to identify clearly design features that have to be imposed by Andra, to transfer to contractors and subcontractors the knowledge they need for the studies, to inform them of the possible flexibilities and of imposed solutions, and to correct misinterpretations in due time when they occur.

Question 3: Requirements management

Federal Office for Radiation Protection (BfS), Germany

Question 1: General & context

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The Atomic Energy Act (Atomgesetz – AtG) gives the responsibility for the disposal of radioactive waste to the Federal Government with BfS as the responsible authority (implementer).

Radioactive waste disposal policy in Germany is based on the decision that all types of radioactive waste are to be disposed of in deep geological formations. Intermediate-level waste has been disposed of in the Morsleben Disposal Facility and in the Asse Salt Mine. The Konrad Disposal Facility is licensed to dispose of waste with negligible heat generation. For heat-generating waste a site-selection procedure is under development.

Morsleben Disposal Facility

The former Morsleben salt mine was used as repository for low- and intermediate-level radioactive waste from 1971 until 1998. An application for the licensing procedure for closure was already filed on 9 May 1997. The respective documents were published in 2009. In 2011, a public hearing was organised to discuss objections addressed by citizens that are concerned about the project. Technical installations and residual mine openings of the ERAM (Endlager für radioaktive Abfälle Morsleben) will remain in operation until the start of the closure measures after completing the plan-approval procedure for the closure of the ERAM.

2012. During the German Nuclear Waste Management Commission (Entsorgungskommssion - ESK) reviewed the Safety Case for the Morsleben disposal facility. This Safety Case has been finished in 2009 and serves as a basis for licensing the final closure of the disposal facility. Taking into account the German Safety Requirements for the Disposal of Heat-Generating Radioactive Waste issued in 2010 the Commission gave six recommendations to strengthen the Morsleben Safety Case to fulfil the state of the art which has been evolved since 2009. This shows the difficulty involved in a long-lasting licensing procedure. It will postpone the licensing of the closure for at least 5 years.

For further information see http://www.bfs.de/en/endlager/endlager_morsleben.

Asse Salt Mine

The former Asse salt mine was used from 1967 to 1978 as disposal facility for low- and intermediate-level nuclear waste and as an URL. In 2009, the BfS took over responsibility for the Asse II mine, holding a licence under the Atomic Energy Act and the Mining Law.

In April 2013, the so-called "Lex – Asse" (§ 57 b AtG) was implemented that requires the retrieval of the radioactive waste before decommissioning the mine. The first exploratory drilling for the planned new recovery shaft (shaft Asse 5), which is required for the transport of the waste to the surface, started in June 2013. To investigate still existing uncertainties relating to the retrieval, the trial phase continued in 2014 with a third drilling in order to investigate emplacement chamber 7 at the 750-m level.

Since summer 2013, the brine intrusion on the 658-m-level is labile. The development of brine intrusion cannot be predicted. Nevertheless, the mission by law requires the immediate and parallel push of the retrieval measures (interim storage for waste, new shaft, technology for waste recovery).

Simultaneously, precautionary measures to stabilise the mine and to minimise the consequences of the possible flooding are implemented. For further information see http://www.asse.bund.de/EN.

Konrad Disposal Facility

The Konrad Disposal Facility had been licensed on 22 May 2002 as a disposal facility for all kinds of radioactive waste with negligible heat generation. Since the licence was confirmed by the Federal Administrative Court on 26 March 2007, the BfS is in charge of converting the former iron ore mine into a disposal facility. For further information see http://www.endlager-konrad.de/EN.

Disposal Facility for Heat-Generating Waste

In order to find a suitable site for a disposal facility for heat-generating waste and in accordance with the Act on the Site Search and Selection of a Repository for Heat-Generating Radioactive Waste (Repository Site Selection Act) a committee has been set up in order to evaluate the Repository Site Selection Act and to propose/recommend a procedure for the site-selection process as well as to draw up and present proposals concerning inter alia safety requirements and geological selection/exclusion criteria by the end of 2015. The committee consists of 33 members representing different parts of society, i.e. science, public groups, Bundestag and Bundesrat and commenced operation in May 2014. The German Bundestag will decide on the major steps of the site-selection further information about committee. process. For the see http://www.bundestag.de/bundestag/ausschuesse18/a16/standortauswahl.

Between 1979 and 2000, the Gorleben mine was investigated for its suitability to host a repository for high-level radioactive waste. Exploration work discontinued between 1 October 2000 and 30 September 2010 (Gorleben Moratorium). On 1 October 2010, the BfS had resumed the exploration activities. In November 2012, all exploratory work at the Gorleben mine discontinued again and was terminated on 27 July 2013. According to the Repository Site Selection Act the Gorleben mine will be included in the site-selection process. The Gorleben mine needs to be kept open for as long as the Gorleben site will not be ruled out in the site-selection procedure. According to the agreement of the Federal Government and the federal state of Lower Saxony in July 2014 the mine workings, which have been kept operational, will be reduced to a minimum, for further information see http://www.bfs.de/en/endlager/gorleben/offenhaltung.html.

Question 2: Information management

Question 2 A

Regulatory requirements

First to mention are the Safety Requirements Governing the Final Disposal of Heat-Generating Radioactive Waste as of 30 September 2010. The safety requirements set out the safety standards that a repository site for heat-generating radioactive waste in deep geological formations must demonstrably comply with the atomic energy legislation.

According to the safety requirements the applicant/operator shall set up a safety management system, which is maintained throughout all phases of the final repository project until decommissioning is complete. He shall make it a top priority to guarantee and continuously improve safety over other management targets, and shall support the development and maintenance of a vigilant safety culture. Safety management must be designed to ensure high levels of trust in the quality of the organisation and in the observance of all safety requirements and existing limits, guidelines and criteria. It must ensure that the operator organisation's safety standards can be continuously assessed by all parties involved in the light of advancing information. Responsibility for the implementation, performance and promotion of safety management lies with the management of the operator organisation. The various management levels within the organisation must promote and support safety management.

All data and documents relevant for the safety statements and for future assessments and decisions must be documented prior to completion of decommissioning. In particular, this shall include:

- The mine survey data for the final repository, including its historical development
- All relevant information regarding the individual waste stored, including its safety-relevant properties
- Planned and executed technical measures during the construction, emplacement operations and decommissioning of the final repository
- The results of all measurement programmes
- · All forecasts made regarding developments in the repository mine and its environment
- All records kept regarding operational safety and long-term safety.

All partial documentation shall, as a minimum requirement, include the relevant events, data and results, the underlying assumptions and framework conditions, documentation of the calculation programmes used, and a description of how the results were obtained.

The documentation shall be updated at regular intervals, whereby out-of-date partial documents shall be left in a suitable format as part of the document set.

Regarding the manner and location of storage, care shall be taken to ensure that all document sets are readily accessible at all times using the currently available technology. The principle of diversity must be observed.

For the period after sealing the final repository, prior to decommissioning, regulations shall be adopted concerning the scope, preservation and accessibility of the documentation to be held on file by the Federal Government by arrangement with the licensing authority. The documentation to be held on file after sealing the final repository must contain all data and documents from the documentation updated during the operating phase which could contain relevant information for future generations. In particular, this should include information regarding the area surrounding the repository mine that must be protected from human intervention in the deep subsoil, and which types of intervention must be subject to special conditions.

Complete sets of documents must be stored in at least two different suitable locations.

Regulations and actions within the organisation / Implemented management tools:

For each project, a file plan exists representing the project structure plan in order to facilitate the allocation of the documented information to logic units. Reference numbers within the file plan reflect the structure of the project to enable a logic allocation of documents to the corresponding file plan number. A record list refers to the file plan and represents the inventory of files, displaying the title of files, time period of filed data, status of documents, number of files and location of hard copies. Individual documents are accessible via an electronic document management system. This management system provides metadata and displays revision processes as well.

Regulations are given for instance, by the regulator in case of the Konrad project where the licence that has been granted includes a clear prescription and requirements of the documentation.

The Safety Standards of the Nuclear Safety Standards Commission provides the KTA 1402 (2012-11) "Integrated Management System for the Safe Operation of Nuclear Power Plants". This standard applies to the planning, execution, checking and improvement of activities that have a direct or indirect influence on the safe operation of stationary nuclear power plants with light-water reactors. As no explicit equivalent standard to RWM exist, the application of the KTA 1402 is compulsory for disposal projects in Germany in order to make sure that documentation is traceable, complete, consistent etc.

The Handbook on Nuclear Safety and Radiation Protection (RSH) contains legal and sublegal regulatory documents applicable in Germany. The documents concern to the fields of nuclear safety, disposal and transportation of radioactive material as well as protection against ionising and non-ionising radiation. In addition, the Handbook offers international provisions and further information about nuclear technology and radiation protection. In chapter 3-9.1 the RSH refers to principles on the documentation of technical documents, dealing with the arguments on documentation like purpose, duties and responsibilities, availability, start, content, extend, revision, storage, saving, management and providing information.

Measures to ensure consistency of documentation are taken by browsing through relevant documents with the purpose of a consistency check. Consistency checks are done within the quality assurance procedure when passing thru the approval check points for the very document and the relating / cited ones.

Further consistency checks referring to a larger field of documentations generally will not be executed periodically but will be performed in case new information will or might lead to changes (e.g. conceptual changes) and provoke inconsistency.

Internal instruction regarding written material regulates the treatment of all kinds of information that that is generated or received regardless of the type of media the information is provided on. The organisational units compile files according to the file plan and are responsible for the identification of the files.

A quality management system is in use, wherein a corresponding quality management manual describes the internal processes that are necessary to pass documents.

Organise information in such a way that it provides guidance and a framework for decision making.

Regulatory requirements

The Safety Requirements Governing the Final Disposal of Heat-Generating Radioactive Waste as of 30 September 2010 state:

A safety management system shall define a strategy and processes to achieve reliable implementation of the safety requirements and continuous improvement in the safety standards of the final repository. This shall also include monitoring the achieved status and initiating concrete processes for improvement.

Safety management comprises the entirety of activities for the proper planning, organisation, management and control of individuals and work, including the necessary processes for advance planning and supply of the necessary personnel, organisational and financial resources, an adequate infrastructure and a work environment that promotes safety, as well as for regulated co-operation with external organisations.

The concept and design of the final repository shall be developed on a step-by-step basis, having weighed up the optimisation targets listed below. Additionally, while operational, the final repository shall be continuously optimised in accordance with the principles of radiation protection and from a safety management viewpoint.

Before making any major decisions regarding the subsequent approach, optimisation shall be performed on the basis of safety analyses and safety assessments including an analysis of possible alternatives. The depth of such investigations shall be based on the safety relevance of the respective decision.

Operation of the final repository shall be measured against similar requirements as the operation of other nuclear facilities.

Prior to any major decision a comprehensive, site specific safety analysis and safety assessment covering a period of one million years must be carried out to provide evidence of long-term safety. This shall comprise all information, analyses and arguments verifying the long-term safety of the final repository, and shall justify the reasons why this decision has been taken.

A safety management system must be set up to achieve safety management. This system must include all specifications, regulations and organisational tools for the handling of safety-relevant activities and processes. All its elements must be derived and justified in an accountable fashion. Interactions, interfaces and delimitations between different processes shall be designed and described in a logical fashion.

The safety management system is an integral component of the overall management system. It must reflect the state of the art as well as the relevant regulations. This integrated safety management system and the processes implemented must be documented in a verifiable format.

The organisational structure of the applicant/operator must be geared to the safety objectives.

It must:

• specify clear responsibilities for content and processes

- promote the gradual optimisation of the project with due regard for continuous advancements in information and findings
- support the internal and external, disciplinary and interdisciplinary exchange of information
- adopt a transparent approach to obtaining, processing and documenting data and results, and
- promote self-critical conduct and a critically inquisitive attitude among all employees, as well as relationships based on trust throughout all areas of the organisation.

All data and documents relevant for the safety statements and for future assessments and decisions must be documented prior to completion of decommissioning.

All partial documentation shall, as a minimum requirement, include the relevant events, data and results, the underlying assumptions and framework conditions, documentation of the calculation programmes used, and a description of how the results were obtained.

The documentation shall be updated at regular intervals, whereby out-of-date partial documents shall be left in a suitable format as part of the document set.

Regarding the manner and location of storage, care shall be taken to ensure that all document sets are readily accessible at all times using the currently available technology. The principle of diversity must be observed.

Regulations and actions within the organisation:

Decisions are taken in meetings, negotiations and by correspondence. These decisions taken during meetings and negotiations are documented via minutes or written agreements. In case the ministry takes a decision which is relevant for and directed to the organisation the decision is submitted as a written policy.

To produce a decision by the head of the office usually a formalised procedure has to be undergone, which consists of the following aspects:

- current situation
- problem
- solutions
- weighing
- proposal for solution
- the head takes a decision based on the outlined aspects.

The necessary background information for the comprehension of specific decisions are usually cited within the document bearing the decision. Via the electronic documentation system the cited documents can be individualised to make the decision traceable.

If the document bearing the decision is not displaying any reference the electronic documentation system provides the possibility to establish links to relevant documents. Although this is not a regulatory requirement, it is strongly recommended.

No systematical or methodical contingency plans are implemented regarding record preservation in the event the project is put on hold or terminated. Furthermore, there is no procedure to decide what information should be kept and when it can be discarded. During the moratorium of the Gorleben project all scientific data had been preserved, evaluated and documented. Summarising reports had been produced to preserve the knowledge in a nutshell. Manage the information so that past decisions and the context in which they were made are traceable.

Regulatory requirements

In case of licensed repositories all decisions are documented in a traceable way and in the context the decisions had been taken within the licensing procedure. Regarding further decisions precise regulations according to granted licences ensure the adequate documentation.

Regulations and actions within the organisation:

Refer to "Organise information in such a way that it provides guidance and a framework for decision making".

All reports are filed in an electronic system. The large amount of reports is sorted hierarchically in such a manner that it is possible to allocate the information to certain categories (e.g. laboratory results, interpretation of basic data, combined interpretation, results of safety assessments, site characterisation). By combining sets of data with a certain decision, the tracing of the reasoning that stands behind the decision is facilitated.

In certain cases explicit reports are written that compile and explain the arguments that lead to a decision. But there is no such regulation within the organisation. These measures are taken depending on the assessment of importance of the decision by the responsible person.

With regard to the importance of public relations the organisation is constantly keeping an eye on the presentation of coherent information.

Facilitate access and transparency to involved audiences.

Regulatory requirements

The Safety Requirements Governing the Final Disposal of Heat-Generating Radioactive Waste as of 30 September 2010 state:

All data and documents relevant for the safety statements and for future assessments and decisions must be documented prior to completion of decommissioning.

All partial documentation shall, as a minimum requirement, include the relevant events, data and results, the underlying assumptions and framework conditions, documentation of the calculation programmes used, and a description of how the results were obtained.

The documentation shall be updated at regular intervals, whereby out-of-date partial documents shall be left in a suitable format as part of the document set.

Regarding the manner and location of storage, care shall be taken to ensure that all document sets are readily accessible at all times using the currently available technology. The principle of diversity must be observed.

Regulations and actions within the organisation:

A central archive of publications (Doris), allowing search strings and evaluation mechanisms and fast retrieval of archived publication. Doris is an online platform for safekeeping and the long archiving as well as providing the availability of publications to the public.

With regard to the importance of public relations the organisation is constantly keeping an eye on the presentation of coherent information.

Dealing with licensing authorities it is good practice to deliver relevant reports as soon as they have passed the QA procedure. In addition meetings take place with the purpose to inform and explain the progress of the project, the content and objective of finalised reports and ongoing activities.

Question 2 B

A long duration of proceedings makes it complicated to maintain and to guarantee consistency of documents. Furthermore, the development of state-of-the-art of science and technology has to be considered. In certain cased reassessments might be regarded being necessary.

During the course of the process revised political decision due to change of government are to be expected. For this reason, on the one hand there is a need for flexible tools to cover and document change of decisions. On the other hand, the traceability of decisions is difficult to guarantee due to different causes for decision change (political & scientific) and their mutual interference. Programmatic changes sometimes are proclaimed via interview or press release. In these cases the decisions themselves are documented, but the reasoning behind the decision is not always traceable. Furthermore from a retro perspective the documents are not always easy to reproduce.

Question 3: Requirements management

Question 3 A

The BfS does not have any specially developed tools (software) for the documentation and tracking of requirements of a legal or regulatory nature. The interaction with the licensing authority or supervisory authority is done in the form of talks in which, among others, also the requirements for the respective repository project are communicated and documented in the minutes. Fulfilment of the formulated requirements is tracked in further talks. Furthermore, there is an exchange in writing between the licensing/supervisory authority and the BfS, in which the requirements for the repository projects are formulated, communicated and whose fulfilment is tracked in a similar way. Information about the requirements is given to the BfS, e.g. in the form of lists or tables, summarised to a report. The reports with the requirements are introduced into the BfSinternal documentation system. Fulfilment of the requirements is documented in corresponding reports or statements and likewise introduced into the documentation system. This way it is ensured that the fulfilment of requirements can be tracked.

Referring to requirements deriving from the mining authority the requirements are part of a granted licence and thus part of official documents. The requirements and their fulfilment are scrutinised by using either commercial software or an electronic documentation system with specific features for that purpose.

The BfS has currently a project-oriented structure, i.e. there is a special department for each repository project. To ensure the exchange between the projects, there are crossproject working groups. E.g. the working group "Long-term Safety", in which all project team members collaborate who deal with the topic "Safety assessments and long-term safety of repositories". Thus it is ensured that all projects have the same information available about the state of the art of science and technology in the field of "safety assessments" and the already existing requirements of a legal or technical nature.

Workshops to specific topics are organised dealing also with legal requirements. These workshops are targeted to members of the scientific community, authorities and or to the public. The results of these workshops are implemented in the proceedings of the project.

Question 3 B

The difficulties in the development or implementation of such tools or processes are rooted in the fact that there is no prefabricated/standardised solution nor software available. That means that the tools/processes need to be designed/developed projectspecifically. It has also to be taken into account that the repository projects last longer, the structures and responsibilities may sometimes change.

Radioactive Waste Management Limited (RWM), UK

Question 1: General & context

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UK Programme

The UK Government, and its devolved administrations, are committed to the safe use, storage and disposal of radioactive waste. Excluding Scotland, geological disposal of higher activity waste has been government policy since 2008. At present no site (or sites) for a geological disposal facility (GDF) have been identified and the UK Government favours a voluntarist approach, based on working with communities that are willing to participate in the siting process. The framework for managing higher activity waste through geological disposal is described in the White Paper "Implementing Geological Disposal" published¹⁴ in July 2014. This paper also sets out a timetable for the process going forward, with next steps involving a high level national geological screening exercise and a review of planning legislation. In Scotland, the policy for the long-term management of higher activity waste should be in near-surface facilities. The Welsh assembly is currently carrying out a consultation on geological disposal, which runs until mid-August 2015.

Note that the policy above refers to higher activity waste only. The UK also has an existing Low-Level Waste Repository in operation near the village of Drigg in Cumbria¹⁵.

Organisation

Radioactive Waste Management Limited (RWM) is the organisation responsible for delivering a long-term sustainable solution for the disposal of the UK's higher activity waste ("implementer"). It does this by: carrying out preparatory work to plan for a GDF, including the production of generic transport, operational and post-closure safety cases; engaging with stakeholders (e.g. the public, national and local governments) on geological disposal; and commissioning focused R&D. RWM also provides advice to waste producers on waste packaging to support storage and disposal in line with UK and Scottish Government policy.

Radioactive Waste Management¹⁶ Limited (RWM) is a wholly owned subsidiary of the UK Nuclear Decommissioning Authority¹⁷ (NDA) – which is responsible for decommissioning 17 of the UK's civil public sector nuclear sites – and which itself is a Non-departmental public body reporting to the Department of Energy and Climate Change¹⁸ (DECC).

- 16. http://www.nda.gov.uk/rwm
- 17. http://www.nda.gov.uk
- 18. https://www.gov.uk/government/organisations/department-of-energy-climate-change

^{14.} https://www.gov.uk/government/publications/implementing-geological-disposal

^{15.} http://llwrsite.com

Question 2: Information management

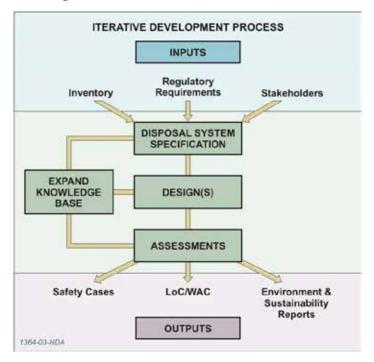
Question 2 A

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Question 2 B

As described in Question 1, the UK programme is currently at a generic stage with no site or sites identified to locate a future geological disposal facility (GDF). As a result there is considerable uncertainty over the geology and disposal concept(s) which will ultimately be selected, and RWM undertakes research, both through its supply chain, through academia and in collaboration with international partners, on a range of possible options. Information needs are determined through an iterative business model as shown in Figure B.14, which is related strongly to the model for safety case development shown in Figure B.15.

Figure B.14. RWM Iterative Business Model



The iterative development cycle ensures that R&D which is undertaken is justifiable and driven by the needs of the safety case. Within Figure B.15 a number of boxes should be noted in particular; these are discussed below. RWM operates a comprehensive management system containing policies and procedures which provide a framework to manage many of the activities and these in turn are subject to continuous improvement.

Inventory

The UK radioactive waste inventory (RWI) is produced every three years and contains a snapshot of wastes and materials in the UK at a specific 'stock date'. The current RWI was sponsored by the Department of Energy and Climate Change and the Nuclear

Decommissioning Authority and dates from 2013. The Disposal System Specification (DSS) team of RWM develops a 'Derived Inventory' (DI) to correspond to each RWI. The DI is based upon the RWI but contains a number of enhancements to make the data more useful for geological disposal (e.g. applying conditioning and packaging assumptions for waste which is not yet packaged). In practice the inventory is subject to uncertainty and the safety case is also used to justify improvements and reductions in uncertainty for key waste streams.

Change control

RWM operates a change control process to ensure that changes to the generic DSS are appropriately managed. Each proposed change (e.g. if a waste producer proposes a new type of waste package with novel characteristics) is documented and reviewed by the Change Control Working Group (CCWG). The CCWG contains representatives from each technical function and is considered to be a sub-group of the Disposal System Development Committee (DSDC). The DSDC is responsible for the scientific and technical development of a geological disposal facility within RWM.

FEPs and safety functions

RWM intends to use both safety functions and FEPs in the production of its environmental safety case and has previously described how FEPs will be used to develop scenarios and computer models for use in performance assessment¹⁹. The NEA international FEP list is currently being used within RWM to aid the development of generic models and to review the completeness of research status reports.

Uncertainty register

RWM is developing an uncertainty register to capture key uncertainties in the disposal system. Some uncertainties can only be addressed when a disposal site or sites are available, while others are prioritised as time and funding allow (see below). At the generic stage RWM maintains an assumptions database to allow the development of generic safety cases without introducing unnecessary constraints on the disposal system.

Research priorities

RWM publishes a science and technology plan²⁰ which identifies RWM's future generic R&D activities. The document contains a detailed list of research tasks describing the Research Need, Research Objective and Scope in addition to an internal customer (e.g. safety case, site-selection, facility design, etc.). Each research task is allocated a Scientific Readiness Level (SRL) which indicates how well the topic is currently understood, and how it may be progressed through generic research. SRL's have proven to be a useful tool to discuss and prioritise research.

Data integrity and control

RWM operates a competence management system, with each member of staff assessed against one or more competences. To demonstrate competence, sufficient evidence must

20. http://www.nda.gov.uk/publication/science-and-technology-plan-ndarwm121

^{19.} Overview of the FEP analysis approach to model development, L.E.F. Bailey and D.E. Billington, Nirex science report number S/98/009, November 1998.

be provided for each item in the competence definition (e.g. training, past project experience, qualifications etc.) and these are considered by the Chief Scientific Advisor and appropriate Head of Department. Competencies are reviewed on a regular basis to ensure staff remain competent in their appropriate areas.

Data and models which underpin RWM's generic safety case are each covered by a dedicated policy and procedure. RWM has recently developed a system to manage its data using XML based Data Definition Forms and Data Use Forms. These allow parameter values to be recorded along with information on its uncertainty, provenance, applicability and relevance for a particular use, together with any links to underpinning technical documents. All data are assigned an owner and must be reviewed by a member of staff with an appropriate competency before use.

In addition to the DSDC, which deals with the technical development of the disposal system, RWM operates a Programme Board which is responsible for Programme delivery (e.g. making decisions on timing, funding etc.) in line with the RWM Business Plan. The Business Plan is a high level strategic document which describes the company's strategic objectives and corporate targets in each financial year, in addition to the key activities and funding required to achieve these. This in turn is related to the NDA business²¹ plan which describes the strategic objectives and expected progress for each of its disposal sites and subsidiary companies which in turn are agreed with government.

^{21.} http://www.nda.gov.uk/publication/nda-business-plan-financial-year-beginning-april-2015-to-financial-year-ending-march-2018/

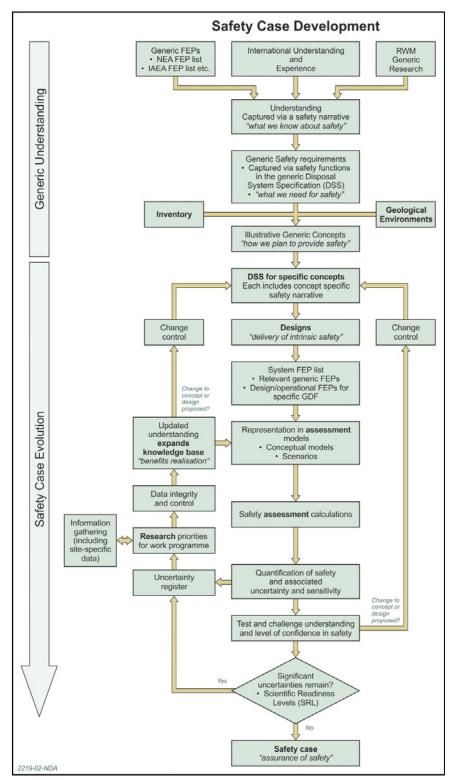


Figure B.15. Iterative Safety Case Development

RWM has recently introduced benefits management into all of its programme management arrangements. RWM has developed a programme level benefit map

identifying which end benefits the programme needs to realise in order to achieve the company's strategic objectives and therefore the RWM mission. Given the long-term nature of the GDF programme, these end benefits refer to benefits that will be realised in future decades, therefore to measure progress against these benefits and to focus the RWM work programme on benefits that need to be realised in the nearer future, RWM has developed a set of "intermediate benefits".

At project level, benefit mapping workshops have been held for each project and function in the RWM programme, resulting in "benefit maps" for each project. These benefit maps show how the project's outputs, together with any necessary enabling changes and/or business changes, contribute towards delivering the programme level intermediate benefits, and therefore show how each project contributes to the delivery of the strategic objectives and mission.

All documents described above are stored on the NDA's Electronic Document and Records Management System (EDRMS) which provides extensive capabilities for search, records management (e.g. disposition schedules), access control and auditing.

Both RWM and NDA are bound by UK Government rules on information governance²² and records retention, with public records produced by either party being deposited with The National Archives for long-term retention. NDA has recently been given permission by The National Archives to build a Nuclear Archive at Wick in Scotland as a place of deposit for public records related to the UK's nuclear legacy. The Nuclear Archive will follow the policy set by The National Archive to ensure that records remain usable in the future.

NDA and RWM make the majority of their published documents available for free download on the website: http://www.nda.gov.uk/publications

Both parties are also bound by the Freedom of Information Act which allows any interested party to request other records which have not been published, subject to certain statutory exceptions.

Although it is not possible to produce a full safety case for a disposal facility until a possible site or sites are available, RWM has published a generic Disposal System Safety Case (gDSSC) to provide an overview of how such a safety case would be produced in future. This suite of documents is intended to provide confidence that such a facility could be built should a suitable site be available. The document has a multi-level structure, as shown in Figure B. 16, and was reviewed by UK regulators, the government appointed Committee on Radioactive Waste Management (CoRWM), and is available to all other stakeholders (e.g. potentially interested communities) on the website above. RWM intends to update the gDSSC in the near future to capture changes which have occurred since 2010.

^{22.} http://www.nda.gov.uk/sharing-expertise/detail/#information-and-knowledge-management

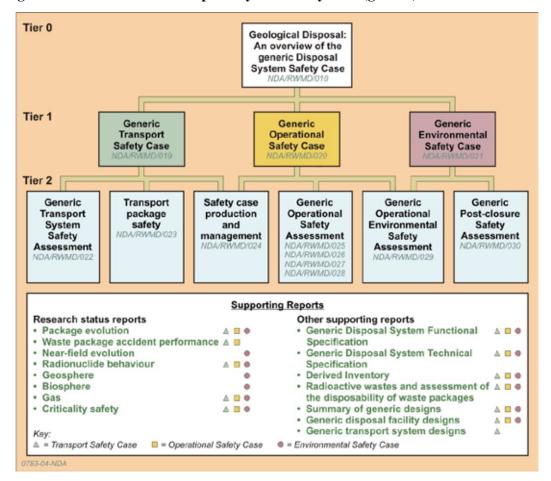


Figure B.16. RWM Generic Disposal System Safety Case (gDSSC) Document Structure

Note: the information above is intended to provide a high-level overview of a very broad topic. Further information can be provided on any given area of interest.

Question 3: Requirements management

Question 3 A

/

Question 3 B

RWM operates 'requirements management' as part of its generic Disposal System Safety Case (gDSSC) and the company organisational structure includes roles of Specification Manager and Requirements Manager.

The requirements on the disposal system are captured in the Disposal System Specification (DSS) which comprises two documents:

- the Disposal System Functional Specification²³ (DSFS); and
- the Disposal System Technical Specification²⁴ (DSTS).
- http://www.nda.gov.uk/publication/geological-disposal-generic-disposal-system-functionalspecification-december-2010

These are published as supporting reports to the gDSSC (Figure B.16). The DSFS is a relatively short document (~23 pages) which identifies and summarises high-level requirements on the disposal system. This is used to communicate these high-level requirements to a range of stakeholders and any changes to the document must be approved by the RWM Board of Directors. The DSTS is a longer document (~100 pages) for a technical audience and underpins the DSFS by describing the more technical requirements and constraints of the disposal system in more detail and provides a justification for each requirement. The DSTS also includes planning basis assumptions which are used by other RWM departments (e.g. engineering/design to produce illustrative designs); these will need to be reviewed and updated as the site (and disposal concept) selection process progresses.

The iterative development process (shown in Figure B.15) in response to question 2 is used to identify the technical requirements. A change control process, also described in response to question 2, is used to manage updates and improvements to the disposal system requirements in the DSFS and DSTS.

Requirements on the disposal system are identified from a range of sources. At the generic stage, requirements come from:

- Regulation and legislation (UK, European, international);
- Stakeholders (e.g. UK Government, NDA, GDF users²⁵, local communities); and
- UK waste inventory for disposal.

As the site selection progresses, requirements relating to each specific site will be developed. In addition to the DSFS and DSTS, RWM maintains a Waste Package Specification (WPS)²⁶ which is intended to help waste producers package their waste in a form which is suitable for the disposal system which RWM is developing. The WPS is a multi-level suite of documents, as shown in Figure B.17, which, at the highest level sets generic requirements for all waste packages, before developing more detailed requirements for particular types of waste and then specific waste package designs.

RWM is not currently utilising specialist requirements management software although the use of such products (IBM Rational DOORS) has been investigated and may be utilised in future.

At present the biggest difficulty in developing requirements management arises because of the generic nature of the UK programme. This tends to result in requirements which are relatively high level when considering post-closure safety. These will need to be developed further, ultimately into acceptance criteria, when a potential site or sites are available and the safety cases are further developed. At present illustrative disposal concepts (e.g. KBS-3V) and illustrative disposal system designs are utilised for reference so that viable options are not prematurely closed. This must be balanced against the need to make decisions at the current time as waste is packaged by producing sites.

Additional difficulty arises because of the sheer complexity of the disposal inventory which includes numerous different types of legacy wastes from the UK's historic research

26. http://www.nda.gov.uk/publication/generic-waste-package-specification-nda_rwmd_067

^{24;} http://www.nda.gov.uk/publication/geological-disposal-generic-disposal-system-technical-specification-december-2010

^{25.} RWM convenes a information exchange meeting with GDF users twice a year to support ensuring GDF users requirements have been appropriately captured in the DSFS.

programmes. This leads to a wide range of different waste packages, which should preferably all be handled in a single disposal facility.

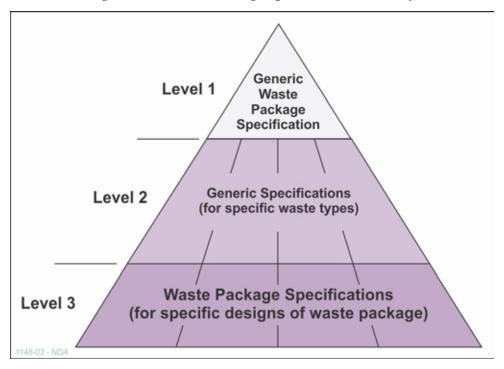


Figure B.17. Waste Package Specification Hierarchy

Department of Energy (DOE), United States

Question 1: General & context

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Abe VAN LUIK (1944–2016) Physical Scientist Carlsbad Field Office (CBFO) of the Department of Energy (DOE)

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RES is an affiliate group of Nuclear Waste Partnership (NWP), the M&O contractor for operations at the Waste Isolation Pilot Plant (WIPP) in the United States. The role of RES is to support the Department of Energy (DOE) and NWP in certification, permitting, regulatory compliance and environmental issues at the WIPP.

The Department of Energy/Carlsbad Field Office (DOE/CBFO) is responsible for managing all activities related to the disposal of transuranic (TRU) and TRU-mixed waste in the geologic repository, 2 150 feet (650 m) below the land surface at the WIPP, near Carlsbad, New Mexico. The main function of the Passive Institutional Controls (PICs) programme is to inform future generations of the long-lived radioactive wastes buried beneath their feet in the desert. For the first 100 years after cessation of disposal operations, the rooms are closed and the shafts leading underground sealed, WIPP is mandated by law to institute Active Institutional Controls (AICs) with fences, gates and armed guards on patrol. At this same time a plan must be in place of how to warn/inform future generations, after the AICs are gone, of the consequences of intrusion into the geologic repository disposal area.

A plan (Certification Compliance Application (CCA 1996)) was put into place during the 1990s with records management and storage, awareness triggers, permanent marker design concepts and testing schedules. This work included the thoughts of expert panels and individuals. The plan held up under peer review and met the requirements of the US Environmental Protection Agency (EPA 40 CFR 194.43).

Today the Nuclear Energy Agency (NEA) is co-ordinating a study called the "Preservation of Records, Knowledge and Memory (RK&M) Across Generations" to provide the international nuclear waste repository community with a guide on how nuclear record archive programmes should be approached and developed. DOE is co-operating and participating in this project and will take what knowledge is gained and apply that to updating the WIPP programme. At the same time DOE is well aware that the EPA and others are expecting DOE to move forward with planning for the future WIPP PIC's programme; so a plan will be in place in time for WIPP's closure slated for the early 2030s. The DOE/CBFO WIPP PIC's programme in place today meets the regulatory criteria, but complete feasibility of implementation is questionable, and may not be in conformance with the international guidance being developed.

International guidance currently under development may suggest that the intergenerational equity principle strives to warn the future, however, in doing so not to

unduly burden present generations. The DOE/CBFO is developing conceptual plans for re-evaluating and revising the current WIPP PIC's programme. These conceptual plans will suggest scientific, regulatory and technical work that must be completed to develop a "new" PICs programme that takes the best ideas of the present plan, blended with new ideas from the RK&M project, and will result in a more common sense approach to the records management and markers portions of the PICs programme.

Question 2: Information management

Question 2 A

Specific regulatory requirements for records management for the WIPP can be found in 40 CFR Part 191.14(c), "Disposal sites shall be designated by the most permanent markers, records and other PICs practicable to indicate the dangers of the wastes and their location."

More detailed regulatory requirements for records management for the WIPP can be found in 40 CFR Part 194.43(a)(2), "Placement of records in the archives and land record systems of local, state, and federal governments and international archives that would likely be consulted by individuals in search of unexploited resources. Such records shall identify: (i) The location of the controlled area and the disposal system; (ii) The design of the disposal system; (iii) The nature and hazard of the waste; (iv) Geologic, geochemical hydrologic, and other site data pertinent to the containment of the waste in the disposal system, or the location of such information; and (v) The results of tests, experiments and other analyses relating to backfill of excavated areas, shaft sealing, waste interaction with the disposal system, and other tests, experiments, or analyses pertinent to the containment of waste in the disposal system, or the location of such information."

Though these regulations provide a frame work as to what information is to be collected for archiving they fall short in practical implementation. The requirement of placement of these records in local, state, and federal governments, and international archives cannot be met since there is no international archive and local and state governments are hesitant to engage in such a task. The US National Archives (36 CFR Part 1254) will not accept but a limited amount of information that has to be filed to a specific filing code developed specifically for WIPP archives. To date a WIPP specific filing code has not been developed. Additionally, state and local archives each have their own specific archiving limitations and requirements that have to be met individually.

Since the regulations do not identify specific documents that are to be archived, the DOE identified in their CCA-1996, the documents that will be archived. These documents are:

- · Land Withdrawal Act, Public Law 102-579, October 30, 1992,
- Final Safety Analysis Report and the addenda which describes the disposal phase of the WIPP,
- Final Environmental Impact Statement for WIPP and the Supplement(s) to the Environmental Impact Statement,
- No-Migration Variance Petition and the No-Migration Determination for Disposal,
- Resource Conservation and Recovery Act Permit,
- · Certification of Demonstration of Compliance with Title 40 CFR 191,

- environmental and ecological background data collected during the preoperational phase of WIPP and summaries of data collected during the disposal and decommissioning phases of WIPP,
- records of the waste containers contents and disposal locations within the WIPP repository,
- · drawings defining the construction and configuration of the repository and shafts,
- drawings, procedures and the design report(s) describing how the waste was emplaced; how the rooms, drifts, and panels were closed; and how the shafts were backfilled and sealed,
- · detailed maps describing the exact location of the repository, and
- design, drawings and specifications for Permanent Markers.

So as to not contaminate, misguide and interfere/influence the decisions and justifications for those decisions of future generations with what can only be identified as speculation of future needs, only the documents listed above will be archived. Any documents related to guidance or suggesting of a framework for decision making will not be included so that future generations will perform these tasks dependent upon the facts included in the documents listed above along with conditions and needs of that future time period. It would be impossible to estimate what type of framework or guidance would be needed since there are an infinite number of scenarios of future situations that would need this information and those scenarios would change with each generation.

To ensure that access to the most pertinent location, potential hazards of intrusion and land use restrictions information is readily available, the DOE will develop a WIPP summary document. This document will be distinctively bound. The receiving archive will be requested to locate and catalogue this summary volume such that it is readily available to the general public with particular emphasis on availability to potential natural resource investigators, historians and archaeologists. These summary documents will be prepared and translated into the six recognised United Nations languages. The receiving archive will determine which language version shall be archived. The initial form of the information should be on archival quality paper.

Currently, there are no plans to account for the possibility that technological tools for data management will become obsolete. It will be the requirement of the archive to ensure that as technology changes, the data management of the archive will change accordingly.

The regulatory requirements stated above are required whether the facility is in operation, put on hold or terminated.

Question 2 B

The difficulties encompassed so far in the development/implementation of adequate management tools and information management are twofold. First, the regulatory environment in the United States does not require final approval and implementation of a passive institutional programme until the submittal of the final certification reapplication prior to closure of the repository. Due to this situation, this programme is funded to such a small extent that it is impossible to commit the needed resources to timely and effectively develop, test and implement all major portions of the programme.

Second, the regulatory requirements for long-term records management and the entire passive institutional programme are too vague and have made assumptions that cannot be met. One example is the assumption that the records will be accepted by an international archive. As of the date of this questionnaire, no such archive exists or is even being

considered. The regulatory requirements for a passive institutional programme and hence record archive plan need to be rewritten and updated to reflect the status of international, regional and local archives as they currently exist. Working with the regulatory interests to reflect these changes to the requirements are the primary future challenges for longterm records management at nuclear waste repositories in the United States.

Question 3: Requirements management

Question 3 A

To implementers

The processes implemented to ensure that the geological disposal program in the United States proceeds in a manner that complies with the requirements imposed is twofold. Regulatory documents involved with the long-term requirements (40 CFR 191 and 194) are through the Environmental Protection Agency (EPA) via the certification process that occurs every five years. This five year review ensures that the repository is in compliance with regulations for the previous five year period and updates the certification baseline as needed. This long-term certification is primarily concerned with the radiological constituents of the repository.

Should changes to the certification be needed more frequently than every five years, a Planned Change Request (PCR) is submitted by the DOE. This notice sent to the EPA, primarily requests a change to the disposal process or facility and can involve review by regulators, stakeholders and the public with the possibility of public hearings dependent upon the significance of the change being requested.

The second part of the US regulatory process is permitting. The permitting process is on a ten year scale and is primarily concerned with the non-radiological aspects of the repository. This regulatory process is controlled through the state and is renewed every ten years. Should a change be requested prior to the ten year cycle, then a Permit Modification Request (PMR) is submitted. Depending upon the significance of the PMR being submitted, the PMR can be classified one of three different classes and may or may not involve stakeholder and public review beyond the normal regulatory review.

Whether the PCR or PMR is significant or non-significant determines the level of regulatory review and stakeholder /public involvement. In some cases the change submitted to the certification/permit can require a peer review or expert judgement. In these cases a team of experts is gathered to review and provide comment on the change being submitted. This process takes years to complete.

To regulators

No comment.

Question 3 B

Difficulties experienced in implementing the management tools/processes in the course of the deep geologic disposal of nuclear waste program in the United States are primarily focused on the existence of more than one regulation (long-term vs. short-term repository function) and regulator (federal vs. state). Most of the regulatory requirements for deep geologic repository performance cross multiple regulatory lines and must be approved by both regulatory agencies. A PCR and/or PMR may be approved by one regulator and ignored or disapproved by another.

Recently, President Obama commissioned an expert panel (Blue Ribbon Panel) to investigate and review the status of nuclear waste disposal in the United States. The results of this panel were a recommendation to institute one governing agency that would oversee and enforce regulations specifically pertaining to the disposal of nuclear waste in the United States. This new agency would work with state and local governments to regulate nuclear waste disposal to the highest standards while minimising the redundancy of multiple regulators. To date, no action has been taken on this recommendation.

Implementation of the Blue Ribbon Panel's recommendations will be the future challenge regarding the management of the deep geological disposal of nuclear waste in the United States.

Institute for Radiological Protection and Nuclear Safety (IRSN), France

Question 1: General & context

Muriel ROCHER PRP-DGE/SEDRAN/B4S TSO muriel.rocher@irsn.fr

Roles of IRSN

IRSN, a public authority with industrial and commercial activities, was set up under Article 5 of French Act No. 2001-398 of 9 May 2001, enacted through Order No. 2002-254 of 22 February 2002. This Order was amended on 7 April 2007.

The Institute is placed under the joint authority of the Ministries of Defence, the Environment, Industry, Research and Health.

It is the nation's public service expert in nuclear and radiation risks, and its activities cover all the related scientific and technical issues. Its areas of specialisation include the environment and radiological emergency response, human radiation protection in both a medical and professional capacity, and in both normal and post-accident situations, the prevention of major accidents, nuclear reactor safety, as well as safety in plants and laboratories, transport and waste treatment and nuclear defence expertise.

IRSN, as a TSO, interacts with all parties concerned with these risks (public authorities, in particular nuclear safety and security authorities, local authorities, companies, research organisations, stakeholders' associations, etc.) to contribute to public policy issues relating to nuclear safety, human and environmental protection against ionising radiation, and the protection of nuclear materials, facilities and transport against the risk of malicious acts.

Dr Muriel Rocher is in IRSN since 2004 as a nuclear safety engineer; she carries out research projects and safety assessments related to geological and hydrogeological issues, including siting and seismic hazard, for low or high- level long-lived waste disposal facilities (respectively near-surface and deep underground projects). In addition, she was particularly involved in the development of the national guiding principles for low-level long-lived waste disposal siting. She is the main contact person for the on-site follow-up of the R&D performed by Andra in the Meuse/Haute-Marne underground laboratory. She acted as work package leader in the EU FP7 SITEX project (2012-2013) and is involved in the SITEX-II project (2015-2017, EU Horizon2020 NFRP-05) as a deputy to the coordinator. She is a member of NEA/RWM/IGSC.

Dr Christophe Serres has been with IRSN, France for some 22 years and is currently Head of Safety Assessment Department for Radioactive Waste Disposal Facilities and Natural Radioactivity. This department is in charge of performing technical safety reviews in support of the French Nuclear Safety Authority of existing or future radioactive waste disposals, radioactive waste packages to be stored or disposed of and of impact of past mining activities regarding release of Uranium and other elements in the environment. He is strongly involved in international co-operation at various levels: in particular, he chaired the IAEA GEOSAF (2008-2011) project on safety of deep geological disposal and co-ordinated the Euratom 7th framework SITEX project (20122013) on the establishment of a co-ordinated Expertise Function in support to regulatory body at European level. He is the IRSN representative for the NEA/RWMC.

Current status of the French national programme regarding geological disposal (Cigéo Project)

France is nearly at the final stage of site selection and at an intermediate stage for the updating of disposal facility's reference design (several reviews of a partial safety case have taken place). A URL is operated since 2000.

In the feasibility Dossier provided by Andra (the operator) to the government in 2005, Andra defined a zone of 250 km² in which data acquired in its Bure underground laboratory could apparently be extrapolated. In 2009, Andra defined a more restricted interest area ("ZIRA", 30 km2) in this previous zone, for implementation by means of thorough geological reconnaissance, with a view to site the repository. IRSN has assessed the merits of the criteria used by Andra for the choice of this interest area, taking into account the results of survey campaigns by Andra, and notably the consistency of such criteria with the requirements associated with the implementation of a geological disposal from the point of view of nuclear safety and radiation protection.

Following the feasibility Dossier, the 2006 Planning Act provided a general planning for the disposal facility development: the following step should have led to the repository licence application for the implementation of the DGR at the end of 2014, and its review during 2015 could have led to promulgate a new law detailing requirements concerning reversibility. The Planning Act also provided for a broad public consultation taking place during the second half of 2016. The licence application of the new disposal facility was planned to be authorised by a decree at the end of 2016.

However, the Cigéo Project was submitted to the public through a public debate from May to December 2013, based on a detailed description of the project objectives, its main features, a proposal for an implementation site, its socio-economic stakes, its estimated cost and its impacts on the environment and on the regional development. The outcomes of the public debate, published on 12 February 2014, recommended a more progressive development for the industrial project, especially by including a pilot stage at the beginning of the licensing, before commissioning. Consequently, the initial planning given in the 2006 Planning Act is actually under modification (see below). Following this public debate and taking into account the conclusions of previous reviews from IRSN, Andra published in the French "Journal Officiel" the proceedings of its Board of directors on 5 May 2014. It proposes a blueprint for the Cigéo operation which, after consultation with the stakeholders and approval by the state, would be implemented by Andra. The key point is the definition of the pilot phase mentioned below.

Considering its schedule of studies of industrial design, Andra will by 2015 provide the state with a proposal for a master plan for the operation of Cigéo to, as well as a Safety Options report (DOS) and a report on technical options for reversibility to the regulatory body. On theses grounds and using their final draft studies, Andra will submit a safety case in support to the application (at the end of 2017) for the licensing. Although it depends on the decisions made by the regulator, the licensing of the facility is planned for 2020. The first part of the pilot stage will occur without any waste, and commissioning is planned for the beginning of the second part of the pilot stage, with the descent of the first waste packages, in 2028.

Question 2: Information management

Question 2 A

First of all, it worth noting that IRSN obtained in July 2007 the ISO 9001 certification as well as its renewal in July 2010 and 2013, for the quality management system applicable to all its activities, "the performance of assessments, research and other work in the fields of nuclear safety, radiation protection and the control of nuclear and sensitive materials" (Excerpt from approval certificate). Its quality system, organised in specific domains (e.g. support for public authorities, R&D/maintaining skills, information systems management...), is regularly controlled by the certification body and improved through internal audits and management reviews. Besides quality management, IRSN activities are structured through an MTP (mean term planification), in which is specifically identified the axis programme D3P12 dedicated to the relevant research necessary to enhance safety assessment related to future waste disposal and natural hazards.

IRSN's management of R&D related to geological disposal

The research activities carried out by IRSN are developed in consistency with conclusions drawn from the stepwise regulatory process that allows periodically addressing the remaining issues that must be dealt with to improve the safety demonstration. The expected outcomes of IRSN R&D programme are clearly identified with respect to the safety review approach, paying in particular a specific attention on which phenomena must be studied by the TSO so as to ensure appropriate independent judgement of the level of safety that the repository may reach. It is also a duty for the TSO to be able to deliver an opinion on the consistency and degree of confidence of the data produced as well as on the ability of the implementer to realise, at the industrial scale, components that will perform "as designed".

A research programme has been launched initially to support IRSN's assessment of Andra's file on the feasibility Dossier in 2005. Taking into consideration the feedback and main conclusions drawn from this file's review, IRSN has identified a number of important issues, grouped hereafter as "key safety issues". This research program is now structured upon the new main steps related to the development until 2017 of the Cigéo Project, until the licence application to be submitted in 2017 for the creation of the disposal facility.

Few issues, which relate only to the Meuse/Haute-Marne site, are presented hereafter as examples: the confinement capabilities of the sedimentary host rock, the perturbations due to excavation or due to the interactions between different components, the waste degradation, the uncertainties on corrosion rates of metallic components, the construction/operational safety (accounting for reversibility), the sealing capabilities, the long-term performances of the repository...

These topics correspond to IRSN's pluri-annual research programme related to geological disposal mentioned above (MTP axis D3P12), on which IRSN relies to develop its staff skills and to anticipate the needs for new knowledge essential to perform high quality comprehensive safety reviews.

IRSN's research programme is annually updated as described below and periodically reviewed by a scientific committee and organised in order to address the "key safety issues" highlighted.

Each of these areas of scientific or technical expertise is described via one or several specific forms named "fiches affaires" picturing the road map of MTP axis D3P12 for coming 4 years. These forms treat the following sections:

- 1. The definition of needs, with (i) main issues, objectives and risks, (ii) key steps in terms of safety evaluation where these results will be needed, (ii) a list of external or IRSN users and (iv) references.
- 2. The definition of the research studies, with (i) the state of the art and the description of actions and (ii) IRSN or external partners contributing to the action and/or to the funding.
- 3. The milestones and associated due dates.
- 4. The foreseen means of promotion of R&D results (publications, communications...).

In order for collaborators and management to help to ensure an adequate follow-up of the roadmap, in accord with the quality processes defined by IRSN for research, A specific numerical tool has been developed for the department to follow and/or to inform on the progress of these studies through the defined milestones (their internal review, redefinition of objectives, changes of deadlines...). These studies may be carried out internally at IRSN or through a partnership (collaboration or sub-contracting) with other institutes, universities...

When milestones correspond to the successive steps of a study (minutes of kick-off meetings, experimental results, intermediate or final study reports...), the last one is generally dedicated to the writing of an internal summary report or factsheet, which comprises the conclusions of the study in terms of safety, directly pertinent for IRSN's expertise. This summary, once validated, is communicated to waste management staff and to other IRSN teams that could be interested.

These "fiches affaires" are updated each year, notably on the basis of:

- Experience feedback given at the end of each technical review of the implementer's safety case (or review of a part or a specific theme in the safety case);
- The progressive development of the project, in order for IRSN to be prepared for future reviews (which thus require to be planned...), as well as the changes in the national programme until the submission of the licence application;
- Aspects associated with society's evolution, in particular those related with the social concerns (including the needed in natural resources), the advances in technology ...

Archiving and traceability of past decisions

A difference must be made between having currently access to numerical registered and properly managed documentation, and archiving, where IRSN, being a public body, must comply to the norms edicted by the Interministerial Department of the Archives of France (SIAF). Electronic documents are not, as now, recognised as an archiving standard for written documents at IRSN, only paper is.

Several tools are used to numerically handle IRSN's documentation, notably regarding its regulatory reviews (exchanges of mail or technical documents with implementers, with the public authorities or other stakeholders) and R&D (i.e. all the IRSN process of decision on R&D orientations, as well as the obtained results and the way they are used in technical expertise). Several examples are given below:

- Since the mid-nineties, entering and outgoing mail is handled through software of mail processing. The current software, PLEIADE, has 2 functions:
 - first, it is a platform which registers (timestamp) and digitalises (with OCR) all inbound mail, then delivers it electronically to the recipients correspondingly to specified rules. Follows a seemingly process all outbound mail from IRSN as well as all internal documents that needs to be registered is digitalised by the IRSN senders and electronically delivered to the specified recipients (originals may be physically sent). If necessary, recipients can then transfer the documents to others. Every action is publically historicised.
 - Second, it is an electronic document management (EDM): all these documents are indexed, thus enabling the users to make document retrieval, but only to visualise the content of documents if the authorisation level (following given rules) associated to a document enables him to do so.

In particular, all the milestones associated with the R&D actions described above, whether remaining internal or being transmitted outside of IRSN, are numerically registered through PLEIADE.

- MINERVE is a platform which allows following and registering all the scientific communications on which IRSN participates, from their internal cycle of review/validation until their publication.
- The publication of IRSN's Ph.D. theses, post-doctoral reports, as well as manuscripts of Habilitation to conduct researches on its public website "archives" also contributes to the constitution of a relevant documentary set. In the same way, several regulatory reviews and R&D results are summarised on IRSN's website related to the Cigéo Project (see below). This website thus provides safety-relevant information for the public.
- In order to improve accessibility and exchange, IRSN conducted the CCST project (Scientific and technical knowledge capitalisation system): now operational, the software enables a full-text research and analysis engine of several databases (among which those mentioned above) where the Institute's scientific documents are stored.
- In parallel to these EDM, the department devoted to expertise of waste packages and disposals developed its own internal wiki website named "twiki", where each research topic, assessment or any other subjects which is meant to be shared inside the department, is developed on one or several pages by each collaborator. These pages describe the main steps of an R&D project; they present the results and collect the reports, publications and so on. Documents preferentially refer to links to the above databases.

It must be noted that some old documents do not exist in these databases and that in such cases classical archives must be relied upon.

Apart from this numerical access to documents, all documents managed in the Institute falls within the following French legislation, and SIAF supervision, among which:

- the Heritage Code, <u>Livre 2</u> on the archives, in particular, the collection, conservation and protection of the public archives ;
- the <u>Décret 79-1037</u> of 3 December 1979 relating to the jurisdiction of public archives and services co-operation between administrations for the collection, conservation and communication of public archives, as well as to the communicability of the archives documents ;

• the <u>Circulaire</u> of 2 November 2001 on the management of archives in public institutions.

Archives must mainly be kept in order to being produced for legal or juridical matters (short and mean term), and on the long term for historical matters (long term, public domain). Documents are managed through a records management table (Tableau de Gestion des Archives) which identifies typologies of documents, and for each kind of relevant document, where it must be kept, by who and for how long, for each one of the 3 periods thus defined : "currently used", "intermediary" and "historical". At the end of each period, documents are meant to be sorted out and eventually discarded depending on the applicable rules.

In the first period, documents are generally gathered in comprehensive sets concerning a specific subject (as well received than produced by IRSN), and kept by the collaborator in charge in dedicated boxes in his/her office. These documents and files can thus be easily transmitted to a colleague in case of change person in charge of the topic

Concerning the paper documents dating from before 2000, that do not systematically exist numerically, IRSN is currently proceeding (since nearly 3 years) in the collection, sorting out and arrangement of all paper documents related to R&D and expertise since the 1980s for long-term archiving, in particular those associated to the projects of disposal since the beginning.

This archiving is a way to account for the possibility that technological tools for data storage) will become obsolete. The metadata of these documents (title, date...) are numerically saved and associated with the location of the documents. Therefore, in case of any regress in the project to a previous step, as for example in case of conceptual change or even abandon of the actual site choice (Meuse/Haute-Marne), it will be possible to retrace all the steps of decision and to find studies on the other potential concepts or sites for geological disposal.

Transparency and easy access to IRSN's review reports and R&D results

On IRSN's point of view, transparency to the stakeholders means both informing the public on IRSN's results of expertise and having exchanges being maintained over time, including consultation with interested parties in the decision process.

About information of the Public, the n°2006-686 Act from 13 June 2006 on Transparency and Safety in Nuclear Matters renovates the legislative framework applicable to nuclear activities and control in depth. It creates the necessity to provide information to the public by the French safety authority (ASN). As presented above, IRSN's public website allows free access to many of IRSN review reports and opinions that supported a decision by the regulatory body, as well as R&D results and scientific publications.

In addition, IRSN develops its own public website related to the Cigéo Project. To prepare and supply the public debate on Cigéo Project from May to December 2013, IRSN prepared short summaries, giving either its knowledge on research areas and key aspects that would deserve further work regarding the safety demonstration needs (on diffusion experiments, detection of natural discontinuities in clayey rocks, sealing experiments, interactions on host rock with concrete or steel...) or its view on various strategic and sometimes controversial topics (such as reversibility, storage vs. disposal, separation and transmutation, operational phase, inventory of

waste...). These summaries, thus providing salient information for the public, were published online²⁷. This website will be regularly updated and could be translated in English in the future.

IRSN makes every effort to supports the local communities by providing them with resources and data that allows them to conduct their own study. An example of a local community group is the CLIS (Local Commission on Information and Follow-up) of Bure (near Meuse/Haute-Marne laboratory) consisting of people representing the local and regional communities, as well as a geologist and a nuclear medical doctor. The purpose of the CLIS is to learn more about the project, understand the science behind the elements presented to them and disseminate information to other members of the community. To favour closer exchanges with the CLIS of Bure, an IRSN correspondent is mandated since 2013 to participate to the meetings of the CLIS.

Finally, in order to help the society getting involved in the decision-making process of geological disposal at a more national level, IRSN launched in 2012 with the ANCCLI (national group representing the local committees) and the CLIS of Bure a technical dialogue, which is designed to be sustainable in the long run. This action aims at clarifying the safety issues associated with Cigéo from different points of view and providing technical lightening elements, for instance through reports and opinions expressed by IRSN, which are accessible to a large audience. Meetings are held on a regular basis, tackling different topics over the years. To most recent ones took in 2014 on natural resources and on reversibility, and in 2015 on the operational hazards and coactivity. At IRSN governing board, a pluralistic core group has been established with the aim of involving stakeholders from various fields (citizens, trade unions, politics...) in the strategy of research in safety development in order to account early in the definition of the research programmes of expectations or concerns from the civil society.

Question 2 B

It worth noting that, even if the IRSN archiving is progressing, in compliance to the French norms, it is always carried out in great suffering because no resource (human and funds for a dedicated staff, for an archivist, time for collaborators...) is initially prioritised for such activity ("fifth wheel on the wagon"...).

Question 3: Requirements management

Question 3 A

IRSN's management of competences

The technical review of safety of geological disposal necessitates a large panel of knowledge and skills, to co-ordinate following an adapted management of human resources as well as competence maintenance through training and tutoring. In addition, it requires a well-considered organisation of the team(s) so as to facilitate permanent dialogue between the varieties of represented profiles.

²⁷

http://www.irsn.fr/dechets/cigeo/Pages/Documents-IRSN-debat-public-Cigeo.aspx#synthese

The EU SITEX project in 2012-2013 defined the variety of knowledge and skills needed for technical review of safety of geological disposal, and gathered them in a (non-exhaustive) series of four main families of expert profiles (see Deliverable 4.1, "Available technical review guidance and further needs"):

- *"Environmental experts":* environmental scientists and risk experts in long-term safety, who carry out R&D and are able to use their scientific knowledge in environmental science to argue their expertise;
- "Operational risk experts & material engineers": experts for any possible identified hazards during construction and operational phases, material & civil engineers, scientists as well as conventional underground experts; these experts may also carry out R&D and use it to argue their expertise;
- "*Numerical modellers*": experts in numerical simulation, in code development and mathematicians who support the work performed by other profiles of experts and who have a transversal role, carrying out modelling and implementing software programs matched to the needed expertise; these experts may also carry out R&D, to improve the performance of a code or the phenomena being modelled;
- "*Non-specialised experts*": these experts both have a central role in the expert team and possess a global view of the review as a whole: "safety experts" have high level expertise on different aspects of a safety case and co-ordinate the reviews performed by others; experts in the assessment of long-term safety and operational safety (scenario development...) also need to integrate data and knowledge from other experts.

This SITEX project also illustrated the evolution of the need for experts with different profiles during the implementation of a geological repository (see Deliverable 4.2, "A plan for competence development in expertise of radwaste disposal safety"). As an example, environmental experts are more needed during the beginning of the project ("concept phase", "siting phase"), while operational risk experts are more needed later ("design phase", "construction phase" and "operational phase").

Because of the complexity and such large scope of issues to be addressed, IRSN promotes a multidisciplinary approach integrating experimentalists, modellers and experts of safety who work together on each of the topics of interest for safety, either in a same team or in a close collaboration. This synergy between research engineers and experts in safety assessment is a valuable tool to ensure consistency and quality of technical assessment. In particular, it is important to enhance discussions between experts in long-term safety and those in operational safety so as to weigh the pros and cons for each design option. Regarding competition between long-term and operational safety, IRSN actively participated to the GEOSAF2 IAEA project in 2014-2015.

Scientific partnerships with research facilities and universities is the preferred strategy of IRSN in order to be able to take benefit of high level scientific skills in different specialities and for a duration compatible with the planned time frames of the assessment process (several decades).

In order to apply in the facts these considerations, the Direction of waste management in IRSN consists in 3 departments (see Figure) in the same building and at the same floor, sometimes sharing a same office. The department SRTG (Service de Recherche sur les Transferts dans la Géosphère) is dedicated to research associated to waste management, in terms of transfers in near-surface and in soils at depth. This service is notably in charge of servicing and maintenance of the IRSN's underground experimental station at

Tournemire. Another department SEDRAN (Service d'expertise des déchets radioactifs et de la radioactivité naturelle) is devoted to expertise and associated studies and modelling, notable regarding remediation, waste disposals and waste packages. The third department SCAN (Service de caractérisation des sites et des aléas naturels) is dedicated to expertise and research in natural hazards (earthquakes and flooding) regarding the safety of all nuclear plants and disposals.

In addition, thematic working groups, transverse to these 3 departments are in charge of exchanging information on recent progresses in R&D developed by one department, on needs in R&D to prepare a technical review by another, and finally to plan future R&D programmes. Seminars are organised every 3-4 years with the participants and staff to take time to discuss of the organisation of these working groups.

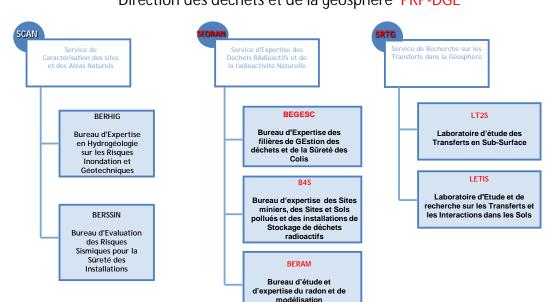


Figure B.18. Departments of IRSN Division of waste management (PRP-DGE) Direction des déchets et de la géosphère PRP-DGE

These 3 departments gather the 4 families of expert profiles described above, i.e. environmental experts, operational risk experts & material engineers, numerical modellers and safety experts, except some very specific operational risk experts. In fact, experts in non-natural hazards during operation phase (explosion, fire, ventilation, criticality...) are present in other divisions at IRSN. To maintain information and exchanges with these experts, a working group has been organised since 2010, named "EXREV" (EXploitation-REVersibilité).

In terms of competence maintenance, the 3 departments try to maintain both efficiency and durability for the competences judged mandatory for future expertise as well as equilibrium in the main families of expert profiles described above. This means having several persons competent in the same domain (i.e. several geologists, geomechanicians...), but if possible with complementary profiles, to limit the cases of persons with knowledge or a unique and irreplaceable business, as well as to test to work in pairs.

Process of review of a safety case

IRSN more or less follows the four phases specified in the IAEA SSG-23 (8.1) for each regulatory review (pre-review phase, initial review phase, main technical review phase and completion phase).

As an illustration of such development of the review, IRSN has developed a monitoring of action file named "BSA" ("Bordereau de suivi d'affaires") gathering information on the development of a review, collecting information from the request from the regulator to his final use of the IRSN's review, with intermediary steps such as the preliminary analysis, the setting up of the review team (IRSN divisions participating to the review) and the final IRSN's review. This tool is the room for collecting feedback from the way internal exchanges took place (between IRSN divisions). It also collects the technical difficulties met to perform the review and which development in R&D would have helped or would be necessary in the future. This kind of management tool also serves to identify if the technical review progresses well (to be finished at the fixed dead line, if the implementer's document is acceptable, if reviewers will correctly answers to the regulatory request or referral...) and to give various indicators in the quality process fixed by the expert team.

Development of regulation and guidance

In order to check that regulations and guidance are complied with when reviewing a safety case, IRSN refers to the French guidance developed for geological disposals (Safety Guide on Radioactive Waste Disposal in a Deep Geological Formation, "Guide de sûreté relative au stockage définitif des déchets radioactifs en formation géologique profonde", ASN, France). IRSN participated to each phase of the development of this guide (last version in 2008). Nevertheless, in France, regulation is rather "non-prescriptive", which means that the licence applicant must propose and justify the methods developed for the safety assessment, even if it must prove to be in conformity with acceptance criteria and norms defined by the regulatory body.

In addition, IRSN actively participates to the development of guidance related with the safety of geological disposal facilities at international level, as for example through the IAEA projects (GEOSAF, GEOSAF2, HIDRA...), the NEA groups (IGSC, FSC...) or the European projects. The main objectives are to share experience feedback from the most advanced countries in the development of geological disposals as well as to harmonise the regulation. As an example, one of the aims of the EURATOM FP7 SITEX project in 2012-2013 was to identify the aspects of the Safety Case where development and/or harmonisation of regulatory guidance would be necessary in order to ensure mutual understanding of the expectations of the regulator when assessing the compliance of the Safety Case with the safety requirements (see Deliverable 2.1, "Overview of existing technical guides and further development"²⁸).

Question 3 B

As previously said, the competence maintenance in safety of geological disposal has to face a particularity of such project, because competences needed should evolve progressively with the evolution of the disposal project. As for example, environmental experts are less needed when the operational phase arrives and needs increase for operational risk experts & material engineers: such change of necessary competences implies a robust personnel management system.

²⁸ http://sitexproject.eu/#public

Even if it is well known from tens' years that needs in competences will progressively change with the progress of the project of geological disposal, it is difficult in reality for people to abandon their preferences in research and to recruit people with a totally different field of competences.

Japan Atomic Energy Agency (JAEA), Japan

Question 1: General & context

Hitoshi MAKINO System Integration and Planning Section Research organisation makino.hitoshi@jaea.go.jp

After 1987, generic R&Ds on geological disposal of HLW (vitrified waste) had been carried out and then outcomes of comprehensive R&Ds had been summarized as the first progress report (H3 report) released in 1992 to show feasibility of geological disposal in Japan and the second progress report (H12 report ²⁹) released in 1999 to confirm its technical reliability.

Move from the generic R&D phase until 1999, when H12 report had been published, to the implementation phase from 2000, when "Designated Radioactive Waste Final Disposal Act" and "Basic Concept of Safety Regulation on High-Level Radioactive Waste Disposal" were enacted, and three investigation stages (literature survey, preliminary investigations and detailed investigations), construction phase, operation phase and closure/environmental monitoring phase were planned.

And the Nuclear Waste Management Organization of Japan (NUMO) was established as an implementer of final disposal of HLW in Japan ³⁰. NUMO has been conducting open solicitation of municipalities nationwide seeking areas to carry out feasibility study from 2002, but no entry until now leads delay of the programme.

After 2000, the disposal programme in Japan moved from the generic R&D phase to the implementation phase and, in particular, R&D activities relating site investigation have become an increased centre of focus. Two URLs (Mizunami (crystalline rock)³¹ and Horonobe (sedimentary rock)³² had been launched at that time.

In 2012, the Japan Atomic Energy Commission of Japan published "Research and Development on Nuclear Power in the Future Should Be (Statement)" and pointed out a need of R&D on not only disposal of vitrified waste but also direct disposal of spent fuel in Japan. This leaded to launch new R&D activities on direct disposal of spent fuel in Japan.

Progress of siting process and movement to the next phase within the programme need communication with and acceptance by stakeholders, and contribution and decision by government and regulators.

There is still no clear statement about regulation of the geological disposal in Japan except for the safety review for licensing to decide move forward to operation phase.

- 31. JAEA HP, Tono Geoscience Center, http://www.jaea.go.jp/04/tono/tgc_e/index_e.html.
- 32. JAEA HP, Horonobe Underground Research Center, http://www.jaea.go.jp/english/04/horonobe/index.html

^{29.} JNC (2000), H12: Project to Establish the Scientific and Technical Basis for HLW Disposal in Japan, http://www.jaea.go.jp/04/tisou/english/report/H12_report.html.

^{30.} NUMO HP, http://www.numo.or.jp/en/

Question 2: Information management

Question 2 A

The problems of information overload were recognised during a comprehensive assessment of HLW disposal feasibility released as the H12 report. This problem is exacerbated by progress of R&D after the H12 report including URLs activities and, especially, a Japanese volunteering approach to siting of a DGR, which requires particular flexibility in the tailoring of site characterisation plans, repository concepts and associated Performance Assessments (PAs). Recognition of this situation led, in 2005, to develop and implement an advanced KMS (JAEA KMS³³) aimed to facilitate JAEA's role as the supplier of background R&D to support both implementers and regulators of geological disposal in Japan. The JAEA KMS consist of some main tools/functions.

The first one is an argumentation modelling (Figure B.19). It is a well-established tool in Knowledge Engineering and can be implemented in a number of different ways. The argumentation model developed in the JAEA KMS could be applied to structure complex multidisciplinary knowledge in a geological disposal project and also to check whether the requirements for R&D are dealt with properly in the light of the overall safety case argumentation³⁴).

Application of argumentation modelling is a useful process/tool to manage requirements and associated R&D plans, processes, decisions and outcomes (data, information, knowledge, documents, tools etc.) in a systematic and intelligible manner. The safety case can be seen as the top-level goal of all works carried out within a geological disposal project. The resultant argumentation model can be developed in a top-down manner, highlighting the constraints on decisions set by upper level requirements relevant to the safety case and the consequences of decisions on all interlinked topics. Requirements correspond to claims in the argumentation model and completeness of arguments for each claim would be an indicator to judge sufficiency and/or insufficiency of R&Ds corresponding to the requirements. Preservation of rationales and supporting information ("Knowledge note": Figure B.20) linking to each element of an argumentation model can facilitate to trace safety-relevant or decision-relevant information and those revisions in a structured manner. Those features of argumentation modelling imply its applicability for not only knowledge management but also requirement management (see the answer for the Q4A).

Experiences to date within the JAEA KMS project have shown that this approach is well suited to breaking down complex multidisciplinary problems in RWM.

The JAEA KMS includes other some useful tools to integrate the knowledge of specific areas, for example,

Expert system (ES) development tools that particularly focus on capturing tacit knowledge using rule-based (IF...THEN format) (Figure B.21) or case-based approaches and,

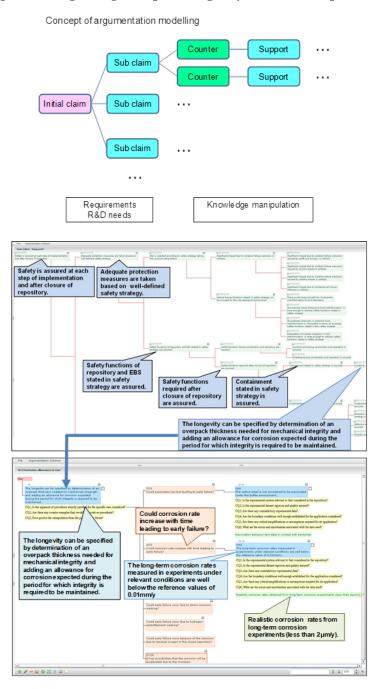
^{33.} H. Makino, K. Hioki, H. Osawa et al., A Challenge on Development of an Advanced Knowledge Management System (KMS) for Radioactive Waste Disposal: Moving from Theory to Practice, New Research on Knowledge Management Technology (Edited by Huei-Tse Hou), InTech, 2012, pp.165–184.0.

³⁴ http://if.quintessa.co.jp/CoolRepEN/index.php/knowledge-management-system

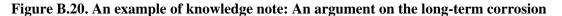
• Electronic Performance Assessment Report (e-PAR) that comprises not only a linked set of text, tables and figures corresponding to the contents of conventional PA report but also a function to execute calculations with computational tools that are used to produce those contents.

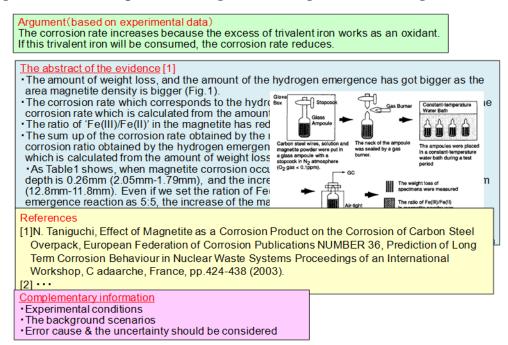
Those tools will also help to structure, record and preserve processes, decisions and outcomes through R&Ds in specific areas that would correspond to low-level elements in an argument model.

Figure B.13. An example of argumentation modelling: Development of claims and arguments regarding over pack longevity on the developed AM editor



MANAGING INFORMATION AND REQUIREMENTS IN GEOLOGICAL DISPOSAL PROGRAMMES





Development of conventional type database (e.g. JAEA-TDB, JAEA-SDB/DDB, Buffer material database³⁵) has been and will be carried out. Integration of databases, technical reports and QA records etc. as a Knowledge Base is a planned innovative approach.

Periodical reporting and review (domestic, international) is an essential and basic measure to structure, record and preserve data, decisions and outcomes and also to properly transfer these to the next programme stage and the next generations. Introduction of 'CoolRep' concept is a new approach of reporting process. 'CoolRep' is an advanced, Internet-based approach to manage documentation and provide a useful interface with users – both technical and non-technical. It allows the vast volumes of relevant information to be presented in a user-friendly, hierarchical manner. 'CoolRep' type reports will ease maintenance and update through the project duration. JAEA has release CoorRep H22³⁶ to present outcomes of R&D until FY 2009 and will release updated version, CoolRep H26, within FY 2014.

^{35.} JAEA HP: http://www.jaea.go.jp/04/tisou/english/index/e-index.html.

^{36.} Official version in Japanese: <u>http://kms1.jaea.go.jp/CoolRep/</u>. Prototype English version: http://if.quintessa.co.jp/CoolRepEN/

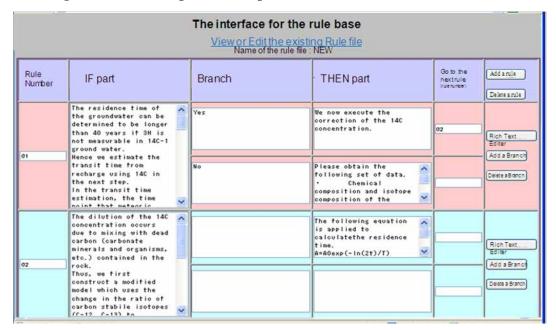


Figure B.4. An example of development of rule-based ES on the ES editor

Question 2B

JAEA has proceeded introduction of the KMS concept into the field of geological disposal project and application of some KMS tools to practical R&D programme in a step-by-step manner. Some areas have had successful outcomes by application of the KMS but not overall area. For the KMS activities to become common, strong leadership of top-management and understanding and active involvement of actors/users (for example, manager and researcher in various areas) are key issues.

Development of the JAEA KMS has been set as one of main tasks in the JAEA R&D plan of geological disposal, and also will be set as a core tasks in the future plan. Primary importance issues and a challenge in the next step of the JAEA KMS would be further promotion and maintenance of active involvement of actors/users. Regarding technical sides, sophistication of functions, especially user-interface of the JAEA KMS tools, to attract, facilitate and satisfy various types of actors/users would be an important challenge. On the other hand, concrete presentation of specific requirements from both implementer and regulatory regarding knowledge preservation and the structuring of the information in the safety case would also be a key issue.

Question 3: Requirements management

Question 3 A

In recent years NUMO (the implementer of final disposal of HLW in Japan) has been going through an intense phase of developing its own tailored requirements management system $(RMS)^{37}$ as it was identified that:

^{37.} NUMO: RMS 2010 Requirements Management Systems (RMS): Status and Recent Developments – Information Exchange Meeting Report – NUMO-TR-10-07 (2010).

- Requirements management (RM) is a central part of ensuring safety as part of the disposal programme,
- RM provides measures to meet the various requirements from the stakeholders involved.
- Furthermore, it aids confidence building,
- As the disposal programme continues over a period of more than 100 years and the constraints and premises are likely to change within this time frame, RM should be a continuous process with a clear long-term scope.

While, JAEA (a research organisation to support both implementer and regulator) has been trying to manage requirements and associated R&D in a systematic and intelligible manner through development and application of the JAEA KMS concept/tools, especially argumentation modelling described in the answer for the Q3A. Requirements correspond to claims in an argumentation model and completeness of arguments for each claim would be an indicator to judge sufficiency and/or insufficiency of R&Ds corresponding to the requirements. This feature of argumentation modelling will facilitate to introduce requirements with various aspects from implementer, regulator, stakeholders and R&Ds activities, and can help to track down possible conflicts, dependencies and causalities among those requirements in a systematic manner.

Application of argumentation modelling as a common process/tool for management of both requirements and knowledge would be possible and be an effective way.

Question 3B

From the viewpoints of JAEA (a research organisation to support both implementer and regulator), difficulties and future challenges in implementing requirement management would have a lot in common with them described in the answer for the Q3B regarding knowledge management.

Swedish Radiation Safety Authority (SSM), Sweden

Question 1: General & context

Georg LINDGREN Swedish Radiation Safety Authority Regulator E-mail: georg.lindgren@ssm.se

The Swedish Radiation Safety Authority (SSM) has a mandate from the Swedish Government within the areas of nuclear safety, radiation protection and nuclear nonproliferation. The authority is, among many other things, responsible for the evaluation of the reactor owner's research, development and demonstration (RD&D) programme for nuclear waste. This programme has to be handed to the authority every three years. Moreover, SSM is responsible for the evaluation of licence applications concerning nuclear facilities, including final repositories for SNF and other nuclear waste. The decisions to approve the RD&D programme and licence applications lie with the Swedish Government with SSM's evaluation statements as input for the decisions.

Currently SSM is reviewing an application for a final repository for SNF that has been handed in by the Swedish Nuclear Fuel and Waste Management Company (SKB). According to SKB's plans construction of the repository should start around 2020. A final repository for low- and intermediate level operational nuclear waste called SFR is in operation since 1988. SKB has filed an application to expand SFR to be able to also deposit low- and intermediate level decommissioning waste. This application is currently reviewed by SSM. SKB plans to apply for a final repository for long-lived low- and intermediate-level waste around 2030 according to SKB's latest RD&D programme from 2013.

Question 2A

There are legal requirements concerning the RD&D programme. Moreover, there are regulatory requirements on the contents of safety analysis reports for licensed waste repositories. There are also regulatory requirements on the archiving of information at nuclear installations. The archiving of information produced at authorities is also regulated by legal requirements.

RD&D programme

The reactor owners are obliged to have a RD&D programme that shall ensure that a safe handling of nuclear waste and SNF can be achieved. The programme has to be reported to SSM every third year for evaluation of planned R&D, documented research results, alternative handling and storage methods, and the planned activities. The government has to approve the RD&D programme and may put conditions on the further programme. The requirement for the reporting of the RD&D programme should thus lead to a structuring of the information that is needed for the authority and government to evaluate the programme and decide on its adequacy. A large part of the RD&D programme deals with research needs to underpin the safety analysis and the programmes thus should contribute to the objectives of the safety case.

There are no explicit requirements on how the implementer handles the information that is the basis for the RD&D reports. In practice, the RD&D reports have referenced published research reports and the information should thus be maintained and traceable to that level. In general these reports are publicly available.

Safety case

Regarding the safety case there are regulatory requirements on the main contents of a safety analysis report for a licensed facility. There are also requirements on the reporting of analysis methods. In the general advice to the regulations it is stated that information should be traceable. There are no explicit requirements on the contents of a license application. In practice the current license applications include a first preliminary safety report, which have been structured in a way similar to the regulatory requirements for licensed repositories.

A prerequisite for SSM's licensing review is that the licensing documentation is adequately transparent and traceable. If this should not be the case SSM would ask for clarifications and improvements.

SSM puts regulatory requirements on the archiving at nuclear installations of documentation that relate to radiation safety. For instance, licensing documentation including waste characteristics and results of monitoring of the surroundings of the facility shall be archived for long times, i.e. substantially longer than 100 years. The licensee shall ensure that the information can be transferred to new media if required. When the information is transferred it shall be ensured that all information is reproduced correctly. It is required that the archive is transferred to the national archives when the nuclear operations cease. Thus it is foreseen that the safety case shall be archived for as long as the national archives function.

There are SSM regulations stating that optimisation must be performed in the final management of SNF and nuclear waste. In the general advise to the regulation it is stated that preservation of knowledge about the repository could reduce the risk of future human impact. A strategy for preservation of information should be produced by the implementer so that measures can be undertaken before closure of the repository. Examples of information that should be taken into consideration include information about the location of the repository, its content of radioactive substances and its design.

SSM's management system

The authority has a management system that puts requirements on the review and evaluation process, internal decision making and documentation. The system considers general legal requirements on decision making and documentation at Swedish authorities. The management system is certified according to ISO 9001 and 14001. The system has been developed with consideration of IAEA's standard GS-R-3 the Management System for Facilities and Activities. The ISO and IAEA standards require internal and external audits.

SSM's evaluation reports and statements to the government are according to general legal requirements publicly available and have to be filed. According to SSM's management system, statements to the government regarding license applications shall include a review report that underpins the statement. Thus SSM's statements should be traceable and the documentation available as long as the national archives function.

Question 2B

The management of information during a waste management programme is certainly a challenge. There are legal requirements on authorities concerning filing. Basically all information entering and leaving the authority has to be filed. The files have to be transferred to the national archives according to certain rules. Thus all this information should be preserved. The retrieval of information should thus be possible. It may, however, be time consuming to find a certain piece of information if it is not known in which file the information can be found.

In addition to the preservation of the information it should also be ensured that there is competence available to obtain an adequate understanding of the information to be able to draw adequate conclusions. This is a challenge that has to be considered given that the waste management programme will be longer than a working life and certainly longer than most employments. The current planning in SKB's RD&D programme extends to 2075.

SSM is by the government tasked to contribute to national competence for current and future needs within the competence area of the authority. SSM shall therefore initiate research, education and studies as well as development activities. SSM's management system reflects these tasks with processes for competence building and research.

Question 3: Requirements management

Question 3 A

To regulators:

Development of regulations

SSM has a mandate to issue regulations regarding the safety of nuclear installations and radiation protection related to radioactive waste. In SSM's management system the process of developing regulations and guides is central. An internal steering document outlines how the process should be performed. An initial analysis is an important aspect before new regulations are to be implemented. For existing regulations a periodical revision is foreseen. If adequate, a consequence analysis has to be performed before issuing new regulations. Selected other authorities are given the possibility to make statements regarding the consequence analysis. The management system process also includes public hearings. If necessary, EU or international notification procedures have to be performed.

Another contribution to the development of a structured and comprehensive set of regulations and guidance are international reviews. SSM has participated in the Western European Nuclear Regulators Association (WENRA) co-operation. The Swedish regulations have been compared to the WENRA reference levels for waste management. As a result of this work the regulations have been revised. Furthermore, SSM was in 2012 reviewed by IAEA in an Integrated Regulatory Review Service (IRRS) effort. It was recommended by the review team that SSM should develop a consistent and more comprehensive set of regulations and general advice. SSM is currently working with this task.

Regulatory compliance

There is a stepwise licensing process for nuclear waste facilities in Sweden. SSM reviews the application and documentation required in each licensing step with regard to legal and regulatory requirements. Licensing review is a core process in SSM's management system. Several steering documents outline how a review should be performed. Generally, a review plan is required that specifies the objectives of the review, which legal and regulatory requirements are the basis for the review, how the review is organised, which competences are needed, as well as a time and work plan. Typically a technical review is performed, which might be supported by external experts to get information on detailed delimited issues. Within this technical review SSM has to make judgements on how different aspects, for instance interdependencies between operational and long-term safety aspects should be handled. The bases for such judgements are the relevant legal and regulatory requirements. The review process also includes a national consultation to gather information from stakeholders. Moreover, SSM's management system includes requirements regarding the preparation of decisions before the directorgeneral issues a statement concerning a licence application for a final nuclear waste repository to the government. The government's decision may include conditions to the licence. SSM can issue conditions based on the regulatory requirements once a licence has been granted by the government. The fulfilment of these conditions may be checked by SSM through further reviews or inspections.

Question 3 B

SSM has developed processes for the review of licence applications. It can be noted that the interpretation of laws and regulations that have been developed at a comparatively general level with regard to the licensing process at hand may be a challenging task. At the same time it can be noted that the programme and licensing process should become more effective if the implementer has knowledge of the regulatory body's interpretation of the legal and regulatory requirements. Regulatory reviews within a pre-licensing framework may contribute to a better understanding of the regulatory body's interpretation of the legal framework. Within the framework of the RD&D programme SSM (at that time SKI and SSI) reviewed and gave general advice on safety analyses developed by SKB at different stages in the programme.

Under the assumption that a licence for a SNF repository would be granted to SKB, future challenges relate to a change of focus of the spent fuel programme from a pre- to a post-licensing phase. The requirements regarding RD&D that are most important in the pre-licensing phase should become less important whereas the requirements relating to the construction and operation of a repository become central. This change of focus may need to be reflected in the regulatory requirements and SSM's management system.

Appendix C: Statements from questionnaire responses used as a basis for this report

Motivation for the development of systematic methods and tools in IRM

Andra	Management of rapid proliferation	of information as projects progress.
		Knowledge increases as the project is running – impact on earlier statements/analyses etc. must be assessed.
		Use of contracts e.g. in design development /ensuring that Andra's firm requirements are recognised by contracts and also where there is flexibility.
		Overall approach to knowledge management (ISIS) – emphasis on traceability, ease of access and consistency.
BfS		Given the long timescales, structures and responsibilities (vis a vis requirements) may change.
		A long duration of proceedings makes it complicated to maintain and to guarantee consistency of documents. Furthermore, the development of state-of-the-art of science and technology has to be considered.
		During the course of the process revised political decision due to change of government are to be expected – need for flexibility in information management tools.
		Programmatic changes sometimes are proclaimed via interview or press release. In these cases the decisions themselves are documented, but the reasoning behind the decision is not always traceable.
		Regulatory requirement that all data and documents relevant for the safety statements and for future assessments and decisions must be documented prior to completion of decommissioning.
IRSN		It must be noted that some old documents do not exist in these databases, and that in such cases classical archives must be relied upon.
		IRSN's point of view, transparency to the stakeholders means both informing the public on IRSN's results of expertise and having exchanges being maintained over time, including consultation with interested parties in the decision process.
Posiva		The continuous iteration between long-term safety requirements formulation, design and implementation is necessary yet challenging as design development often occurs at the same time as requirements development.
		Some design requirements and specifications are not easy to trace – i.e. developed from earlier iteration loops of long-term safety, design and production that were only partially reported.
		Historical requirements to be integrated in RMS often not well documented, have different purposes, do not have any clear rationale, may be poorly formulated, variable in level of detail.

MANAGING INFORMATION AND REQUIREMENTS IN GEOLOGICAL DISPOSAL PROGRAMMES

	The regulatory requirements are themselves evolving along the development of the repository programme and this introduces additional hurdles to RM and design development work.
	As the disposal programme continues over a period of more than 100 years and the constraints and premises are likely to change within this time frame, RM should needs to be a continuous process with a clear long-term scope.
	For the implementer, RMS arises from the need to document and integrate requirements from a range of sources, driven by a range of considerations (LT safety, operational safety, engineering practicality). Regulator: means to check that all the requirements in its regulations are fulfilled and to facilitate the licensing review process.
	Requirements are continuously and iteratively updated due to additional progress in system understanding or feedback from the authorities.
RWM	Early (generic) nature of the programme, meaning that repository site/design is not fixed and requirements mostly limited to those at high level, but nonetheless waste is being produced and packaged so decisions on waste acceptance are needed.
SSM	It needs to be ensured that there is competence available to obtain an adequate understanding of the information to be able to draw adequate conclusions. This is a challenge that has to be considered given that the waste management programme will be longer than a working life and certainly longer than most employments.
	The requirements regarding RD&D that are most important in the pre- licensing phase should become less important whereas the requirements relating to the construction and operation of a repository become central. This change of focus may need to be reflected in the regulatory requirements and SSM's management system.
	Regulatory requirement that information supporting the safety case should be adequately transparent and traceable
SÚRAO	There may be legal obligations to the free access to information that need to be respected
	Much information from R&D whose relevance to the safety case may not be directly apparent – needs structuring.

Structured organisation/documentation of knowledge and requirements

Andra	System of reference documents (site description, repository materials, etc.) that are regularly updated.
	PARS is based on a breakdown of the evolution of the repository in different situations: each of these situations corresponds to the phenomenological state of part of the repository or its environment at a given period in the repository lifetime – input data (beyond repository general architecture and definition of components) is Andra's acquired scientific knowledge.
BfS	Fulfilment of the requirements is documented in corresponding reports or statements and likewise introduced into the documentation system. This way it is ensured that the fulfilment of requirements can be tracked.

JAEA	Periodic reporting and review (domestic, international) is an essential and basic measure to structure, record and preserve data, decisions and outcomes and also to properly transfer these to the next programme stage and the next generations.
Posiva (on VAHA)	System for organising (LT safety) requirements hierarchically from level 1 (legal and stakeholder requirements) to level 5 (design specifications).
	A tool to manage the requirements and provide traceability and as a communication tool between long-term safety and design and development work.
	Organised as a database and it is an internal tool, not accessible by others.
	The addition of the design basis report, documenting the safety bases of the requirements at level L3 and L4 in VAHA, to the SAFCA report portfolio greatly helped clarifying some of the requirements bases and improving them.
	Consists of a short document to communicate high-level requirements to a range of stakeholders and a longer documents for technical audience that provides justification of requirements.
RWM (on WPS)	Supports waste acceptance.
	3-level suite of documents, giving (i), generic requirements, (ii), WP-specific requirements and (iii) WP design specification.
RWM (on DSS)	Supports safety case.
SÚRAO	Structuring of information achieved by a list of documents: safety report, plan for monitoring, QA programme, etc., all of which are considered part of the safety case.
SSM	The (regulatory) requirement for the reporting of the RD&D programme should thus lead to a structuring of the information that is needed for the authority and government to evaluate the programme and decide on its adequacy.
	RD&D reports have referenced published research reports and the information should thus be maintained and traceable to that level. In general these reports are publicly available.

Relationship between information management and requirements management

JAEA	needed to show requirements ar	able to management of both requirements and information (knowledge e met). Requirements correspond to "claims" in an argumentation model. ols should help identify conflicts dependencies and causalities among nner
		Requirements correspond to "claims" in am argumentation model. Structured nature of concept/tools should help identify conflicts dependencies and causalities among requirements in a systematic manner.
		Completeness of arguments for each claim would be an indicator to judge sufficiency and/or insufficiency of R&Ds corresponding to the requirements
		Argumentation approach: completeness of argumentation supporting each claim in the argumentation model indicates sufficiency of R&D to show that a requirement is met

NIROND	Safety & feasibility statements tree provides KM and RM tool: safety and feasibility statements are often expressions of the requirements on the disposal system as a whole, the various subsystems and the individual components.
	Also, requirements expressed by the stakeholders such as the retrievability aspects are translated in the safety statements.
	The substantiation of the lower-level 'leaf' statements is based or technical documents, and the argumentations resulting from it. The evaluation of these arguments identifies open issues that may need to be addressed through RD&D to strengthen an underpinning argument, since an open issue that has a direct effect on the lowest-level leaf statements will affect the ones above. The relevance and significance of any open issues pertaining to the statements can be evaluated quantitatively by means of a RD&D plan consisting of experimental or desk studies, exploratory or safety calculations or an analysis to capture expert judgement.

IRM methods and procedures

- NWMO: **Project Lifecycle Management System** ensure data and their associated background information (i.e. assumptions, decisions, revisions etc.) developed during conceptual design, preliminary design, detail design, construction/installation and commissioning phases are controlled, readily available and traceable.
- Posiva: Need for data freeze as far as possible during one phase before progressing to the next.
- NIROND: comprehensiveness promoted by use of storyboards.
- **Configuration management** (NWMO: given the long duration and iterative approach, conceptual and preliminary designs require a traceable history of key changes to the design and its requirements to facilitate licensing and knowledge management):
- NWMO: regulations require that applicants and licensees employ configuration management.
- Posiva: Changes are managed through the **configuration management system**: changes assessed for their impact on the overall configuration.
- SSM has developed processes for the review of license applications; licensing review is a core process in SSM's **management system**.
- SSM: Generally, a review plan is required that specifies the objectives of the review, which legal and regulatory requirements are the basis for the review, how the review is organised, which competences are needed, as well as a time and work plan.
- The review process includes a national consultation to gather information from stakeholders.
- SSM: The interpretation of laws and regulations that have been developed at a comparatively general level with regard to the licensing process at hand may be a challenging task.
- DOE (WIPP): 5-yearly certification process (primarily concerned with radiological constituents of the repository); ensures repository is in compliance with regulations for the previous 5 years; 10-yearly permitting process (primarily concerned with non-radiological constituents of the repository).

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- Proposed modifications to the disposal process or facility requiring a change to the certification are handled through a **Planned Change Request (PCR)** submitted by DOE to the EPA. Similarly, changes to the permit are handled through a **Permit Modification Request (PMR)** that is submitted to the state.
- SSM: an initial analysis is an important aspect before new regulations are to be implemented.
- SSM: For existing regulations a periodical revision is foreseen.
- SSM: The management system process also includes public hearings. If necessary, EU or international notification procedures have to be performed.
- SSM: International reviews and participation in WENRA.
- Posiva: The development of a hierarchical and comprehensive system of longterm safety requirements for a disposal alternative that has been innovated and refined for more than a decade unavoidably entails significant iteration, and hence close co-operation, between requirements formulation, safety assessment and design development.
- Posiva: a close co-operation among barrier-specific experts is also to be sought since setting requirements on a given barrier has implications on other barriers.
- ONDRAF/NIRAS: **dedicated interaction meetings** (including for requirements not yet expressed via SF statements) QA measures are attached to the MoM to ensure traceability of each action identified in these meetings.
- BfS: A **quality management system** is in use, wherein a corresponding <u>quality</u> <u>management manual</u> describes the internal processes that are necessary to pass documents.
- BfS: Measures to ensure consistency of documentation are taken by browsing through relevant documents with the purpose of a consistency check. Consistency checks are done within the **quality assurance procedure**.
- NWMO: Data Clearance Instruction a procedure that confirms safety assessments are based on the correct engineering and geoscience data.
- NWMO: assessments are developed in a systematic, transparent and traceable manner, using FEPs to ensure comprehensive consideration of site characteristics, waste properties and receptor characteristics and their lifestyles.
- NWMO: Interdisciplinary meetings ensure that information from engineering and geoscience is integrated appropriately into the safety case as the project evolves.
- Andra: review process of data and models by internal experts of the different "information users" (i.e. design studies, phenomenological evaluation, safety assessments).

Databases and software tools to support IRM

- NIROND: Complementary to these statements is the so-called "SCR environment" (implemented on a KM system). The SCR environment has been developed in the Ondraf/Niras KM system with its own metadata and objects. The SCR environment supports the reporting of a particular study–which can spread over a long time traceability of decisions, link of RD/&D to SC objectives.
- NIROND: Minutes of Meetings (MoM) environment. The MoM template allows a meeting secretary to identify each discussion point with a unique ID allowing to trace and filter actions related to a particular issue, or assigned to a specific

expert. Similarly to the "SCR", the MoM environment can be linked with the safety statements. A formal reviewing process is also implemented.

- JAEA: Expert system (ES) development tools that particularly focus on capturing tacit knowledge using rule-based or case-based approaches.
- JAEA: Integration of databases, technical reports and QA records etc. as a Knowledge Base is a planned innovative approach.
- JAEA: "CoolRep" is a web-based reporting software that allows the vast volumes of relevant information to be presented in a user-friendly, hierarchical manner. 'CoolRep' type reports will ease maintenance and update through the project duration.
- STUK has its own RM database to check that all the requirements in its regulations are fulfilled and to facilitate the licensing review process.
- BfS: Referring to requirements deriving from the mining authority the requirements are part of a granted licence and thus part of official documents. The requirements and their fulfilment are scrutinised by using either commercial software or an electronic documentation system with specific features for that purpose.
- IRSN's public website allows free access to many of IRSN review reports and opinions that supported a decision by the regulatory body, as well as R&D results and scientific publications.
- NWMO: The <u>Repository Metadata (RepMet) Management Project</u>³⁸, which will have a strong connection to the RK&M project and be affiliated to the IGSC, is aiming to create sets of metadata that can be used by national programmes to manage their repository data, information and records in a way that is harmonised internationally and suitable for long-term management; RepMet deals with the period before closure. The NWMO is participating in both programmes.
- BfS: decisions within an organisation the necessary background information for the comprehension of specific decisions are usually cited within the document bearing the decision. Via the electronic documentation system the cited documents can be individualised to make the decision traceable.
- BfS: The large amount of reports is sorted hierarchically in such a manner that it is possible to allocate the information to certain categories (e.g. laboratory results, interpretation of basic data, combined interpretation, results of safety assessments, site characterisation). By combining sets of data with a certain decision, the tracing of the reasoning that stands behind the decision is facilitated.
- IRSN: Documents are managed through a records management table (Tableau de Gestion des Archives) which identifies typologies of documents, and for each kind of relevant document, where it must be kept, by who and for how long, for each one of the 3 periods thus defined : "currently used", "intermediary" and "historical". At the end of each period, documents are meant to be sorted out and eventually discarded depending on the applicable rules.
- Posiva: storage servers (Posidoc and Kronodoc): used to store reports, meeting minutes, correspondence with regulator, working material.
- Posiva: intranet service to facilitate (informal) information exchange (working drafts)

^{38.} NEA RWMC. 2014. Vision Document for the Radioactive Waste Repository Metadata Management (RepMet) Project. Nuclear Energy Agency. Radioactive Waste Management Committee.

- BfS: Individual documents are accessible via an electronic **document management system**. This management system provides metadata and displays revision processes as well.
- Posiva: safety assessment database used to record data and how it is used in modelling, and also be manage changes in data.
- Andra: specific data management tools:
- Databases dedicated to raw data acquisition, storage and consultation
- Posiva: Assessment database data that are structured and integrated in a way that it helps for choosing the model or the value of a parameter for phenomenological assessment, design studies or safety assessments.
- IRSN: In parallel to these EDM, the department devoted to expertise of waste packages and disposals developed its own **internal wiki website** named "twiki", where each research topic, assessment or any other subjects which is meant to be shared inside the department, is developed on one or several pages by each collaborator. These pages describe the main steps of an R&D project; they present the results and collect the reports, publications and so on. Documents preferentially refer to links to the above databases.
- IRSN: a specific numerical tool has been developed for the department to follow and/or to inform on the progress of these (RD&D) studies through the defined milestones (their internal review, redefinition of objectives, changes of deadlines...).
- IRSN: The publication of IRSN's Ph.D. theses, post-doctoral reports, as well as manuscripts of Habilitation to conduct researches on its **public website** "archives" also contributes to the constitution of a relevant documentary set. In the same way, several regulatory reviews and R&D results are summarised on IRSN's website related to the Cigéo Project (see below). This website thus provides safety-relevant information for the public.
- IRSN: software enables a **full-text research and analysis engine** of several databases (among which those mentioned above) where the Institute's scientific documents are stored.
- BfS: A **central archive of publications** (Doris), allowing search strings and evaluation mechanisms and fast retrieval of archived publication. Doris is an online platform for safekeeping and the long archiving as well as providing the availability of publications to the public.
- NWMO: **Records Management System** (SharePoint) for storing physical and electronic records, having index, search and reporting capabilities.

Memory/archiving

- Andra: memory project: distinguish "passive-memory" mechanisms documents etc. and "active memory mechanisms" e.g. informing the public.
- BfS: Complete sets of documents must be stored in at least two different suitable locations.
- BfS: The documentation to be held on file after sealing the final repository must contain all data and documents from the documentation updated during the operating phase which could contain relevant information for future generations. In particular, this should include information regarding the area surrounding the repository mine that must be protected from human intervention in the deep subsoil, and which types of intervention must be subject to special conditions.

- NIROND: All information and knowledge generated in the NIROND RD&&D programme is stored on discs, with a rotation cycle of 1, 2, 3, and 4 weeks whereby the discs that are not in use are safely stored outside with a company that has archiving and safely storage of data as its core business.
- NIROND: .In the period 2004-2008 all relevant scientific and engineering reports of the previous RD&D programmes (1978-2000) deemed valuable were digitised and 2 paper copies were made to create an overall project library. These are the current formal measures regarding the preservations of records for future programme stage (e.g. for monitoring purpose or project shut down).
- IRSN: A difference must be made between having currently access to numerical registered and properly managed documentation, and archiving, where IRSN, being a public body, must comply to the norms edicted by the Interministerial Department of the Archives of France (SIAF). Electronic documents are not, as now, recognised as an archiving standard for written documents at IRSN, only paper is.
- Why archive: retrieval of information e.g. supporting past decisions, reduce risk of future human impact.
- What to archive: Information about the location of the repository, its contents and design and the safety case.
- How: SÚRAO: archiving R&D reports in printed and electronic form.
- SÚRAO: record management and discarding plan is a legal obligation and defines categories of records to be kept.
- NWMO: On an annual basis, records are assessed to verify they are correctly indexed, attached and filed to ensure preservation and protection from loss or deterioration.
- NWMO: Records Management System allows for records to be sent to off-site storage.
- NWMO: **Information Technology Standard** guides the storing and backup of analytical, scientific and design software, as well as related software tools and datasets. Records kept in electronic form are regularly backed up in accordance the Standard.
- NWMO: Reports and files prepared in support of a licence are stored permanently; reports and files prepared for other purposes are retained for a minimum of 7 years.
- NWMO: the maintenance of appropriate and reliable data storage systems is considered within the NWMO **Quality Assurance programme**.
- NWMO: Paper records are filed in file cabinets.
- NWMO: The NEA Radioactive Waste Management Committee (RWMC) initiative on the Preservation of Records, Knowledge and Memory (RK&M) across Generations³⁹ was launched to minimise the risk of losing records, knowledge and memory, with a focus on the period of time after repository closure.
- SSM: a strategy for **preservation of information** should be produced by the implementer so that measures can be undertaken before closure of the repository. Examples of information that should be taken into consideration include

NEA RWMC. 2015. Preservation of Records, Knowledge and Memory Across Generations (RK&M): Phase-II Vision Document. Nuclear Energy Agency. Radioactive Waste Management Committee.

information about the location of the repository, its content of radioactive substances and its design.

- BfS: No systematic or methodical contingency plans are implemented regarding record preservation in the event the project is put on hold or terminated. Furthermore, there is no procedure to decide what information should be kept and when it can be discarded.
- IRSN: is sorting out and arrangement of all paper documents related to R&D and expertise since the 1980s for long-term archiving, in particular those associated to the projects of disposal since the beginning.
- NWMO: Sufficient information is archived to ensure an independent specialist, competent in the field concerned, could reconstruct the assessment and duplicate the results without undue difficulty. This includes computer model runs.
- SSM: Regulatory requirements on the archiving at nuclear installations of documentation that relate to radiation safety:
 - licensing documentation including waste characteristics and results of monitoring of the surroundings of the facility shall be archived for long times, i.e. substantially longer than 100 years.
 - information can be transferred to new media if required.
 - when the information is transferred it shall be ensured that all information is reproduced correctly.
 - It is required that the archive is transferred to the national archives when the nuclear operations cease. Thus it is foreseen that the safety case shall be archived for as long as the national archives function.
- SSM: legal requirement that regulatory evaluation reports and statements to the government are publicly available and have to be filed.
- According to SSM's management system, statements to the government regarding licence applications shall include a review report that underpins the statement. Thus SSM's statements should be traceable and the documentation available as long as the national archives function.
- BfS: Regarding the manner and location of storage, care shall be taken to ensure that all document sets are readily accessible at all times using the currently available technology. The principle of diversity must be observed.

Key remaining challenges

- Since geologic disposal is a first-of-a-kind project there is lack of operational experience in general and also in requirements setting and management process.
- JAEA: Strong leadership of top-management and understanding and active involvement of actors/users (for example, manager and researcher in various areas) are key issues.
- Andra: (i), collecting all raw data in the databases is not easy for some of them (data partnerships, theses, etc ...), (ii), the level information for reading and understanding the raw data files and getting the traceability of the processing and analysis was often limited, requiring return to the technical reports or specifications.
- NWMO: existing culture at the organisation carries the momentum of all progress achieved to date, adding to the challenge of implementing new policies and procedures.

- NWMO: Adopting the new **configuration management system** across the NWMO will require training and skill maintenance.
- IRSN (on competence management): This means having several persons competent in the same domain (i.e. several geologists, geomechanicians...), but if possible with complementary profiles, to limit the cases of persons with knowledge or a unique and irreplaceable business, as well as to test to work in pairs.
- IRSN: competence needs vary as programme progress– difficultly in maintaining the right spectrum of competences.
- NIROND: The desire of a full and integrated traceability resulted in the development, the maintenance and the use of a sophisticated KMS that takes a lot of resources, daily involvement and good will of each user. Despite this high level of sophistication, the lack of clear rules resulted in some traceability issues.
- NIROND: need to strike balance between flexibility of use and the rigidity of standardised and structured processes & activities by setting on the one hand what are the fundamental rules on which a KMS should be based and that each user should follow and, on the other hand, what are the "nice-to-use" functionalities of a KMS or "nice-to-do" practices.
- NIROND: "transversality", e.g. the impact of the requirements emerging from the long-term safety on the operational safety or the feasibility aspects.
- IRSN: It worth noting that, even if the IRSN archiving is progressing, in compliance to the French norms, it is always carried out in great suffering because no resource (human and funds for a dedicated staff, for an archivist, time for collaborators...) is initially prioritised for such activity ("fifth wheel on the wagon"...).
- BfS: There is no prefabricated/standardised solution nor software available for repository RMS. That means that the tools/processes need to be designed/developed project-specifically.
- SSM: it may be time consuming to find a certain piece of information if it is not known in which file the information can be found.
- RWM: Requirements on waste packages: Complexity of wastes, especially due to the presence of "legacy wastes", leading to a wide variety of waste packages.
- Posiva (re SAdb): change management, i.e. putting in place an efficient notification process that can give a quick feedback on the impact of a given change in a parameter and notifies the persons using the parameter so they can provide feedback on the impact of the change in their work.
- Posiva (re VAHA) (configuration management): ensure that the changes are correctly classified and that subtle changes that might have an impact on safety are identified.
- Andra: wide range of stakeholders may lead to some conflicts in requirements need for trade-offs regular meetings with all stakeholders etc.
- Posiva/Andra: There will be situations in which different requirements might be in conflict. For example, operational safety related requirements might be in conflict with long-term safety related requirements with respect to rock support.
- NWMO: Record Management System cannot accommodate the 3D design and structure drawings that define the conceptual systems considered within these assessments. Consequently, these drawings exist as multiple copies on shared drives. NWMO is now implementing a **Product Lifecycle Management system** to ensure data such as these are controlled, readily available and traceable.

- NWMO: Version control and revision locks are partly dependent on staff discipline.
- NWMO: **Records Management System** cannot accommodate the model simulation results for the two geospheres under study.
- NWMO: Revision of geosphere models due to new site information becoming available will depend on earlier versions remaining functional; otherwise, models may have to be rebuilt. The NWMO is investigating data management systems for spatially organised geosphere information, including metadata, for traceability.
- NWMO: **Records Management System** is document-based and includes some manual record-keeping systems.
- NWMO: printed materials have to be analysed (and occasionally, revised) for **configuration management** to include indexing, cross-referencing and retrieval capability.
- DOE: Existence of more than one regulation and regulator; changes proposed via PCR and/or PMR may be approved by one regulator and rejected by the other.

Some other statements

- Types of requirements: internal/external, requirements arising from the long-term or operational safety, from the nuclear and mining regulations, those arising from the design specifications, etc.
- BfS: For each project, **a file plan** exists representing the project structure plan in order to facilitate the allocation of the documented information to logic units.
- NWMO: Internal Safety Assessment Procedure defines requirements for safety assessments, including planning, scenarios, criteria, data collection, reviews and documentation of the results.
- SÚRAO: all important information documented in referenceable reports.
- SÚRAO: calculations used standardised software and are held by SÚRAO so that they can be checked, i.e. for data tracing purposes.
- Several tools are used to numerically handle IRSN's documentation, notably regarding its regulatory reviews (exchanges of mail or technical documents with implementers, with the public authorities or other stakeholders) and R&D (i.e. all the IRSN process of decision on R&D orientations, as well as the obtained results and the way they are used in technical expertise.)