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International Experiences in Safety Cases for Geological Repositories (INTESC)

Outcomes of the INTESC Project

NEA No. 6251

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FOREWORD

Disposal of long-lived radioactive waste in engineered facilities or repositories, located in suitable deep underground geological formations, is being developed as the reference solution in numerous national programmes. A cornerstone of national decision making and societal acceptance of deep geological disposal is confidence that such repositories can protect humans and the environmental both now and in the future. The evaluation and evidence for the safety of geological disposal are compiled and documented in a "safety case" that supports decision making at each stage in a stepwise process of repository development.

The nature and purpose of the safety case was described in the NEA publication *Post-Closure Safety Case for Geological Repositories: Nature and Purpose* (2004). It defines the safety case as "the synthesis of evidence, analyses and arguments that quantify and substantiate a claim that the repository will be safe after closure and beyond the time when active control of the facility can be relied on". A safety case is more than just the calculated numerical results of safety indicators; it also presents the underlying evidence, models, designs and methods that give confidence in the quality of the scientific and institutional processes as well as in the resulting information and analyses.

A safety case is presented, most often by organisations responsible for implementing waste disposal solutions, at specific points in the process of repository development. The safety case becomes more comprehensive and sound as a programme progresses. A safety case is typically used to support a decision to move to the next stage of repository development, but it could also be prepared to help review the current status of a project.

Since the initial documentation and definition of the safety case concept, there appears to have been notable convergence among national and international organisations in the understanding and development of safety cases for geological disposal. To take stock of such progress, the NEA Radioactive Waste Management Committee – through its Integration Group for the Safety Case (IGSC) – undertook to survey and to analyse International Experiences in Safety Cases for Geological Repositories: the INTESC project.

The INTESC project analysed existing safety cases, and their elements, to provide an overview of progress during the last decade, to identify key concepts and to give insight into regulatory expectations on the contents and review of safety cases. A major input for the project was responses from IGSC members to a detailed questionnaire regarding the context and contents of national safety cases, including the underlying evidence, assessment basis and presentation of the safety case. Using the questionnaire responses as a starting point, the IGSC organised a workshop in 2007 to further assess the state of the art in developing safety cases (areas of agreement and disagreement) and to identify and develop understanding of issues that may need further work by the IGSC.

This report documents the outcomes of the INTESC project. It takes account of the responses to the INTESC questionnaire as well as the results of the workshop. The project has shown that the purpose and concept of a safety case are generally understood, accepted and adopted within radioactive waste management programmes worldwide. Programmes are preparing safety cases in line with most of the elements suggested in the 2004 NEA publication cited above, although there are some differences in interpretation and presentation. Some important trends are emerging, such as the use of safety functions and the role of a geosynthesis. Further development of some aspects and tools, such as quality assurance programmes and requirements management systems, can be expected as safety cases are further refined to support programmes moving toward implementation of geological disposal. Many of the topics identified may merit further work in the international arena.

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Appendix C. **Compilation of answers to the INTESC questionnaire**

1. INTRODUCTION

The nature and purpose of the safety case has recently been described in the NEA publication *Post-Closure Safety Case for Geological Repositories: Nature and Purpose* (NEA, 2004). According to this publication, a safety case is:

> "the synthesis of evidence, analyses and arguments that quantify and substantiate a claim that the repository will be safe after closure and beyond the time when active control of the facility can be relied on."

The safety case becomes more comprehensive and sound as a programme progresses and is a key input to decision making at several steps in the repository planning and implementation process. A key function of the safety case is to provide a platform for informed discussion whereby interested parties can assess their own levels of confidence in a project at a given planning and development stage, and identify the issues that may be a cause for concern or on which further work may be required.

Recently, there has been notable convergence in documents published by national and international organisations in the understanding and development of safety cases for geological disposal. The IAEA Safety Requirements WS-R-4 (IAEA, 2006), the NEA brochure on the safety case (NEA, 2004), and the presentations at the NEA International Symposium on the Safety Case in January 2007 (NEA, 2008a) as well as several recently published safety reports all show a significant assimilation of the principles by national organisations that were set forth in the NEA report, *Confidence in the Long-term Safety of Deep Geological Repositories: Its Communication and Development* (NEA, 1999a) and subsequent documents, such as those produced by the NEA Working Group on the Integrated Performance Assessments of Deep Repositories (IPAG-3) (NEA, 2002).

At the 38th meeting of the NEA Radioactive Waste Management Committee (RWMC) [NEA/RWM(2005)16], members approved an exercise on "INTernational Experiences in Safety Cases" – namely the INTESC project [NEA/RWM(2005)7], based on the results of a questionnaire, with the following aims:

- Analyse existing safety cases and elements, components of safety cases that are under development and to identify key concepts, including points of consensus and divergence.
- Provide a clear overview of the progress that has been made in the last decade.
- Provide a clear overview of regulatory expectations on the future safety cases.
- Improve awareness of strengths and weaknesses in present-day methodologies for developing and presenting safety cases.
- Provide a state-of-the-art report on practical experiences on safety cases for geological repositories and the lessons learnt from current practices, following the international symposium (NEA, 2008a).

A questionnaire addressing these aims was developed under the auspices of the Integration Group for the Safety Case (IGSC), the Technical Working Group under the RWMC. The questionnaire was provided to IGSC members in May 2006. Answers were received from 19 organisations representing both implementing organisations and regulatory authorities in 11 countries. Some organisations co-operated to provide a joint response. The answers are compiled in Appendix A. The compilation is structured in the same way as the questionnaire, with six sets of questions under themes aligned with elements set out in the NEA safety case brochure (NEA, 2004), namely:

- Purpose and context.
- Safety strategy.
- Assessment basis.
- Evidence, analyses and arguments.
- Synthesis.
- Presentation of the safety case.

Using the questionnaire responses as a starting point, the IGSC organised an INTESC workshop on 1-3 October 2007. The objectives of the workshop were to assess, based on the preliminary findings of the INTESC questionnaire results and outcomes of other current NEA initiatives, the state of the art in developing safety cases (areas of agreement and disagreement) and to identify and understand issues that may need further work by IGSC.

While some time was devoted to discussing areas of consensus, the main part of the workshop focused on topics and issues that appear to be emerging and where development could benefit from an international discussion. The basic structure of the workshop was: presentation and discussion of findings from the questionnaire, working group sessions on key issues and discussion and identification of the path forward.

The current report takes account of the responses to the INTESC questionnaire as well as the results of the INTESC workshop. It provides a short synthesis of the answers to the questionnaire and builds on these by further elaborating on topics and issues that, based on discussions at the workshop, appear to be emerging and where development could benefit from an international discussion. Chapter 2 highlights common elements and areas of agreement regarding safety cases. Emerging issues and challenges are addressed in Chapter 3. Chapter 4 summarises the significant issues and suggests which could benefit from future work by international expert groups such as the RWMC and its IGSC, or perhaps through other fora in the IAEA or the EC.

2. OVERVIEW OF AREAS OF AGREEMENT AND COMMON ELEMENTS

All responding programmes are preparing extensive safety cases (or preliminary ones) in line with most of the elements of a safety case suggested by the NEA safety case brochure (NEA, 2004). There is strong international consensus on a number of issues related to safety cases; these issues were identified primarily through the INTESC questionnaire results and are described below. However, there are some important differences in use or in interpretation and there are some elements in "real life" safety case implementation that are not covered by the brochure. There is also substantial development within some consensus issues. These aspects are further discussed in Chapter 3.

2.1 The purpose of a safety case is well established

As already noted, responding programmes are preparing safety cases (whether extensive or preliminary ones) in line with most of the elements of a safety case suggested by the NEA safety case brochure. In addition – judging from the responses from regulatory agencies – most regulations outline the expectations regarding the scope of, and support for, a safety case (or at least, of a safety case supporting licensing procedures). Overall, there are similar approaches and attitudes in different programmes and similar concerns expressed from the participating regulators. It appears that safety cases under development by implementers already address many of the issues identified as significant by regulators.

The concept of a safety case is not a novel thing. Explicit safety cases are required, for example, for military systems, the off shore oil industry, rail transport and the nuclear industry. But one of the specific challenges of the safety case for a geological repository is the need to consider post-closure safety and, consequently, much longer timescales. From a regulatory perspective, it has long been established that providing the evidence for the support of the claims made in the safety assessment is just as important as the safety assessment calculations themselves.

International consensus in the geological disposal community also points to the need to complement the safety assessment with broader arguments and evidence to support the contention that the conclusions that may be drawn from the quantitative results of the safety assessment are robust, and the need to go through an iterative process with different loops, both internally and within a national step-by-step decision-making process.

Reflecting these trends in 1999, the NEA produced a report titled *Confidence in the Long-term Safety of Deep Geological Repositories: Its Development and Communication* (NEA, 1999a), which outlines the emerging confidence-building and confidence-communication practices being developed at that time in various radioactive waste repository programmes. This effort led to the NEA safety case brochure (*Post-Closure Safety Case for Geological Repositories: Nature and Purpose*, NEA, 2004), which contains the first formal definition of the safety case for deep geological repositories. The IAEA Safety Requirements WS-R-4 (IAEA, 2006), co-sponsored by the NEA and issued in 2006, encompass concepts similar to those in the earlier NEA documents. According to the questionnaire responses, the definition of safety case has been broadly accepted by all repository programmes.

The purpose of the safety case is also well established. According to the NEA safety case brochure and IAEA WS-R-4, a safety case includes a robust safety assessment based on a set of reasoned and substantiated arguments for confidence in the safety of the system (despite the recognised uncertainties) to support a decision to move to the next phase of its development – whether site selection, construction license application, operation, or final closure. The contents, type and amount of information that a safety case may include vary with the decision at hand. For example, a safety case to support the siting decision is very different from one that supports the construction license decision after extensive site characterisation. The latter would incorporate data and site-specific knowledge gained during years of scientific study, while the former is typically based on scientific understanding of a more generic nature, possibly supplemented by some surface-based data.

Additionally, different arguments and levels of detail are needed to address the different audiences concerned with the safety of a proposed facility. There must be only one safety case that is fully internally consistent, but different portions, and different levels of detail, can be tailored to the interests and technical expertise of different audiences. Indeed, one of the strengths of a safety case is that it is based on several independent lines of reasoning, which may each be suitable or meaningful to different audiences.

The methodology for assembling and presenting the safety case is also well established, although some elements are subject to different interpretation, as discussed in the following sections.

2.2 Operational and organisational aspects

Confidence in the safety case rests to a large extent on operational and organisational procedures in developing and maintaining a safety culture. Providing the means and incentives to ensure a safety culture is also of key regulatory concern. The basic responsibility for developing a safety culture rests with the implementer. Judging from questionnaire responses, all national programmes aim at management strategies that are in agreement with good management and engineering principles and practice, e.g. implementation of a quality plan, consideration of stakeholder requirements, allocation of resources and co-ordination of activities. The questionnaire responses show that:

- Most programmes apply a stepwise approach to repository implementation.
- All programmes adopt an interative and stepwise approach to repository design and the focus of the safety case work.
- All programmes are subject to formal safety case quality assurance (QA) plans within the overall quality management system of the organisation. Such QA plans are defined to various degrees of detail depending on the repository development stage.
- External experts used to aid decision-making are selected on the basis of reputation, experience and references, and expert recommendations are thoroughly documented.
- Effective integration of information and knowledge coming from the different fields of the programme is ensured, for example, by a high-level overall integration team.
- Key safety issues govern programme priorities.
- All programmes make provisions for storing information in some type of document and information management systems.

2.3 Treatment of uncertainties

Uncertainty assessment is a key component of the assessment strategy in most cases. In addition, uncertainty management is a driving force when moving from one step to another and guides the identification of development needs.

The assessment of a repository relies on the understanding of the behaviour of the repository components that has been acquired at a given stage of the development programme. This understanding is founded on a large body of scientific knowledge and on the development of a repository design, taking into account inevitable uncertainties when considering evolution over hundreds of thousands of years. In addition, safety is a main driver in design, such that design choices are oriented towards robust solutions, in part in order to compensate for potential lack of knowledge. Finally, uncertainties are systematically investigated and their potential effects examined and taken into account in the safety assessment.

In most safety analyses, deterministic and probabilistic calculations are seen as complementary and both approaches are applied. Conservative assumptions are acceptable to handle situations where knowledge is lacking, phenomena are poorly understood, or undetected features of the geological setting could exist. Regulators generally accept stylised approaches for assessing certain aspects of scenario analysis, for example, when uncertainties cannot be readily quantified or bounded or when the probability of some initiating event can be estimated but the timing is unknown; such scenarios include, assessing future human actions and for assessing the biosphere evolution (NEA, 2006). In stylised modelling, certain assumptions or parameters are set even if they cannot necessarily be shown to hold based on current scientific understanding; thus, even if they are constrained by scientific understanding and are often pessimistic, they are still to some extent arbitrary. However, the extent of stylisation is still a matter for interpretation. Many programmes consider “what-if” cases, for example, postulating loss of barrier function(s). However, their rationale, as well as views on whether such scenarios lie outside the main risk contribution, varies between respondents.

Several approaches for handling diverse opinions on data or models are given. Examples include: consulting a safety assessment team separate from the experts providing the scientific documentation; developing probability distribution functions to represent diverse sources of information on parameter values; considering what-if cases to assess alternative models or assumptions; convening expert panels and meetings; obtaining review by outside experts. Above and beyond such methods, the resolution of conflicting opinions is served by the development of the safety case through multiple iterations, which allows early recognition of contradictory opinions and, thus, provides time for obtaining relevant information to resolve issues.

2.4 Role of the biosphere

There is general agreement that the biosphere is not considered to fulfil any safety functions but its properties influence especially how potential groundwater contamination would be distributed into the environment and this needs to be assessed. Some regulations provide quite specific guidance on how to handle this issue, e.g. by prescribing stylised approaches for how to convert geosphere releases into dose, how to handle future climate changes, and how to address potential changes in future human behaviour.

2.5 Consistent and sufficient information base

There is wide agreement that a description of the system concept – i.e. a description of the disposal system, its components, and their safety functions (including assessment of their actual implementation) is a key part of the safety case. According to the NEA safety case brochure, the presentation of scientific data and understanding in a safety case should highlight evidence that the information base is consistent, well-founded and adequate for the purposes of the decision being supported by a specific safety assessment. The assessment methods, models, computer codes and databases must also be clearly and logically presented. All respondents generally support these goals.

Specific examples on how the scientific understanding is demonstrated include:

- Usual scientific means of quality control (e.g. publication in peer-reviewed journals or independent expert review of technical work products).
- Multiple lines of reasoning and multiple lines of evidence: support of key features of the disposal system by wide-ranging information, including from laboratory and field data and from observations of natural systems (including natural and anthropogenic analogues).

- Investigation data, if such exist, demonstrating that conditions at repository depth have been unchanged for very long times or that changes of such conditions are caused by well-known processes (i.e. demonstrating stability and predictability).
- Systematic identification and evaluation of uncertainties, including their relative importance to safety and measures taken to compensate for or to reduce them.

It should be noted that the supporting arguments are seldom based on a single piece of evidence. It is the chain of arguments, rather than any individual argument, that is important. A primary interest is in "reasonable" predictability and stability of the geological system. It is recognised that most geological systems evolve with time. All details of this potential evolution are not needed for demonstrating safety, but there is a need to establish well-reasoned bounds for the future evolution.

Examples for demonstrating that all relevant scientific information is taken into account include:

- An iterative approach in which the model and databases and conclusions are progressively refined as new knowledge arises; results and open issues from prior iterations are reviewed regularly to re-assess their importance and validity; and account is taken of past independent technical reviews and input from all relevant disciplines.
- Systematic assessment and documentation of Features, Events and Processes (FEPs) and FEP interactions to identify model requirements.
- Systematic reviews both internally and by experts not directly involved in the assessment.
- Various international exercises with exchanges and discussions in workshops and working groups.

2.6 Actions to check reliability and plausibility

In evaluating performance and safety indicators, actions are taken for checking the reliability and plausibility of safety cases. There are well-established ways of checking individual parts of a safety case including:

- Validation against large-scale experiments or field data.
- Various quality assurance procedures.
- Comparison with simplified analytic approaches.
- Comparison with independent safety evaluations of the same or comparable systems, if available.
- Peer review and various international exercises.

Furthermore, the iterative approach, by which the safety case is progressively refined and reviewed, provides a means for "testing" the completeness, coherence, internal consistency and robustness of the safety case as a whole. Systematic identification of safety functions and the establishment of criteria for the safety functions – along with documentation and justification of the process and decisions – appears to be an important but still emerging approach to prioritise issues, integrate information and scientific understanding, identify key uncertainties and assess the relevance the safety.

These actions concern the "quality of underlying scientific understanding". Confidence in the plausibility of results can also be enhanced by providing multiple lines of reasoning for safety in addition to the calculated numerical values of e.g. dose or risk. Such complementary evidence and lines of argument may include observations of natural systems to support that safety over geological timescales is achievable at the site in question or studies to demonstrate the feasibility of engineering designs.

Some of the assessments in national programmes show doses and/or risks at or above acceptance levels – in altered evolution scenarios or other cases of low likelihood, or at very late times. However, in light of the uncertainties about the occurrence of such events (and also in view of the possibilities to avoid or to reduce the consequences of such scenarios), judgements will need to be applied in these cases to decide ultimately whether they are considered to violate compliance with regulation. Complementary indicators in addition to dose and risk are also used, mainly for illustrative purposes, and their selection reflects the measures that have been discussed in various international fora, e.g. radionuclide flux to (and resulting concentrations in) the biosphere, activity releases from the repository or radiotoxicity of the waste. There are proposals in some countries to give higher weight to so-called “additional” or “complementary” indicators.

There is a general aim to demonstrate that the system can be implemented reliably (i.e. without deviations that would be unacceptable for safety) using existing technology and, according to the responding implementers, this has also generally been achieved. Potential defects in manufacturing or implementation are taken into account to a varying degree, largely depending on the repository concept and on the importance of such defects in terms of safety, as well as taking into account the degree to which production and implementation procedures have been developed and specified. Generally, the strategy to deal with remaining uncertainties is to assess their potential impact on safety, and, based on the results, devise plans to resolve safety-relevant uncertainties through ongoing research and development (R&D), site investigation and repository design activities, as appropriate.

2.7 Multiple complementary lines of evidence

The analyses related to the safety of a repository are based on a wide variety of information, including an extensive programme of site characterisation and laboratory testing, comparative and corroborative analyses, as well as natural and man-made analogues. By utilising a variety of independent methods, techniques, and perspectives, scientists and engineers develop confidence in the reliability of the results of the models and analyses that would not otherwise be possible. It is important to define and carry out the analyses that feed a safety case so that these different lines of evidence are made clear and not hidden in the potentially large and complex reports documenting the technical basis underlying the safety case. These points are further elaborated in Section 3.4.2. It should also be acknowledged that the listed points are not necessarily fully independent pieces of evidence, but may be interrelated.

2.8 Synthesis

Some assessments conclude that there is adequate confidence in the possibility of achieving a safe repository to justify a positive decision to proceed to the next stage of planning or implementation. Other assessments would be expected to make such conclusions at the points when a safety case is put forward to support decision, for example as part of a licensing application. Furthermore, all assessments contain at least preliminary conclusions regarding safety.

2.9 Presentation of the safety case

The most extensive and detailed documentation of a safety case is generally aimed at a technical audience and often (depending on the stage of repository development) for review by the regulator. It is usually presented in a principal safety report supported by several main references and a number of more detailed and technically specialised reports. It may also be noted that most regulators have issued, or plan to issue, documents on how they will review a safety case.

In applicable cases, a summary of the safety case is, or will be, presented in an Environmental Impact Assessment. Shorter summaries and brochures are prepared for wider audiences. Only some respondents appear to give an important role to other media (e.g. computer graphics, videos) in addition to printed documents in presenting the safety case to different audiences.

3. EMERGING TRENDS AND CHALLENGES IN SAFETY CASE IMPLEMENTATION

While there is generally a broad consensus on the scope and need for a safety case, there are some important examples of differences in use or in interpretation and there are some elements introduced during recent safety case implementation. There is also substantial development within some issues for which consensus already exists.

3.1 Overview

The questionnaire answers and workshop discussions show there are elements of the safety case – as described in the 2004 NEA safety case brochure – that are still developing and gaining in use, have variations in interpretation or are not yet widely used. There are also elements of safety cases that are not reflected or go beyond the ones in the brochure. This allows the identification of evolving themes worth further consideration and elaboration.

3.1.1 Elements developing and gaining in use

Several safety case elements listed in the NEA brochure are developing and are gaining in use, although it is not clear from questionnaire answers if this reflects evolving attitudes and terminology or is a result of the further development of individual safety cases. Examples of such developments include:

- The application of data clearance procedures (i.e. selection of input data and discussion and quantification of input data uncertainty).
- Use of automated knowledge management systems to handle the vast quantity of data and information involved, to help ensure the necessary knowledge is accessible to all stakeholders and to help identify information gaps so that supporting R&D can be effectively prioritised.
- The development of plans and tools for the preservation of information in the very long term.
- The development of siting and design strategies in which final adjustments to repository layout will be made according to the specific characteristics of the rock revealed during the construction stage.
- The development and application of the concept of "safety functions", both by implementers and regulators.

3.1.2 Variations in siting and design strategy

There are several areas in which the siting and design strategy vary among national programmes:

- While several barriers are normally used, strict application of the multi-barrier principle is not required in all programmes. Instead, a multifunction principle is applied.
- Some countries require the use of "best available technology" (BAT). Even when used, this concept – as well as that of "optimisation" – is subject to interpretation, although it appears generally accepted that due consideration should be given to economic and other societal factors, i.e. taking into account what is reasonably achievable in making design decisions.
- Post-closure monitoring is planned by most organisations but this is not necessarily seen as a key component of the safety case.

- Some safety cases address the possibility for retrievability, particularly in order to demonstrate its feasibility. Only a few programmes take actions on revising disposal concepts to dramatically facilitate retrievability. There is also a high-level requirement, explicitly stated in some national nuclear energy legislation, that such actions must not compromise long-term safety. In some programmes, retrievability is considered to be an issue related more specifically to design and operational safety; whether it is addressed in the safety case then depends on the extent to which the structure and scope of the safety case are focused on long-term safety (Section 3.3.4.).

3.1.3 Variations in implementing the assessment strategy

There are also variations in the implementation of some elements of the assessment strategy:

- Most regulators, but not all, accept a separate treatment of future human action scenarios. Some, but not all, assessments consider the risk to the intruder.
- Most implementers apply some alternative conceptual models of site or repository behaviour, but the degree of consideration of alternative models is a matter of discussion between implementer and regulator. Furthermore, some implementers argue that before site investigations take place, the large uncertainties that may be associated with the geological environment may make qualitative arguments in the safety case more meaningful than quantitative performance assessment (PA) calculations at this stage. These qualitative assessments would then be used to scope uncertainties and identify data requirements for the site investigation programme and to guide the development of the repository concept and safety case at later stages.
- While the fundamental aim of a deep geological formation waste repository is the protection of humans and the environment in the short and long term, there are different degrees of emphasis placed on the various safety functions contributing to this protection. Some programmes appear to focus on the radionuclide retention aspects of the safety functions. Others put more emphasis on the containment (isolating) functions and derive safety functions related to the ability of the system to provide this containment. To some extent, this difference in attitude depends on the disposal concept and the properties of the host rock considered.
- Transparency and traceability are both of key importance in the safety case. On the one hand, arguments in the safety case should be presented as transparently as possible, which implies clear, reader-friendly, and relatively brief descriptions. On the other hand, traceability of decisions and data demands a highly detailed approach that may also address the relative merits of multiple arguments or information. Striking the proper balance between transparency and detailed referencing is a challenge that, experience shows, can be partly (but not necessarily completely) overcome by the use of hierarchical documentation. (Section 3.4.3.)

3.1.4 Elements not yet widely used

Only one respondent directly addressed the possibility to discuss explicitly “the general strength of geological disposal” in the safety case. Possibly this is an issue to be (or, perhaps, already has been) addressed at the national policy level; but of course, the analyses and safety case must support a conclusion on the safety of geological disposal as a waste management strategy.

Judging from questionnaire responses, there is little distinction between arguments presented for safety and confidence and “complementary arguments” and this division may not be useful. Few respondents use the term “reserve FEP”, e.g. features, events or processes ”that are currently omitted on the grounds of conservatism, but good prospects for improved scientific understanding, models and data mean that they may be included at a later stage of the repository programme” (NEA, 2004) even if the generally conservative approach in safety assessment is indeed applied.

3.1.5 Elements of safety cases not reflected or beyond the ones in the brochure

There are elements adopted in safety case implementation that are not fully reflected in, or go beyond, the ones in the NEA 2004 brochure. Some important examples of this are:

- Preparation of a geosynthesis, i.e. assessing geoscience information from a variety of perspectives such as structural geology, hydrogeology, and geochemistry and synthesising this data into an integrated geosphere model that is consistent with the knowledge and history of the site in a cross-disciplinary manner. While the value of such an integrated understanding of the geosphere is more and more widely recognised, the format and presentation of the geosynthesis vary between respondents.
- Account of the construction and operational period. It is widely acknowledged that some account must be taken of the construction and operation phases in order to define an initial state for the post-closure phase. Some programmes are now examining in more detail the thermal, mechanical, hydraulic and chemical processes/alterations for construction and operation using a similar methodology as for subsequent, post-closure stages – but there is no consensus on the approach or on whether it is important for post-closure safety (and even if so, whether it ought to be included in the long-term safety case). A few programmes already have included a preliminary assessment of the operational safety (through classical methods) in their safety case.
- Integration aspects, especially linkage of safety assessment with engineering and research programmes.
- Submission of a comprehensive number of papers to academic journals or other quality-assured proceedings to support critical arguments of key issues by demonstrating that they are credible and acceptable to the broader scientific community.

3.1.6 Evolving themes

The findings from the INTESC questionnaire and the subsequent discussion within the INTESC workshop demonstrate that there is a strong development on safety case matters, which can be divided into the following three themes:

- **Safety and assessment strategy**. There are several aspects of the safety and assessment strategy – i.e. the high-level approach for achieving safe disposal, along with how the given system is analysed – that are currently evolving. There is considerable development regarding the use of safety functions, approaches to integration, the application of QA, and in the management and treatment of uncertainty in describing the geosphere by, for example, developing a geosynthesis and applying indicators other than dose or risk.
- **Relationship between long-term safety and design, construction and operational periods.** Developing the design basis and evaluating the implications for long-term safety of the implementation of the design, construction work and operations are key components of the safety case. The safety case should establish the long-term safety goals and design requirements and should demonstrate how the design and actual construction would ensure that these requirements are met. This issue is receiving increased attention since many programmes are now approaching implementation.
- **Other contributors to confidence in safety.** The INTESC questionnaire addresses many of the technical, scientific, and documentation requirements that are necessary to provide confidence, or at least to not undermine confidence, in a safety case. There are several additional opportunities to enhance confidence, however. These were not comprehensively

covered by the INTESC questionnaire or answers as they are not yet routinely implemented in current safety cases. However, they are being actively developed and were discussed at the INTESC workshop. Such additional contributors to confidence are judged to have the potential to play an important role in future safety cases.

These themes are further discussed in the following sections.

3.2 Safety and assessment strategy

There are several aspects of the safety and assessment strategy – i.e. the high-level approach for achieving safe disposal, along with how the given system is analysed – that are currently evolving. As noted above, there is considerable development regarding the use of safety functions, approaches to integration, the application of QA, in the management and treatment of uncertainty, in the description of the geosphere (by, e.g. developing a geosynthesis) and in applying indicators other than dose or risk.

3.2.1 Safety functions

The compilation of questionnaire responses (Appendix A) shows that the concept of safety functions has increased in use and emphasises how the concept was derived from the concepts of containment, retention and isolation inherent in the strategy of geological disposal.

The basic purpose of long-term waste management is to protect human health and the environment against the associated risks. After completion of the disposal process, the waste is passively confined for a long period of time on the basis of multiple long-term safety functions requiring no human intervention.

Earlier evaluations of safety principles for geological disposal have concluded that a strict application of the "multiple barrier principle" is not feasible for nuclear waste disposal (e.g. NEA, 2002). It is generally noted that safety does not simply consist of placing successive physical barriers between the living environment and radioactive waste and that it may be more relevant to consider the multiple safety functions that need to be maintained through proper siting and selection of repository components.

A more developed use of "safety functions" as a methodological element is observed in several recent safety cases or safety assessments. These emerging approaches usually consist of de-constructing the high-level and long-recognised functions of containment, isolation and retention into more detailed functions or requirements on specified parts of a repository system, e.g. a canister. These detailed safety functions are used for structuring the analysis, for scenario development, for uncertainty management and for feedback to repository design. The definition and role of safety functions do, however, vary considerably, even among safety cases where they are given a more salient role. In this Section, some aspects of this emerging trend are discussed.

3.2.1.1 Definitions of safety functions

A number of different meanings of the term safety functions can be observed in safety cases. Definitions relating to high-level functions often refer to general properties of the entire repository system. Such high-level functions are referred to, for example, in the French safety rule and in the IAEA Safety Requirements W-SR-4 (Box 3.1); the IAEA standards also acknowledges that a safety function may be provided by means of a physical or chemical property or process that contributes to safety.

Box 3.1 **Role of safety functions according to the IAEA safety requirements on geological disposal of radioactive waste, W-SR-4** (IAEA, 2006)

"3.26 The natural and engineered barriers shall be selected and designed so as to ensure that post closure safety is provided by means of multiple safety functions. That is, safety shall be provided by means of multiple barriers whose performance is achieved by diverse physical and chemical processes. The overall performance of the geological disposal system should not be unduly dependent on a single barrier or function."

"3.27 A barrier means a physical entity, such as the waste form, the packaging, the backfill or the host geological formation. A safety function may be provided by means of a physical or chemical property or process that contributes to safety, such as: impermeability to fluids, limited corrosion, dissolution, leach rate and solubility; and retention ..."

"3.30 Containment of waste implies designing for the minimal release of radionuclides…"

"3.33 Isolation means retaining the waste and its associated hazard away from the biosphere in a disposal environment that provides substantial physical separation from the biosphere, making human access to the waste difficult without special technical capabilities, and that provides a very slow mobility of most of the long lived radionuclides. Isolation is an inherent feature of geological disposal."

Definitions relating to lower-level safety functions typically can be directly related to properties of barriers or repository components. These can be considered "performance indicators" (as discussed in Section 3.2.5 of this report) if they do not relate directly to a specific safety aspect. For example, the safety function description in Andra's "Dossier 2005 Argile" (Andra, 2005) constitutes a formalised way of deconstructing, in a top-down manner, the understanding of the overall repository system into the "actions" that contribute to safety. Each function is characterised by: a performance level, the period during which the function has to be available and the component(s) (one or more) that must fulfil the function (Figure 3.1). Some indicators allowing assessment of the performance of individual components with respect to their function may be defined. Meanwhile, SKB defines, in the safety assessment SR-Can (SKB, 2006), a safety function as "*a role through which a repository component contributes to safety*". A typical safety function in the SR-Can assessment, as well as in many other programmes, is the capability of the canister to provide a corrosion barrier. A list of the canister safety functions used in SR-Can is given in Figure 3.2. Other organisations use somewhat different terminology to describe a similar conceptual approach; for example, Ondraf/Niras (Lalieux *et al.*, 2007) use the term "safety and feasibility statement". These are developed and structured in a top-down manner, starting with the most general (highest-level) statements and progressing to increasingly specific (lower-level) statements. Lower-level statements generally describe key properties or performance criteria that the system should fulfil in order to satisfy higher-level statements about broader safety goals that the system is designed or intended to meet. In the United States repository programme for high-level waste and spent nuclear fuel, the term "barrier functions" is used for lower-level safety functions because they typically involve the evaluation of supporting performance indicators; despite the different terminology, the intent and application are similar: to evaluate and illustrate the contribution that a component or process makes to the performance of the system.

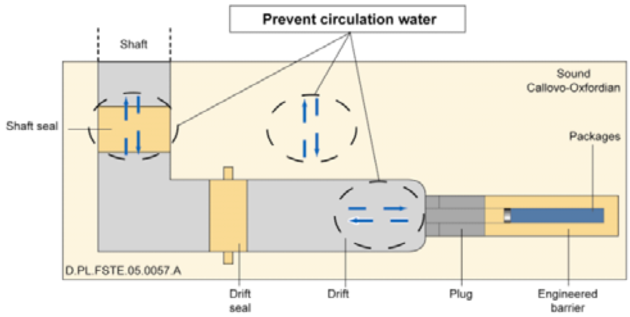
The differences in defining and applying safety functions are caused by different approaches to safety demonstration – which, in turn, reflect the variety in national regulations and, more important, in repository concepts where safety is achieved in different ways. There appears to be no reasonable way to harmonise in detail these varying uses of safety functions. Rather, as for many other cases where practises in safety cases vary between programmes, it is important to clearly define the terms for the context in which they are used. It may also be useful for programmes to put their own definitions in context by referring to uses of similar terms in other programmes/safety cases and explaining the differences. Examples of definitions of terms related to safety functions are given in Box 3.2.

Figure 3.1 **Example from Andra “Dossier 2005 Argile”**

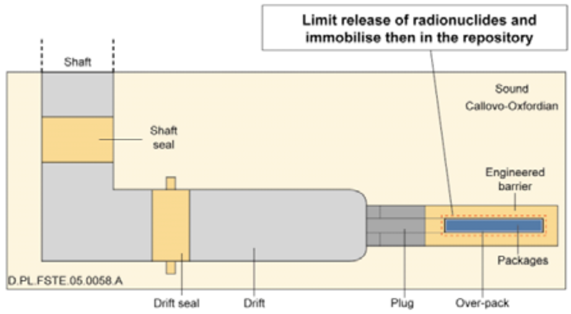
The fundamental safety function “protecting the human being and the environment against hazards associated with the dissemination of radioactive substances” can be e by three high-level safety functions, which are at the core of the long-term safety assessment: (i) prevent water circulation in the repository, (ii) limit the release of radionuclides and immobilise them inside the repository, and (iii) delay and reduce the migration of radionuclides toward the environment.

Post closure Safety functions over time

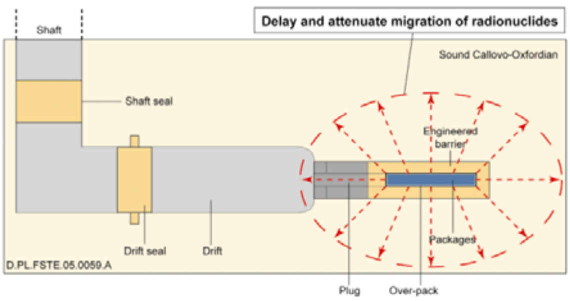
- “Opposing the circulation of water ”
  - Control of the water flow
  - Reflects the requirement for sealing resaturation



- “Limiting the release of radioactive nuclides and immobilising them within the repository”
  - Control of the thermal flow (C-type waste and SF) during the initial thermal phase
  - Reflects the requirement to protect the waste packages from water and place them under favourable physicochemical conditions (pH…)

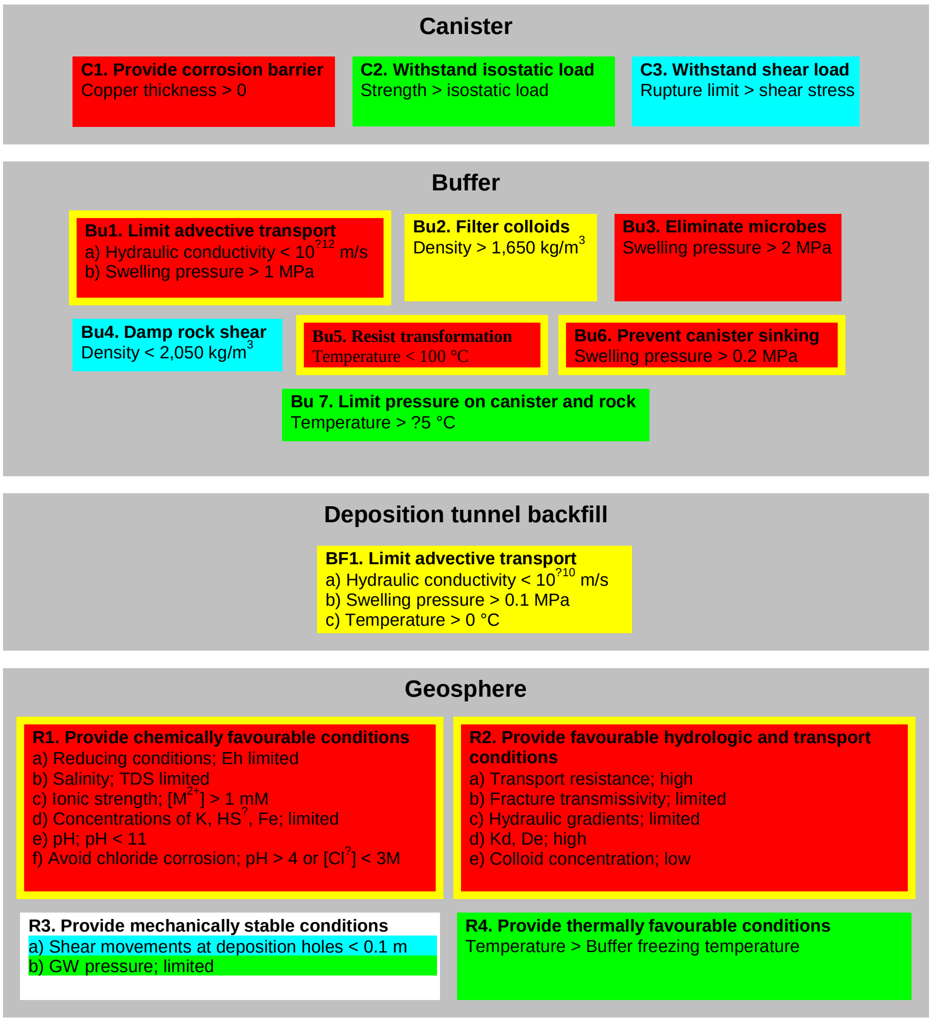


- Delaying and reducing the migration of radioactive nuclides”
  - Controls the radionuclide flow
  - Acts after radionuclides have been released in the geological medium
  - Reflects the transport properties, time for diffusive transport process



Related to the derivation of safety functions is the issue of completeness. The question of whether a derived set of safety functions is complete, in the sense that captures all relevant aspects of safety, must be addressed in relation to the intended use of the functions in a safety case (which, as noted above, relates to the stage of repository and safety case development). Completeness is supported by a systematic and structured derivation of safety functions that has, at its foundation, the safety strategy and high-level or conceptual safety functions. “Completeness” cannot ultimately be proved, but the comprehensiveness of safety functions can be supported and checked by various methods (depending on their use), such as reviewing them in the light of known long-term processes and international FEPs lists.

Figure 3.2 **Safety functions (bold) as defined in SR-Can** (SKB, 2006)**, safety function indicators and safety function indicator criteria (definition see Box 3.2)**



When quantitative criteria cannot be given, terms like "high", "low" and "limited" are used to indicate favourable values of the safety function indicators. The colour coding shows how the functions contribute to the canister safety functions C1 (red), C2 (green), C3 (blue) or to retardation (yellow). Many functions contribute to both C1 (i.e., corrosion barrier) and retardation (red box with yellow board).

Box 3.2 **Examples of definitions of terms relating to safety functions**

A. **ANDRA "Dossier 2005 Argile"** (Andra, 2005)

- Safety functions constitute a formalised way of breaking down the overall understanding of the repository system into the "actions" that contribute to safety. These actions are accomplished by the repository's components, the operators or the organisational provisions implemented. Safety functions are established according to the life phase of the repository: distinction is made between the operational and post closure phases.

- The notion of multiple safety functions constitutes a generalisation of the notion of multiple barriers. Functions may be redundant, i.e. have the same effect and be able to replace each other, but most of them are complementary and contribute jointly to achieving the safety objectives. The loss of a function then leads to deterioration in the safety level, but this loss can be acceptable if the other functions are maintained.

Box 3.2 **Examples of definitions of terms relating to safety functions** (Cont'd)

B. **SKB SR-Can assessment** (SKB, 2006)

- A safety function is a role through which a repository component contributes to safety. Example: The canister should withstand isostatic load.
- A safety function indicator is a measurable or calculable property of a repository component that indicates the extent to which a safety function is fulfilled. Example: Isostatic stress in canister
- A safety function indicator criterion is a quantitative limit such that if the safety function indicator to which it relates fulfils the criterion, the corresponding safety function is maintained.
- Example: Isostatic stress<isostatic collapse load. The criterion should ideally be fulfilled throughout the assessment period.

C. **Ondraf/Niras** (Lalieux *et al.*, 2007)

- Highest-level safety statement: disposal system will conform to relevant regulatory requirements and general guidance concerning long-term safety.
- Supporting the highest-level safety statement: findings of a formal safety assessment, which includes the results of quantitative analyses of dose or risk for a wide range of evolution scenarios; evidence concerning the individual long-term safety functions on containment and retention that the disposal system is expected to provide and concerning the dilution and dispersion of any contaminant releases from the repository in the biosphere and aquifers.
- Support for evidence: statements about the properties of the disposal system. (For example, support for the containment and retention is the low permeability, fine homogeneous pore structure and favourable geochemical conditions in the Boom Clay.)

3.2.1.2 Independence and complementarity of safety functions

The definition of "safety functions" put forward by Andra captures several key points that are applicable across programmes. Primary among these is the notion that multiple safety functions constitute a generalisation of the notion of multiple barriers by elaborating the various actions that contribute to fulfilling safety objectives. In contrast to the concept of multiple barriers, however, these "actions" may be accomplished not only by the repository's components, but also by their specific properties, by the operators, by the organisational provisions implemented or by a combination of these. Functions may be redundant, i.e. have the same effect and be able to replace each other, but most of them are complementary and contribute jointly to achieving the safety objectives. The loss of a function could thus lead to deterioration in the safety level, but this loss can be acceptable if the other functions are maintained.

On a high level, the functions of containment and retardation (or retention) can be said to be complementary. That is, individually they each contribute to safety and together they determine the level of overall safety. Further, the latter provides safety if the former is not, or is only partially, achieved. These functions can be said to be independent in the sense that they are two different principles for achieving safety. They are, however, not completely independent since some factors affecting containment (e.g. geochemical conditions) can also affect solubility, speciation and retardation. Thereby, changes in a single factor may affect more than one safety function.

If more detailed safety functions are considered, the situation becomes more complex. In a system where a canister has the function of providing containment, there could be several conceivable failure modes of the canister, with various mechanical or chemical causes. Subordinate safety functions to containment may be defined based on (the avoidance of) these failure modes. For example, in the KBS-3 concept, the canisters should provide a corrosion barrier, withstand isostatic load and withstand shear load (Figure 3.2). All these sub-functions must be fulfilled to achieve the superior function isolation. This is, thus, an example where several subordinate functions are necessary requirements to achieve a higher-level function. It is also noted that containment is often regarded as a two-state function in the sense that it is either achieved or not. However, if the ensemble of canisters in a repository is considered, containment could be partial if it is achieved for only a subset of the canisters.

Taking the KBS-3 concept further as an example, a number of sub-functions contribute to achieve the corrosion barrier function: a canister with copper coverage over its entire surface is the ultimate measure of the presence of a corrosion barrier, but several additional factors contribute to minimise corrosion, including limited advective transport in the buffer, favourable transport conditions in the host rock and low concentrations of corroding agents in the groundwater. These are all formulated as subordinate functions to the canister function of providing a corrosion barrier, which is in turn a sub-function to containment. The aforementioned sub-functions relating to conditions in the buffer and the host rock are complementary in the sense that they individually contribute to favourable conditions for providing a corrosion barrier and they together determine the rate of corrosion of the canister. (Transport conditions in the host rock are, in turn, determined by a number of more detailed factors.)

In another example, from the "Dossier 2005 Argile", one function of the repository is to delay and reduce the flux of any radionuclides released. Factors that contribute to limit migration of radionuclides dissolved in water are diffusion-dominated flow, and dispersion and retention within the repository's host formation. To this end, the host clay offers a low permeability, a low diffusion coefficient and a high retention capacity. Radionuclide migration can also be delayed inside certain repository components. Radionuclides that might be released beyond the repository's host formation will disperse, over the long term, in surrounding geological formations before reaching the environment accessible to humans. Backfill is not considered as a "barrier", at least as far as the transfer of radioactive nuclides by water is concerned. (It nevertheless fulfils other functions such as providing mechanical support of the rock and serving as an "obstacle" to any attempts at intrusion into the repository after closure.)

In both examples, the deterioration of a component's ability to fulfil its function does not necessarily mean that the repository's safety is reduced, since complementary components may also contribute to the function. In addition, there exists the possibility to have "latent" functions, which act only upon the failure (often partial) another function. For example, the confinement provided by the waste matrix is latent as long as water does not reach it – i.e. as long as the container protects it. The existence of latent functions makes it possible to achieve and demonstrate safety despite accidental losses of functions (for example, in this case, a loss of the container's sealing integrity).

The complementary nature of sub-functions is commonly found when analysing retardation (or retention) in detail. Given the interactions and multiple functions to which a given system component might contribute simultaneously, true redundancy – in the sense of duplication of identical functions or components relating to safety so that one can be regarded strictly or solely as a back-up for the other – is in general not encountered in repository systems in geological formations. Nevertheless, it is often the case that a higher-level safety function can be fulfilled even if all the sub-functions (or their indicators) are not fully met and this contributes to confidence in the robustness and resilience of the system.

3.2.1.3 Relation between overall safety and detailed safety functions

It is important to note that the overall safety and robustness of a system over time can be assessed only through an integrated evaluation of all safety functions defined for the system in question. Measures of total safety for the entire system are, in general, formulated as regulatory risk or dose criteria with which compliance is to be demonstrated. As noted in the examples above, overall safety may be achieved despite the loss of one or several individual lower-level safety functions as long as the system compliance criteria, e.g. in terms of dose or risk, are met.

3.2.1.4 Use of safety functions

The extent to which – and the purposes for which – safety functions are used varies between organisations. High-level functions like containment and retardation tend to influence the development of the repository concept in a top-down fashion, whereas lower-level functions and indicators feed into bottom-up approaches. Examples of use are:

- To serve as high-level principles (containment, isolation, retention) guiding repository design and siting.
- To identify key issues in a safety evaluation.
  Examples of this can be seen in SKB's interim report of the SR-Can assessment (SKB, 2004), in Andra's feasibility report for "Dossier 2005 Argile" (Andra, 005) and in Nagra's Opalinus Clay report (Nagra, 2003).
- To structure reporting of safety.
  - In SKB's SR-Can assessment (SKB, 2006) a main scenario is analysed in several timeframes and the analyses of each timeframe include a structured account of the status of all relevant safety functions.
  - In Andra's "Dossier 2005 Argile", a chapter is dedicated to the safety functions for both operational and post-closure phases and the results are used as an input to the subsequent safety assessments chapters (performance assessments, managing uncertainties and scenario assessments).
- To derive scenarios.
  - This is an important use of safety functions in SKB's SR-Can assessment. Scenario selection was accomplished by analysing a comprehensive set of safety functions, and identifying the various scenarios that could be postulated to cause a loss of each function. The completeness of this top-down approach was achieved by combining the top-down oriented use of safety functions with a bottom-up, FEP-based approach when indentifying all factors that could contribute to loss of the safety functions.
  - In Andra's "Dossier 2005 Argile", a qualitative safety analysis (QSA) was used to derive scenarios based on an analysis of safety functions and a phenomenological analysis of repository situations (PARS). The QSA aimed to identify those uncertainties – related to component characteristics, evolution, and interaction with other components – that could (i) affect a component's ability to perform a safety function, (ii) influence another component's ability to perform a safety function, or (iii) modify the component's environment in a way that could affect the fulfilment of a component's functions. A review is conducted to confirm that key uncertainties are addressed adequately by repository design and in modelling. This is accomplished by evaluating whether the potential effects of the uncertainties on the safety functions are covered by the normal evolution scenario (SEN) or by one of the four altered evolution scenarios (which examine, for example, possible seals failure, package failure, bore-hole intrusion or and an assumed severe degradation of several safety functions). If, not, then a new calculation case is created and quantified. Specific qualitative analyses of external events were also conducted.
- To prioritise and guide R&D.
  In planning the development of nuclear waste disposal in Belgium, the implementer initially expressed safety and feasibility statements as hypotheses (Lalieux *et al.*, 2007). A key objective of R&D can be seen as developing the assessment basis – including site data, design, and implementation of procedures – needed to transform safety and feasibility statements from hypotheses to well-substantiated claims. An evaluation of the supporting information available for safety and feasibility statements at a given stage of programme development can guide the prioritisation of R&D work at subsequent stages.

- To guide repository design.
  Andra uses safety functions as a basis for developing technical design; the safety functions, which convey in a systematic way the factors deemed necessary to post-closure safety, serve as a link between safety objectives, the features and processes critical to safety functions, and the engineering options that may fulfil safety functions. Numerous features of Andra's repository design were selected or refined to contribute to the main safety functions, including, e.g. the near circular cross-section profile of the engineered structures, their dimensions and dead-end arrangement, the use of low-permeability seals, the backfilling of all drifts and the choice of materials (concrete, steel, clay, and bentonite).

The potential usefulness of safety functions is related to the repository concept under consideration and must be evaluated in the context of the particular concept. The definition and application of safety functions appears more straightforward in concepts with one well defined key component, such as the copper canister in the KBS-3 concept and the clay formation in the Belgian, French and Swiss concepts.

The use of safety functions – and the emphasis that can be put on them in a safety assessment – also depends on the scientific understanding of the system being analysed. The establishment of a comprehensive set of detailed safety functions – and especially the definition of criteria for their fulfilment – relies on considerable information which typically is achieved only through dedicated and site-specific R&D efforts over time. Thus, the level of detail and the use of safety functions reflect the maturity of the scientific understanding and may evolve as the repository concept and safety case are further developed. If safety functions are given a key role in the safety case (for scenario selection or to derive design criteria, for example), it becomes important to demonstrate clearly how they were derived. Therefore, using safety functions for scenario selection may not be feasible in the early stages of developing a repository concept if the relative roles of the repository components have not been defined, at least in a broad sense. This may explain, in part, why the use of safety functions has emerged most strongly in safety assessment for well-established concepts like the Swedish KBS-3 or the clay concepts developing in France and Belgium. For programmes at early stages of development, the identification of safety functions may still be important and useful for structuring the development of system understanding and to identify key uncertainties and research topics.

3.2.1.5 Quantification of safety functions

Quantitative criteria can sometimes be established for the fulfilment of specific safety functions. High-level safety functions like containment and retardation can be regarded as fundamental principles that are often adopted as guiding principles for repository development, siting, etc. Lower-level safety functions are more directly related to specific repository concepts and components and as such, are generally more amenable to being defined by quantitative characteristics. Whether it is possible (and useful) to establish quantitative criteria depends on how the functions have been defined, how they are expressed in safety assessment, and their importance to overall long-term safety.

Numerical indicators and, where possible, associated criteria (usually minimum or maximum values) have been set for a number of functions in the Swedish programme. For example, a safety function of the host rock in the KBS-3 concept is to provide a chemically favourable environment for the repository. An implication of this general requirement on the rock is that the ionic strength of the groundwater should not be too low – in order to avoid colloid formation of the buffer (function R1c in Figure 3.2). Quantitatively, this is expressed by a criterion that the concentration of divalent cations in the groundwater should exceed 1 millimolar. It has been experimentally demonstrated that colloid formation in the buffer (by chemical erosion in the absence of water flow) does not occur above this limit. This is, thus, a straightforward limit to which field observations or results of predictive modelling can be compared to give confidence that the safety function will be fulfilled.

In “Dossier 2005”, Andra assesses the performance of individual components with respect to their safety function using a variety of indicators. These indicators include (i) the relation between convective and diffusive flux in the repository and the host rock, (ii) the overall activity leaving the waste packages, the underground structures and the host rock, as compared to the initial quantity contained in the waste packages, (iii) the activity flux at each of these components, and (iv) the concentration distributions of dissolved materials in the host rock and in surrounding formations.

Quantitative criteria cannot always be established, however, especially depending on how safety criteria are defined. This is the case for the concentration of canister corroding agents in the groundwater for the KBS-3 concept. The concentration should be “low”, but since a range of factors, together with the concentration, control the rate of canister corrosion, it is not meaningful to put a limit on a single factor. The function indicator is still useful even without a criterion, as it reveals an important factor to be evaluated in a safety assessment. The extent to which quantitative measures and criteria are required depends on the purpose of the safety functions in a particular case (see also Section 3.2.5). In any case, quantitative limits must be derived from, or developed in conjunction with, the repository concept under consideration and the scientific understanding of its long-term evolution.

3.2.1.6 Design requirements versus safety function indicator criteria

It is important to clearly distinguish between design requirements and safety function indicators. Whereas design requirements in general refer to the initial state of the repository, i.e. to the system as built, safety function indicators and indicator criteria refer to the state of the system throughout its future evolution during the assessment period. For example, design criteria might require a canister to have a certain thickness upon fabrication and emplacement; in contrast, a safety function indicator relating to thickness could in principle be defined such that the containment function is achieved as long as the thickness is non-zero everywhere on the canister surface. The design requirement (a defined canister thickness in this example) should thus be such that it allows for deterioration (due to corrosion in this example) of the system over time so that the required safety function indicator (non-zero thickness) is fulfilled throughout the assessment period.

Safety function indicator criteria, thus, are not equivalent to, but can be used to help derive, design requirements. Design requirements may be set taking into account not only the results from an analysis of safety functions (and associated criteria), but also accounting for a “margin of safety” – that is, providing a more robust design than is estimated to be needed strictly in view of safety function indicators and system safety assessment. Such margins of safety are accepted as good engineering practice and can improve confidence in the system by accommodating, for example, the possibility of manufacturing defects or uncertainties in modelling. They can be viewed as providing “latent” safety functions (as described earlier in this Section). The degree to which they are applied in design requirements depends on – among other factors – the component, the function it serves, and the degree of conservatism in the underlying analysis on which the design is based. This aspect is further discussed in Section 3.3.1.

3.2.2 Quality Assurance

Essentially all respondents agree on the need for quality assurance (QA). However, while the need for QA is well established, its implementation is typically phased and presents practical challenges.

Formal QA is usually a regulatory requirement that concerns all activities affecting the safety case. Most programmes are subject to formal QA, with safety assessment QA plans being part of the overall quality management system of the organisation. Safety assessment QA plans may cover, for example: routines for project management, reviews, and improvements; identification and prioritisation of FEPs; documentation of important decisions or programmatic changes; knowledge of processes important to long-term safety (and of handling of these processes in the assessment), processes for data clearance (selection of input data and discussion and quantification of input data uncertainty), adequacy of codes, systems for storing or archiving all files, checking performance assessment calculations and maintenance of performance assessment computer programmes.

Some programmes do not (yet) apply formal QA, but nevertheless certainly take measures to ensure quality in their work and its documentation. The need for, and stringency of, QA evolve with the research investment being made, taking to account also the time over which a programme is expected to be in a given phase, and the stage at which licensing is to occur. Typically, the need for QA is great when the duration of a project will span several generations of workers (to assure the usability and traceability of information relied on through time) and when licensing processes or decisions are likely to be controversial or contested.

3.2.2.1 Key quality measures

While high-level, organisation-wide quality management systems and quality management standards, like ISO 9001, provide a framework for quality management, more specific objectives and procedures are needed to ensure the high quality of the safety case work. The management system defines the organisational structure for implementing the quality assurance activities. It also defines the responsibilities and authorities of the various personnel and organisations involved in designing, implementing and auditing quality assurance activities.

It is essential to control the quality of the information handled in the safety case. However, the confidence in a safety assessment and, more generally, in a safety case does not rest solely on the intrinsic quality of the data used. Important other contributing elements to it are that:

- All data are obtained along systematic and well-defined methods.
- Data and scientific and technological understanding are used correctly and along well-defined instructions in assessments.
- The scientific and technological understanding and its use in assessments are sufficiently complete for the decision they support.
- Independent and external reviews of data and arguments are conducted, to the extent appropriate.
- There is a process for systematic treatment of uncertainties in data and understanding throughout the safety case.

All these elements are examples of so-called quality measures, i.e. measures contributing to the confidence in, and the quality of, a safety case.

3.2.2.2 Implementation

Implementation of QA measures, such that they really contribute to quality and are not seen as an unnecessary administrative burden, is a challenge. This requires well-founded quality measures and activities. Examples of generally important activities include:

- Organising the development of the safety case within a quality management system that has established an adequate organisational structure with a clear delimitation of roles of different organisations and individuals.
- A document tracking and management system.
- External peer reviews and audits of key elements that significantly contribute to the safety case, i.e. not only limited to formal internal and external QA audits.

- Systematic development of concepts and designs and of the processes of acquiring evidence, developing arguments and carrying out analyses along a predefined safety strategy and predefined methodologies for safety and feasibility assessments (Section 3.2).
- Checking the completeness of the assessment basis, safety assessments and feasibility assessments using a systematic and defined method in order to identify and prioritise the key issues that need to be addressed.
- Systematic "data freezes" and "model versions" (model and design configuration management) of elements of the assessment basis and safety assessment methodology, in order to ensure that all elements of the safety assessment are handled consistently.
- Systematic and well-defined uncertainty management throughout all activities of safety case development contributing to an assessment basis that structures uncertainties in the same way as they are used in (safety) assessments.
- Validation and verification of the models and codes used throughout the safety case development, i.e. validation that model adequately simulate the correct phenomena and verification of the correctness of the code.
- Verification of databases, i.e. verification that the databases are scientifically correct and are properly implemented.

3.2.3 Treatment of uncertainty

There are several aspects, and new developments regarding management and treatment of uncertainty. Areas of interesting development are further discussed below.

It should be noted that research on the treatment of uncertainty within performance assessment is part of the ongoing project PAMINA (Performance Assessment Methodologies IN Application to Guide the Development of the Safety Case) being conducted under the auspices of the European Commission (EC) research programme (see www.ip-pamina.eu). One major task in PAMINA is to investigate in detail the advantages and disadvantages of different approaches such as deterministic scenario-based assessments versus probabilistic assessments; assess levels of conservatism and realism in PA; and explore alternative approaches for graphical presentation of results from uncertainty analysis. Other tasks are to test and further develop approaches for the treatment of spatial variability and of uncertainties in parameters, scenarios, and models. Based on the results of these assessments, the PAMINA project will produce a guidance report on the handling of uncertainties in PA. Because past IGSC projects as well as the ongoing PAMINA work address this issue in some detail, it was not discussed during the INTESC workshop; however, some important points can be drawn from the responses to the INTESC questionnaire.

3.2.3.1 Methods for defining scenarios

The INTESC questionnaire responses indicate that there are several main approaches to defining or developing scenarios. In some assessments, scenarios are identified using a "bottom-up" approach that begins by assessing a range of external events or conditions (e.g. climate change scenario, intrusion scenario, initial defect scenarios) that may trigger changes in the disposal system or affect its performance. For those scenarios that are deemed possible for a given system, the consequences are assessed to determine their relevance to long-term performance and safety. Other programmes structure the scenario definition using a "top-down" approach, i.e. identifying first the crucial safety functions and then focussing on what combination of conditions could jeopardise one or more "safety functions". (See also the discussion on safety functions in Section 3.2.1).

There is no conflict between a "bottom-up" or a "top-down" approach; in fact, they are often used in combination, with one applied as a primary method to identify scenarios, and the other serving as a confirmatory tool. This is the case, for example, in Andra's "Dossier 2005 Argile "(Andra, 2005a-c), in which analyses of safety functions were used to derive "altered evolution scenarios", which were further defined based on feedback from Andra's site understanding, analysis of situations taken into account internationally, and the recommendations of the applicable safety rule (RFS III.2.f, 1991 version).

Any detailed account of a repository evolution will require the consideration of a large number of coupled features, events and processes (FEPs) such as groundwater flow, corrosion, earthquakes, etc. Safety functions have the potential to provide a logic for how this accounting is structured, e.g. by identifying key high-level issues around which the reporting can be centred (e.g. canister failure modes) or by providing a structure for scenario selection as in SKB SR-Can (SKB, 2006). Similarly, in Andra's "Dossier Argile" (Andra, 2005), safety functions and FEPs were used to define a "reference scenario" (or normal evolution scenario) and "altered scenarios" (or divergent/alternative scenarios; Andra 2005a-c). FEP lists or FEP databases (such as the international FEP database compiled by NEA [NEA, 1999b]) are essential tools, but they have evolved (at least in more advanced programmes such as those responding to the questionnaire) to become mainly a tool for checking completeness in a system (and scenario) description that has been derived earlier or using other methods. In recent safety assessments it is rarely the case that system identification and description starts with a FEP list that then is further developed, although FEPs analysis and identification can be a key activity when developing concepts or approaching novel siting environments.

3.2.3.2 Use of alternative conceptual models

Regulators generally require assessment of alternative conceptual models if there are uncertainties in the underlying conceptual understanding. However, there is always a question on how extensive the search for alternatives needs to be and this is often also a matter of discussion between regulator and implementer.

Most implementers apply some alternative models and generally, the identified alternatives are propagated through the safety assessment. However, in order to avoid "variant explosion" different strategies are applied: for example, developing and propagating only hypotheses judged to significantly affect the outcome; keeping other hypotheses on a "watch list"; or integrating only the more conservative concept into the assessment system model.

The ambition level is likely to depend on the stage of the programme. Before site investigations take place, the large uncertainties that may be associated with the geological environment may make qualitative arguments in the safety case more meaningful than quantitative PA calculations or full development of numerous potential conceptual models. These qualitative assessments would then be used to scope uncertainties and to identify data requirements for the site investigation programme and to provide strategy and guidance for the development of the repository concept and safety case at later stages.

At least some regulators hold the view that alternative models should be based on independent reasoning, be equally probable (at least approximately) and be composed of a self-consistent set of properties and geometries. Some implementers may not necessarily support this and rather view alternatives as part of hypothesis testing. Also, some define "alternative models" to handle uncertainties where a model, if chosen, is not demonstrably conservative, or to involve models that appear more comprehensive than the selected reference model but have been less thoroughly validated.

3.2.3.3 Documenting process understanding

Several programmes document their process understanding in knowledge reference documents, or "process reports". The reports describe the knowledge base and interactions with other processes, sensitivity cases, and remaining uncertainties for each process. Such a systematic review process provides a basis for identifying and handling remaining uncertainties (e.g. on phenomenology, models, data, or component characteristics). Based on such information, a method can be established for handling a given process in the safety assessment.

3.2.3.4 Means of quantifying and documenting data uncertainty

Data and data uncertainties are often systematically assessed and documented according to established routines and reviews. Quality assurance is achieved, e.g. through the use of a template for data uncertainty documentation, through clearly defined roles for participating experts and generalists and by the use of external reviews, as may be appropriate, prior to finally establishing input data for the assessment. Effective communication – between people collecting and managing data and the modellers who use the data – is essential.

3.2.3.5 Expert judgment and resolving conflicting expert opinions

Safety assessment documentation should provide a clear and complete record of the decisions made and the assumptions adopted in developing the model(s) of the waste disposal system, including the use of expert judgement. The need for traceability requires that scientific and technical decisions should be reported, including relevant description of the expert judgement supporting choices of strategies, models and parameters used in the safety case.

Formal expert panel elicitations can be a tool for strengthening confidence in judgements of uncertainty in situations with an insufficient data basis. There are few cases available for reported formal expert elicitation, however, which implies that it is considered appropriate for only specific situations. The process can be time – and effort – intensive and requires very well-defined goals regarding the information to be obtained. The resource implications in relation to the potential gains must also be considered. Formal and independent reviews carried out on behalf of the implementer are also seen as important (and are even required in some countries).

From a regulatory perspective, it is expected that the treatment of uncertainties encompasses the treatment of contradictory expert opinions. Several examples of handling diverse sources of opinion are applied. However, there may be a matter of discussion regarding how best to manage and document this. Implementers apply several means of handling diverse opinions, including:

- Established documentation procedures for experts to take into account all relevant available sources of information, to draw conclusions regarding uncertainties and, based on these conclusions, to prescribe a defendable way of handling a given process in the safety assessment.
- Choosing experts who either represent or are asked to take account of the range of views represented in the scientific and technical community as a whole; and who interact with others in their own field and in other relevant fields.
- Recording all meetings with experts, including decisions taken, and entering the records or technical notes into the project documentation system.
- Separating the documentation of judgements made by the safety assessment team from the scientific documentation and judgements made by independent experts, and responding to the expert recommendations indicating disagreement, rejection, or agreement and acceptance.
- If necessary and appropriate, requiring that the experts involved must review documentation for the portions or aspects of the safety case that is influenced by their input.
- Establishing that technical document authors are responsible for the use of information from all sources, including reviews, and should follow normal scientific methods and practices in incorporating external input into their work.

- Developing the safety case through multiple iterations, which allows early recognition of contradictory opinions (and an opportunity to evaluate their importance) and provides time for obtaining relevant information to resolve issues.
- Using probability distribution functions to represent diverse sources of information on parameter values as well as what-if cases to consider alternative models or assumptions.
- Comparing with assessments and FEPs from other countries with broader similar geological disposal concepts.

3.2.3.6 Treatment of component defects and failures

Regulators expect implementers to take into account the potential failure modes of the containment and isolation systems. There are various approaches for handling how component "defects" and "failures" are treated in safety assessment. Different approaches may be used to assess situations in which failures, defects and mishaps are postulated to become evident during implementation (e.g. transportation accidents which could affect repository installation and thereby influence long-term performance) and those that would not be expected to be detected during operation (e.g. material failures in engineered barriers). The latter are conceptually equal to other FEPs (i.e. an undetected fault) and have to be handled similarly in scenario development and safety assessment, whereas the former allow the possibility that the effects can be managed and mitigated by measures taken during the operational period. The effects of such defects or failures during operations may need to be taken into account in post-closure safety assessments if they lead to altered states of the disposal system at the time of closure, which form initial boundary conditions for post-closure assessments.

Potential defects in components are taken into account by a varying degree, largely dependent on the repository concept and on the attendant importance of defects in the safety case. Defects are generally more important in concepts where the integrity of the engineered barriers is a key contributor to safety. INTESC questionnaire results indicate that potential causes and types of defects for waste containers are often assessed. Potential defects in manufacturing or emplacement of other parts of the system, e.g. regarding buffer and repository sealing, may also be evaluated. Repositories for low-level or intermediate-level waste tend to be less sensitive to engineering defects.

3.2.3.7 Role of "what-if" cases

Analyses carried out to explore parameter sensitivity and the impact of uncertainties include structured parameter variations as well as single parameter "what-if" cases. "What-if" cases are acknowledged by regulators as a means to assess disruptive events that cannot be integrated directly into the normal evolution scenario, and as a means of illustrating the significance of individual barriers and barrier functions. Such scenarios might also be used to address stakeholder concerns or to demonstrate the robustness of certain aspects of the system. However, some caution is recommended in the presentation of results from "what-if" calculation cases, since they may convey a distorted picture of the factors contributing to risk.

Most assessments consider "what-if" cases or "severely degraded scenarios" but the interpretation of what is actually meant by such cases varies. They usually concern an assumed loss of barrier function(s) or consist of systematically reducing the performance of the safety functions to exceed the bounds of the normal evolution scenario. However, the rationale for them, as well as views on whether they lie outside the main risk contribution, varies slightly between programmes. For some programmes, "what-if" cases are limited to those that, while physically possible, lie outside the range of possibilities reasonably expected to occur according to the scientific understanding available to the safety assessors. Other programmes may go further and examine cases that are not at all physically plausible but are used as tools for testing or demonstrating the resilience and integrity of the repository concept, and for demonstrating multiple safety arguments or issues of concern identified by stakeholders or requested in review. An example of such a latter case would be to assess the implications of entirely removing the engineered barrier system. Especially in this latter instance, the "what-if" case is not at all be realistic, as may serve only to illustrate aspects of (the robustness of) the protective capability of the repository system.

3.2.4 Importance of the geosynthesis

According to the NEA safety case brochure, the assessment methods, models, computer codes and databases must be clearly and logically presented. All respondents generally support this goal and there are several examples of specific actions for meeting these ambitions. An important example is the geosynthesis: that is, collecting geoscience information from a variety of perspectives such as structural geology, hydrogeology, and geochemistry and synthesising this data into an integrated geosphere model that is consistent with the knowledge and history of the site. While the geosynthesis is not discussed or highlighted in the NEA brochure, its importance has been noted within the IGSC and it is also the primary focus of the AMIGO Project ("Approaches and Methods for Integrating Geologic Information in the Safety Case") organised by the IGSC.

3.2.4.1 Role of the geosynthesis

A geosynthesis is a documented representation of the geoscientific findings from site characterisation and its evaluation based on current geoscientific understanding. The geosynthesis should:

- Provide a coherent and believable basis to understand the geosphere – i.e. the host formation, both near and far field – at time and space scales relevant to repository safety.
- Rationalise an understanding of the geosphere based on site-specific data and multiple lines of reasoning across different geoscientific disciplines to constrain possible alternative interpretations and descriptions of the site.
- Present information and data sets that describe the geosphere and its evolution relevant to repository safety and that meet the information needs of safety assessment and engineering functions.
- Contribute complementary evidence to support safety case statements regarding the significance of processes affecting site stability, isolation and containment properties, radionuclide release and mobility in the sub-surface and other issues relevant for the safety functions.

Possibly starting with presentation of such information in several reports by Nagra (Nagra, 1994 and Nagra, 2002), preparation of a geosynthesis has gained in importance over the last years. Geosyntheses are, for example, developed both in Sweden (e.g. SKB, 2005) and in Finland (e.g. Posiva, 2007) as part of the safety cases being prepared.

While there is wide agreement that the geosynthesis should provide the geoscientific basis for the safety case, there appear to be some differences in opinion on how the geosynthesis relates to the safety assessment. At one end, it is viewed that the geosynthesis should provide and substantiate the final input data set for safety assessment. Others (notably SKB and Andra) introduce an intermediate step in the form of a data report as input for safety assessment, arguing that the geosynthesis should essentially be factual and independent of the repository concept, free from the value judgements needed in finally deciding on parameter distributions or values and their level of conservatism. An even more extreme view is to regard the geosynthesis as a high-level conceptual tool that serves foremost as an independent part of the safety case to provide supplementary arguments alongside but not as a direct input to the safety assessment. However, these differences may reflect simply organisational or terminology differences between the programmes; nevertheless, the relation between geosynthesis and safety assessment appears worth further consideration.

3.2.4.2 Confidence in geosynthesis

The confidence in the geosynthesis rests on the qualities of the site and on the quality and structure of the site characterisation programme. Confidence is enhanced for the aspects of the site description that are based on data obtained from a variety of independent characterisation methods.

A geosynthesis will always contain uncertainties, but it is to be remembered that a complete understanding of the site is not required. What is essential is that the site characteristics and evolution be understood insofar as they might affect confidence in the performance of a geological disposal system. The site characterisation and modelling (and the development of the attendant geosynthesis) should continue at least until the body of data and understanding is sufficient for the purpose of safety assessment and repository engineering, or until the body of data shows that the rock at the site does (or does not) satisfy the predefined requirements. This means that it is necessary to assess the uncertainties and the confidence in the modelling on a continuous basis.

Such an assessment of the confidence in the geosynthesis could consider:

- The quality of the measured data, including their accuracy and bias.
- Whether all data are considered and understood.
- The adequacy of the assumptions and methods used to derive unobservable but important numerical data from indirect measurements.
- A systematic identification and quantification of main uncertainties and their cause.
- Possible alternative models and their handling.
- Consistency between disciplines.

These elements then form a basis for an overall confidence statement.

3.2.5 Indicators other than dose or risk

Judging from the answers to the INTESC questionnaire, the selection of safety and performance indicators in addition to dose and/or risk reflect the measures that have been discussed in various international fora. However, the terminology used is not consistent among national programmes; identical or very similar concepts are sometimes denoted differently, while in other cases the same term is used with different meanings. Importantly, the emerging use of safety functions and the evaluation of their evolution against quantitative criteria can also be viewed as applying indicators other than dose and risk (Section 3.2.1, Safety functions).

3.2.5.1 Safety and performance indicators

The objective of using safety indicators other than dose or risk is to achieve additional independent or complementary safety statements. Safety and performance indicators in addition to dose and risk, as well as other arguments, are used in several safety cases to demonstrate, for example, the low consequences of a given radionuclide release to the surface environment and to increase the robustness of the safety case. Definitions are helpful in order to categorise the different kinds of indicators and arguments; such definitions have been proposed in the EC project PAMINA; they are listed in Table 3.1.

Table 3.1 **Definitions of terms with relevance for different indicators proposed within PAMINA project**

	Definition
Safety aspect	A safety aspect is a specific sub-area of the total field of long-term safety that can be addressed independently of others. A repository can be safe with respect to one aspect but unsafe with respect to another. Safety aspects might be human health, quality of human life, groundwater quality, seawater quality, health of non-human biota and many more.
Reference value	A reference value (in the context of repository safety) is a numerical value that quantifies a level of a safety measure with respect to one specific safety aspect that can be proven, or is at least commonly considered, to be safe. Reference values can have a global or a local character.
Safety indicator	A safety indicator is a quantity, calculable by means of suitable simplified models, that provides a measure for the total system performance with respect to a specific safety aspect, in comparison with a reference value quantifying a global or local level that can be proven, or is at least commonly considered, to be safe.
Performance indicator	A performance indicator is a quantity, calculable by means of appropriate models, that provides a measure for the performance of a system component, several components or the whole system in comparison with each other or with the whole system.

The selection of indicators reflects the measures that have been discussed in various international fora. Referring to the definitions in Table 3.1 the most commonly used safety indicators complementary to dose and risk are:

- Radiotoxicity concentration in the biosphere.
- Radiotoxicity flux into the biosphere.

The indicators are compared to respective independent reference values that can be considered safe, like radiotoxicity fluxes or concentration in local aquifers or in drinking water. As long as the estimated fluxes and concentrations are low, they contribute to confidence by illustrating the robustness of the safety assessment – in particular, for longer time frames, for which the uncertainty of dose or risk calculations strongly increases (given e.g. their dependence on certain assumptions regarding human lifestyle and biokinetic factors).

Performance indicators are usually applied to subsystems of the repository. Typical performance indicators used in safety cases are:

- Activity or radiotoxicity inventories in different compartments.
- Mass/activity or radiotoxicity fluxes between compartments.
- Time integrated mass/activity or radiotoxicity fluxes from compartments.

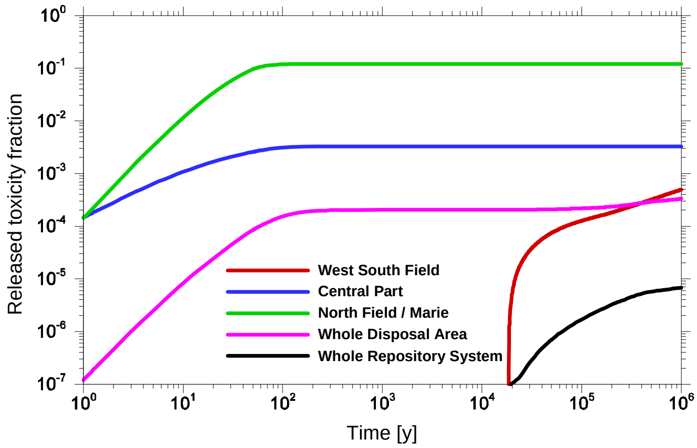
In addition to performance indicators defined in relation to radionuclide releases, indicators may be selected to address other specific safety functions.

Some sub-system indicators are quantities that characterise directly the performance of a specific barrier or system component in fulfilling (one of) its specific role(s). Such an indicator should be calculable with an appropriate model and ideally should be associated with a criterion to which it can be compared in order to evaluate the fulfilment of the related safety function. For example, several such indicators are assessed in the Andra's safety evaluation (Andra, 2005) and by SKB in SR-Can (Section 3.2.1). SKB denotes such indicators as "*safety function indicators*", but this is not a terminology used universally.

Sub-system performance indicators can also be useful for optimisation of the disposal system, to improve understanding of the role played by different system components and to communicate this knowledge, both to experts and the general public. Depending on its intended use, a performance indicator can be developed without associated reference values or technical criteria. The indicator might, for example, illustrate the distribution between mass transiting along and/or in the structures made up of drifts and shafts and the mass migrating through the undisturbed formation.

Another example is provided by the Morseleben safety case (Storck *et al.*, 2004), in which the integrated radiotoxicity flux from different compartments of the repository system was calculated as a function of time, each normalised to the initial inventory of the appropriate compartment (Figure 3.3). This is a very illustrative indicator since the time curves reach asymptotic values and the comparison of these shows how much of the inventory is ultimately retained in each compartment. The results show that less than 0.1% of the inventory of the sealed emplacement areas (West South Field) leaves these; and even from the worst of the non-sealed emplacement areas (North Field/Marie), only 10% of its inventory is estimated to potentially be able to escape. Thus, it could be shown that only a fraction of 10^{-5} of the total inventory potentially leaves the whole repository system and may eventually reach the biosphere.

Figure 3.3 **Normalised integrated radiotoxicity released from different compartments of the Morsleben repository** (from Storck *et al.*, 2004)



3.2.5.2 Other characteristics

Besides the indicators described above, other characteristics are used by some organisations as arguments for the long-term performance of the disposal system in the safety case. The comparison of radiotoxicity of the waste with the radiotoxicity of uranium ore is sometimes used to illustrate that, over sufficiently long timescales, the waste toxicity (generally in relation to ingestion) becomes comparable to natural features such as uranium ore bodies. This is not to suggest that natural uranium ore bodies are risk-free; rather, it serves to relate the hazard or risk from the repository at very long times to known natural systems.

Other characteristics that may be cited are:

- Groundwater age and travel time.
- Salinity of groundwater.
- Depth of formation.
- Required thickness of shielding.
- Container corrosion rates.
- Waste dissolution rates.

These characteristics are very concept- and site-specific and should not generally be denoted as safety or performance indicators (cf. definitions in Table 3.1). In order to contribute as arguments for illustrating the safety of the repository, they need to be connected to statements that are directly relevant for the safety of the system under consideration.

3.2.5.3 Regulatory differences

Regulatory differences exist among countries. Some national safety regulations encourage but do not require the use of indicators other than dose and risk. However, there are exceptions: in Finland, the regulator (STUK) specifies various radiation protection criteria and other indicators for different time scales. For the era of extreme climate changes in the timeframe between several thousand to several hundred thousand years, it must be shown in the safety case that fluxes for selected radionuclides from the geosphere into the biosphere do not exceed specific release constraints. In the United States, the regulations for WIPP establish limits on groundwater concentrations as well as on cumulative releases of radioactivity possing through a certain point in the geosphere.

The use of additional indicators in regulations appears to be gaining in use. In Germany, revised safety criteria are currently under development. A set of safety indicators and corresponding constraints in addition to dose have been discussed to demonstrate containment of radionuclides in the isolating rock zone (e.g. the part of the geosphere surrounding the repository and contributing mainly to the retardation of the radionuclides). The use of these indicators is meant to increase robustness of the safety case because they rely less on the processes in the near-surface aquifers and the biosphere for which predictability is limited. This proposal is, however, still under development and has not been accepted by the authorities so far.

In order to calculate the indicator dose rate, exposure pathways in the biosphere have to be modelled. It is recognised that great differences exist between countries regarding the extent to which regulations allow simplified handling of the biosphere in the safety case. In some programmes, regulations specify not only the biosphere model but also the relevant parameters to be used for the safety assessment; in other programmes, biosphere modelling is addressed only generally in regulation and the implementer must take on the task to analyse and define the range of conditions and processes of the biosphere, which can be quite challenging, particularly for future conditions which can be envisioned.

3.2.5.4 Chemotoxicity

Chemotoxicity was not addressed within the INTESC questionnaire or answers, but was discussed in the INTESC workshop. Non-radioactive hazardous substances are often constituents of the radioactive waste and can also include conditioning and container materials as well as those constituting the buffer, backfill, and seal. Furthermore, some radioactive materials (such as uranium for example) also have chemotoxic properties. The consequences caused by a release of these substances from a radioactive waste repository may be an issue to be covered in the license application and, thus, may need to be addressed in a safety case for the construction of a repository. So far, in only a few cases have the long-term environmental effects of hazardous substances from final disposal of radioactive waste been specifically assessed (e.g. OPG in Canada [Garisto *et al.*, 2005] and Posiva in Finland [Raiko and Nordman, 1999]). Other radioactive waste management programmes (e.g. Andra in France and NDA[1] in the United Kingdom) have attempted to evaluate the chemical toxicity of low- and intermediate-level waste but did not carry out a long-term safety assessment of the potential effects of chemically toxic

1. The Nuclear Decommissioning Agency (NDA) in the United Kingdom subsumed Nirex as the agency responsible for implementing waste management programmes; for convenience, we refer to the agency under its current name (i.e. NDA), but it should be noted that participation in the project, including responding to the INTESC questionnaire, was provided initially by Nirex.

constituents. One reason this has not been done, generally, is that the non-radioactive species in high-level waste and spent nuclear fuel, as well as in engineered repository components, tend not to be readily dissolvable or easily transported, especially in comparison to some key radioactive components of waste.

Moreover, in most countries no comprehensive body of regulations exists prescribing how the releases and associated consequences of non-radioactive hazardous substances must be taken into account within the safety case. In the United States, for the Yucca Mountain Project (DOE, 2002) as well as for the WIPP, these types of potential non-radiological environmental impacts are addressed in a separate environmental impact assessment that is required for compliance with the National Environmental Policy Act but is not an integral part of the repository licensing process. The safety case for licensing purposes addresses only potential radiological consequences of building, operating and closing a repository.

Limits for hazardous substance concentrations may be set by national environmental legislation or regulations. However, although limits for different environmental compartments (in particular, near-surface aquifers or soils for specific land use) exist, in many cases it is not well-defined which values must be used in the context of geological disposal and over what timeframes they would be applied. The consideration of non-radioactive hazardous substances in safety cases may be an issue for further regulatory attention, including guidelines or directives for how assessments would be conducted as well as the definition of suitable indicators and criteria to be used.

3.3 Relationship between long-term safety and the design, construction and operational periods

Developing the design basis and evaluating the implications of the implementation of the design, construction work and operations are key components of the safety case. The safety case should establish and support the safety requirements on design and should demonstrate that the final design and actual construction can meet these requirements in practice. This issue is receiving increased attention since many programmes are now approaching implementation.

3.3.1 Design principles and priorities

Several general design principles have been formulated over the years. However, the application of these principles varies. Generally, regulators require that the safety case should describe the design and characteristics of each barrier or component. Depending on the stage of programme development, the disposal system should be described in adequate detail to provide a clear understanding of how safety and environmental protection will be achieved, and how the different components of the system will interact with each other and with the environment in the long term.

3.3.1.1 Principles

All repository programmes consider, as basic principles, the post-closure safety concepts of passive safety, isolation, and robustness; and seek materials and components (and their associated interactions) that are well-characterised and whose behaviour and evolution are predictable over the required life-time. Other important principles may derive from considerations regarding e.g. radiation protection of workers or mining safety requirements. Design aspects and decisions that relate to operational safety considerations would generally be addressed in separate reports, usually required by national guidelines at pre-defined steps before facility approval and operation; they would need to be included in long-term safety cases to the extent that they also can affect long-term processes, interactions, and performance.

It is important to explicitly state the design principles in the safety case. There is ample guidance in NEA and IAEA documents, in national regulations, and, as examples, in a number of published national safety cases. For example, according to the IAEA Safety Requirements (IAEA, 2006), the natural and engineered barriers shall be selected and designed to ensure that post-closure safety is provided by means of multiple safety functions. However, the interpretation requires some special attention. Already the various NEA IPAG projects concluded that strict application of the "multiple barrier principle" is not possible for nuclear waste disposal (see e.g. the IPAG-3 report, "Establishing and Communicating Confidence in the Safety of Deep Geologic Disposal" [NEA, 2002]). Safety is not necessarily satisfied simply by placing successive physical barriers between humans and radioactivity; it is rather that multiple safety functions need to be maintained through proper selection of repository components. Functions may be redundant, i.e. have the same effect and be able to replace each other, but most of them are complementary and contribute jointly to achieving the safety objectives. The loss of a function may or may not lead to deterioration in the overall safety level. The loss can be acceptable if the other functions are maintained such that overall safety criteria are still met. An alternative means of expressing the "multiple barrier principle", and one which focuses more explicitly on the role to be fulfilled by barriers, is the use of safety functions now being developed in a number of repository programmes (Section 3.2.1).

3.3.1.2 Priorities

The design priorities will be defined by the disposal system concept and the available siting options. On a very general basis:

- Long-term safety should be a main driver for setting design requirements. Safety functions on various levels (Section 3.2.1) appear to be a good means of communication between safety assessment and design and engineering in this respect.
- Some disposal concepts place greater emphasis and rely more significantly on EBS components to provide complete or nearly complete containment of waste, in the direct vicinity of the waste canisters, during part or all of the safety assessment time scale. This approach demands greater attention to the quality and design of the EBS, but usually also depends on the geosphere providing suitable and sufficiently stable conditions to uphold the safety functions of the EBS.
- In concepts where containment and retention within the geosphere also play an important role, site properties must be shown to provide these safety functions over the long timescales considered by the safety assessment; this implies that a good general understanding of the site and its potential evolution is all the more important.

While long-term safety is a main driver in repository design, any facility must also be demonstrated to be feasible to construct (from an engineering perspective) and safe to operate – which impose additional constraints and performance requirements. Long-term safety, operational safety, and engineering feasibility are all essential: none can be disregarded in the design of the repository. Nevertheless, design decisions made to fulfil one requirement may have implications for meeting a different requirement; how to prioritise and reconcile the sometimes competing requirements is an issue receiving greater attention as more national programmes approach licensing and construction milestones.

3.3.2 The iterative design process

Design requirements form only the initial step in an iterative process that extends throughout repository development. The details of the design develop alongside the understanding of the long-term safety of the overall disposal system and the safety functions of its components.

3.3.2.1 Setting and developing design requirements

Design requirements are derived, generally, from the principles and considerations discussed above. In a growing number of programmes, a detailed analysis of safety functions provides the basis from which design requirements are formulated. As discussed previously (Section 3.2.1), design requirements in general refer to the initial state of the repository – i.e. as built – whereas safety function indicators and indicator criteria can apply to the state of the system throughout the assessment period. Thus, design requirement should be established such that, allowing for deterioration of the system over time, the required safety function indicator is fulfilled throughout the assessment period. The post-closure safety assessment needs to include this deterioration as a basis for setting sufficient margins on the design requirements.

The design process is an iterative one in which there is feedback between safety requirements, engineering aspects, and the existing knowledge base – and in which the initial design requirements must be periodically re-assessed in light of new information. Without such feedback, requirements can be formulated that would lead to safety, but are not technically feasible to fulfil with any reasonable design. In such cases, a modification of the concept – i.e. the requirements – is necessary and should be allowed, as long as the overriding design principles and safety functions are maintained. Furthermore, the design must be adapted to the site conditions, which underscores the importance of site characterisation in the design process (although the particular information needs vary according to the disposal concept; see Section 3.3.1). Indeed, it can be important to maintain flexibility in the design to accommodate a variety of new information or additional requirements, as discussed further in Section 3.3.3.

It is essential that all these issues are considered in an integrated fashion starting from an early stage of repository development so that it is confirmed that assumptions made in long-term safety assessments really are practically achievable. Up-front work is needed to systematically identify and define such constraints so that they do not come as unpleasant surprises later in the process. Some full-scale demonstration experiments of key design issues, e.g. at an underground laboratory, may also be very valuable and revealing.

It should also be recognised that the prioritisation of design principles and requirements may change according to the stage of repository development and level of information available. At early stages of a repository development programme, the main issues are usually the feasibility of the concept and the acceptability of sites. At these stages, it may be justified to present robust designs (e.g. highly conservative and potentially overly restrictive ones) if it is important to demonstrate that a safe repository can be constructed with a reasonable use of resources. However, as programmes move towards construction or operation, new evidence and knowledge may become available allowing less restrictive, but still adequately safe, designs, which would be effective and perhaps simpler to implement.

Since the understanding of the system behaviour generally evolves gradually during the process of building a comprehensive knowledge base – which can cover decades – it can be useful to have formal milestones with national or international reviews and corresponding feedback to the implementer (see also Section 3.3.3).

3.3.2.2 Requirement management systems

Formulating, managing and integrating the various requirements on the design are key tasks that, experience suggests, are best started at an early stage. For this purpose, many organisations have implemented computer-based requirement management systems (RMS). Based on the use of RMS thus far in national programmes, some observations are:

- An RMS typically sets out from top-level requirements (i.e. design principles) and traces down into sub-system and detailed-level requirements. Such a structure is suitable for documenting and tracking decisions, as well as for identifying the bases for requirements and detecting potential conflicts between fundamental requirements.

- However, a top-down RMS does not always capture effectively how knowledge is derived or how designs develop in reality. As already noted, safety functions are not always readily interpreted into design requirements that are feasible to implement. Also, detailed investigation of relevant processes may not develop until there are specific engineering solutions to consider. This means that design and associated requirements need to be developed iteratively – using both bottom-up and top-down approaches.
- Developing a useful RMS is not a computer software issue but rather a matter of defining and structuring its content to ensure that its application is practical, efficient and consistent; transparency is essential. Interfaces between different users – e.g. R&D programme, design, site characterisation – need to be established, with a shared vision and shared responsibility.
- The level of detail and resolution of the RMS depends on the stage of the programme. All cannot be resolved at the first instance. Iteration is essential and it must be allowable – and easy (but also traceable) – to change decisions and requirements.

3.3.3 Balance between flexibility and stable conditions for licensing

It is necessary to balance *flexibility* against the *need to show that current design/technology is sufficient for licensing*. On the one hand, given that the construction and operation of a disposal facility can last for decades, flexibility is needed to accommodate new information or technology that becomes available during that time. On the other hand, a definitive, detailed design has to be proposed for licensing and there must be confidence that such a design will achieve the goals of, and criteria for, disposal. This has implications for how updates to information are incorporated in safety cases and at what stage construction criteria are fixed, for example.

3.3.3.1 Importance of the stepwise approach

All programmes adopt an interactive and stepwise approach to repository design and focus of the safety case work. The main rationale for maintaining flexibility is to accommodate technological developments, more precise information on waste types and inventories, new R&D results, and more detailed site understanding that emerge during the long process encompassing site investigation, underground construction and repository operation. Even after licensing there is usually planned to be some performance confirmation programme to monitor the evolution of the repository and to ensure that the basis for the safety case remains sound in light of any new information.

On the other hand, there is a general aim to demonstrate that the given system can be implemented with existing technology and that it meets the applicable safety criteria. That is, the license for constructing or operating a disposal facility must be based on a specific and fairly detailed design; it would not be reasonable to expect licensing of a disposal concept that is only vaguely defined (or expected *a priori* to change) and whose feasibility cannot be demonstrated convincingly.

At key licensing points (i.e. for construction or operation), one should expect a well-developed identification and understanding of the critical issues, in order to minimise the risk that entirely new and very significant issues appear (or that previously identified issues take on unexpected significance) after a license has been given. One way to help control uncertainties is to direct design choices toward solutions offering the greatest robustness: that is, those less sensitive to the effect of external factors or to knowledge gaps.

However, this does not mean that all technical solutions are irrevocably fixed. They could be revised in subsequent licensing steps if a modified design is shown to be more appropriate in technical or economic terms or from the safety standpoint. Integration of safety in the design at an early stage allows adaptations in the design to take account of the other (and sometimes later-arising) requirements of a project (cost, constructability, etc.) without conflicting with the repository's global safety. Specifying optimisation targets too early, or based on incomplete information, can unduly limit design flexibility and eventually lead to non-optimised solutions. For example, specifying a maximum buffer temperature without an adequate scientific basis could unnecessarily prevent further optimisation with respect to specifications for the emplacement density of heat-generating waste, e.g. spent fuel.

A stepwise, iterative design process is, thus, essential to achieve balance between flexibility in developing the repository and the need for stability for licensing. It is also essential for confidence (Sections 3.4.6 through 3.4.8). In short, there should be stability in each step but flexibility between steps. At each milestone, the documentation provided by the implementer usually undergoes extensive reviews. There has to be sufficient flexibility so that important review findings can be implemented and documented for the next step. Especially in the early phases of implementation, these steps do not necessarily need to be formal but can be defined by the implementer.

3.3.3.2 Dialogue between implementer and regulator

A main challenge from the regulatory perspective is to evaluate whether the programme in question has reached sufficient maturity at a given stage of repository development to justify the requisite decision. An important aspect of such an evaluation is to understand to what extent it would be possible to modify an existing design choice or related programme decision; this could be internal to the implementer (e.g. research priorities) or already formalised in decisions (e.g. a previous licensing step). A further regulatory challenge is to review technologies for which there is little available experience and expertise.

A dialogue, beginning in the pre-licensing phase, between the implementer and the regulator is important in this regard. Such dialogue can improve understanding of design decisions and their technical basis; examples would be a review of the R&D programme or dialogue in the framework of the EIA process. Also important are overarching discussions to reach common understanding of the disposal concept as well as the interpretation of safety criteria and requirements (see also Section 3.4.4). Regulations (for long-term safety and also for operational aspects) should be as stable as possible since establishing a design with a "moving target" presents an obvious challenge. Even with a stable regulatory framework and requirements, an increasing level of detail in the design as well as in the interpretation of regulatory requirements can be expected as programmes progress towards implementation – and this is well-served through an ongoing dialogue.

The overall concept, such as a preliminary design, should be mature and stable prior to licensing; however, the implementer should aim at design improvements and the regulator should provide for corresponding flexibility even after licensing, although the degree of flexibility depends on the licensing step. Even after the time of a license application for construction (if applicable) there is still a general need for the implementer to follow the development of the state-of-the-art in relevant fields and, if required, take action to adjust the repository design or operation accordingly. After a certain point, significant changes proposed in designs or materials or other aspects of the physical system will require formal application for an amendment to the license under most regulatory regimes. A continued dialogue after licensing can help ensure that safety-relevant issues are identified and can be effectively addressed within the regulatory framework.

3.3.4 Account of the construction/operation period in the post-closure safety case

Another potential element of safety cases not discussed in the NEA brochure is the increased account of the construction and operational period. From a regulatory perspective, the post-closure safety case should include events and processes occurring even before closure if they can significantly affect the initial conditions or have long-term impacts.

At the early stages of project development, the repository design and corresponding safety case tend to focus on long-term safety as the driving issue and often the most challenging to define. As programmes move closer to implementation and designs (and the safety case) are further refined, the issues become more complex and multi-disciplinary: the design, the selection of engineered components and mining techniques are still driven by long-term safety requirements, but they also need to take into account operational safety and feasibility of construction, avoiding excessive technical complexity. In deep disposal, the possibilities for active monitoring are limited, and operational issues such as ventilation and excavation impose design and operational requirements that might potentially affect long-term performance or disposal system evolution. Indeed, the conditions, duration and uncertainties of the evolution of the operating phase partly define the safety performance in the post-closure phase.

3.3.4.1 Defining the initial state for post-closure assessment

It is widely acknowledged that some account must be taken of the construction and operation phases in order to define an initial state for the post-closure phase as a starting point for long-term safety analysis. This must be based on:

- A good understanding on how the construction/operation will be carried out.
- A good understanding of the thermal, mechanical, hydraulic, chemical biological and radiolytic (THMBCR) processes, which will occur during the relatively long open period, and which likely will last decades even when a post-emplacement retrievable phase is not envisioned.

At a minimum, it must be assured that the construction techniques and operation will not jeopardise key characteristics or undermine important assumptions on which safety is based. Implementers need to identify potential deviations from the expected evolution during the construction/operation period, which can influence the initial state. The quality assurance programme for the construction/operation period must confirm the long-term safety assessment assumptions on the initial state. This includes verifying the quality of engineered barriers as installed: for example, through inspections to detect potential manufacturing defects in containers.

3.3.4.2 Additional issues considered

Beyond the considerations noted above, some programmes are now examining in more detail the THMBCR processes/alterations for construction and operation using a similar methodology as for subsequent, post-closure stages – but there is no consensus on the approach or on whether it is important for post-closure safety. Feedback to the design and construction planning is also considered, e.g. in setting the dimensions of certain components and how to plan construction and repository operation activities so as to limit the alteration or disturbance of the host rock.

Examples of issues considered include:

- Effects of shaft construction methods on repository sealing.
- Hydro-mechanical impact of excavation including the excavation disturbed or damaged zone.
- Modelling of (other) hydro-mechanical evolution in the vicinity of the emplacement tunnels.
- Chemical disturbances of the host rock due to the presence of oxygen in the open repository.
- Drying of the surface layers of the host rock by pre-closure ventilation.
- Resaturation time.
- Thermal impacts.
- Sealing of monitoring wells.
- Consequences of an abandonment of the repository without proper closure.

In some programmes, it is deemed that potential effects of an open period can be excluded from detailed consideration, e.g. in safety assessment calculations, due to their limited impact or reversibility over short timescales (see also NEA, 2006). The treatment of this issue in the safety case may also depend partly on whether an open period is foreseen after emplacement of waste is complete, and if so, how long this period might be. An extended operational/post-operational/surveillance phase may have a significant impact on long-term safety; this needs special attention in programmes with such plans. The specific situations or perturbations to be avoided during construction and operation depend strongly on the specific barriers and safety functions provided by the system and the degree to which these are emphasised in the safety case. The repository may be designed to mitigate the potential impact of disturbances caused by any open period.

3.3.5 Implications of BAT and optimisation

There is not a unified approach for applying best available technique (BAT) and optimisation. Many programmes do not formally require application of BAT. There is, nevertheless, an expectation to show that the technologies being applied are sufficient to meet the safety and other criteria that apply to the repository. Other programmes are required to apply BAT more formally or at least to discuss its implications both with regards to siting and design. There is not a universally accepted interpretation of the word “best”, but it appears generally accepted that the BAT principle should be applied similarly to the optimisation principle: that is, due consideration should be given to economical and other societal factors and to what is reasonably achievable. How to distinguish between BAT and optimisation, as well as how to apply these principles during the various stages of a repository programme, has so far not been well-defined in regulations and therefore is left to the judgement of the implementer.

3.3.5.1 International guidance and directives

International guidance makes explicit reference to principles such as optimisation and BAT. This is evidenced in ICRP 81 (ICRP, 1998), which states that constrained optimisation (optimisation satisfying a dose or risk constraint) is the central approach to evaluating the acceptability of a geological disposal system. It is also formally incorporated in the Integrated Pollution Prevention and Control (IPPC) Directive of the European Community, which requires the application BAT when pollutants may be released in the environment.

ICRP and IAEA recommendations elaborate on the subject, indicating that implementation of optimisation through sound managerial and technical principles is central to provide confidence that protection of the public in the long term has been achieved. International guidance states that decision making should be based on the study of alternatives and should follow a stepwise process where objectives for optimisation are clarified along the programme.

3.3.5.2 Implementing BAT and optimisation in national disposal programmes

In spite of these recommendations, a review shows that there are large differences in the interpretation and progress in implementing BAT and optimisation in national disposal programmes. Many countries have not yet included requirements on optimisation/BAT in their regulations and, without explicit requirements and clear compliance criteria, implementers are reluctant to make reference to BAT.

Common views on the subject are that optimisation and BAT refer to the design process, dictating that obvious improvements of the repository system must be made. It is recognised that in normal engineering work, alternatives are systematically investigated but discarded options may not be reported. BAT could require that the discarded options also be documented.

As noted, the interpretation of "best" in "best available techniques" is not straightforward. Since in-depth investigations can require huge resources, it is not always feasible to investigate multiple options in detail. Only a few alternatives can be evaluated and reported. "Best" must also be understood in the sense of reasonably achievable; due consideration should be given to economical and other societal factors. In addition, the options must fulfil basic requirements; an alternative is not acceptable even if it is the "best" among a set of choices, if it cannot fulfil the safety criteria and also be shown to be feasible. It is not clear, however, whether all the alternatives studied must be shown, *a priori,* to be suitable. This could actually be difficult to ascertain at the outset. In fact, discarding less suitable alternatives is a normal part of the design development process.

It is acknowledged that repository implementation is a long, step-wise process in which decisions must be taken at various times. In most programmes, there is still more focus on demonstrating the existence of technically feasible solutions, but not to irrevocably freeze them. As a result, and although safety is a major criterion, optimisation has not necessarily been fully completed at intermediate stages of a repository development programme. Depending on the progress made in knowledge, improvements may still be possible and could be developed in later phases of the projects. Given the stepwise approach to development, regulatory decisions about whether BAT has been demonstrated may, therefore, be more easily made later in the development process, such as at the time of a license application for repository construction. That is, the developer may not be in a position to fully demonstrate optimisation and use of BAT until much of the iterative development work has been finalised. At early stages, before various licensing steps, the discussion of optimisation and BAT is possibly rather a framework for discussing feedback to remaining development needs. Since the knowledge base will continue to develop and evolve, a "one-time" evaluation of BAT will not be good forever. Therefore, optimisation/BAT is a type of "continuous improvement process": the implementer should be able to show that decisions on alternatives have been taken at the right times based on adequate information.

In any case, optimisation/BAT should not lead to an infinite postponement of decisions. In that respect, ICRP 81 [Para. 78] makes the following recommendation:

> "Judgment is required in the optimisation of protection and in the application of the technical and managerial principles. However, this should not be an open-ended process. More specifically, the Commission's view is that provided that the appropriate constraint for natural processes has been satisfied, that reasonable measures have been taken to reduce the probability of human intrusion and that sound engineering, technical and managerial principles have been followed, the radiological protection requirements can be considered satisfied."

As for implementation, it is acknowledged that system optimisation is a multi-criteria exercise where other factors apart from long-term safety have to be considered (engineering feasibility, transportation, operational safety, retrievability, etc.). Indeed, in some contexts, optimisation and/or BAT are interpreted or intended to apply more broadly than to radiological protection – covering not only, for example, radiological impacts during transportation or operation, but overall environmental or even societal impacts across a spectrum of *criteria*. Regulators need to be involved in the choice of criteria and stakeholders can provide an important input. Constraints need also to be clearly defined (e.g. resources, time).

3.3.5.3 Need for further work

It is not clear if optimisation (in the sense of ALARA) and BAT lead to similar, complementary or conflicting requirements. There is, thus, the need for a sharpened definition of optimisation and BAT, and to specify against what criteria and over what timescales the requirements apply (e.g. optimise in terms of long-term radiological protection, radiological protection overall, or global environmental impacts). International recommendations do not provide sufficient guidance for practical implementation. For countries addressing optimisation and BAT, there is a need for clarifications on the implementation in the regulations, in the framework of the stepwise process: “What does best mean?” and “How and when are compliance judged? A desk study initiated by the NEA RWMC Regulators’ Forum has produced a review of international recommendations on the subject of optimisation/BAT and identified a preliminary list of key questions to consider in order to guide implementation of these principles in national regulations (NEA, 2008b).

3.4 Other contributors to confidence in safety

The foregoing Sections have addressed many of the technical, scientific, and documentation requirements that are necessary to provide confidence in a safety case. There are several additional opportunities to further enhance confidence. Most of these were not explicitly covered by the INTESC questionnaire as they are not yet routinely implemented in current safety cases, but are being actively developed. Such additional contributors to confidence are judged to have the potential to play an important role in future safety cases and were elaborated in the INTESC workshop.

As radioactive waste management programmes advance, it appears that the concepts on developing and communicating confidence expressed in the 1999 NEA confidence report (NEA, 1999a) and in the NEA safety case brochure (NEA, 2004) are confirmed by experience in several countries (e.g. US National Research Council 2001, 2003). According to recent experiences on confidence building and its communication, confidence rests on three important pillars:

- Process*:* there is an appropriate and open stepwise process to develop a repository programme and it is internationally recognised.
- Actors and roles: the roles of the implementer, regulator and other interested and affected parties are well defined and there are effective mechanisms for interaction among all parties.
- Trust*:* there is trust (or at least a certain degree of trust) among all parties.

The process of developing a repository programme is well established and is very similar in the countries responding to the INTESC questionnaire. It involves different stages moving from development of the generic disposal concept through facility siting, operation, and closure. At various points through the process, policy and/or regulatory decisions are involved, although the exact milestones may vary from country to country. Site selection usually involves a policy (or political) decision. See, e.g. Sections 3.3.2 and 3.4.6 for further discussion of stepwise processes.) Repository closure may be followed by a period of monitoring and institutional control (see Section 3.4.11), but this is highly variably among countries.

In terms of actors and roles potential audiences to be addressed by arguments for confidence include:

- The implementer itself, which must have confidence in its proposal.
- The regulator, which must have confidence in its ability to make a licensing decision.
- The scientific and academic community, which may have views on the scientific basis of the safety case.
- The local community, which may have specific concerns (and not related solely to safety).
- The general public, which may have different concerns.
- Non-government organisations representing various viewpoints, and which may support or oppose a decision regardless of confidence by others.

Well-defined roles and effective mechanisms for interaction among implementer, regulator and interested and affected parties are important factors for confidence. Roles imply the safety responsibility of the implementer and licensing responsibility of the regulator. The implementer is the license holder and is responsible for assuring safety to workers and the public, and to the far-distant-future public after permanent closure. The regulator needs to be assured that claims and assumptions made by the implementer have a solid foundations and that work is conducted properly. Clear and effective mechanism must also be instituted for interaction with interested and affected parties (Section 3.4.4).

A certain degree of trust must be shared by all these parties for the repository programme to be effective. It is unlikely that total and unconditional confidence can be achieved by all potential stakeholders, or even between the implementer and regulator. Confidence is conditioned by the recognition of continuing uncertainty, and by the belief that further work will be done properly to provide more assurance of safety as a project continues. Given these realities, it is essential that the local community and the general public have a degree of trust in the implementer and the regulator to make decisions that consider and protect their health and safety. This trust is not based solely on what is shown by technical analyses; recent experience shows that there are important opportunities to build confidence in the way that a safety case is defined, in how it is developed and reviewed, in how the disposal system design is optimised and the safety case updated, and in the level and mode of interactions between implementers, regulators and other interested and affected parties.

The following methods used by various repository programmes were discussed during the INTESC workshop. They are reported here as items proposed for further IGSC work, with a few exceptions:

- Independent review of scientific work.
- Multiple complementary lines of reasoning (e.g. the scientific base for the assessment itself, natural and anthropogenic analogues, corroborative analyses).
- Integration and transparency of information and knowledge management.
- Interactions among implementer, regulator, and other interested and affected parties.
- Consistency with international experience and guidance.
- The stepwise development and decision making process.
- Iterative updates of the safety case throughout the repository programme.
- Flexibility, reversibility and retrievability.
- Institutional measures that contribute to confidence (e.g. reaching internal confidence before communicating it, commitment to integrity, commitment to continuous learning).
- Pilot, test and demonstration facilities.
- Monitoring, performance confirmation and long-term science and technology programmes.
- The handling of the very long time scales.

These items are discussed in more detail in the following Sections.

3.4.1 Independent review of scientific work

Confidence in the scientific understanding can be enhanced significantly if, in addition to fulfilling regulatory and QA requirements for internal independent reviews of technical work, the implementer’s work is seen to have been subject to wide and demonstrably independent external review. This may include:

- Review on behalf of the implementer by relevant experts not involved in the implementer’s programme (e.g. individual national experts, a standing peer review panel or an international review team).

- Less formal "review" by the wider scientific and technical community and civil society in general, by the implementer openly publishing its work and arguments and providing mechanisms for feedback.

Formal technical peer reviews are often conducted by international organisations (NEA is an example) or national advisory bodies established for this specific purpose (France and the United States being examples of programmes with standing technical advisory groups); see also Section 3.4.5, "Consistency with international experience and guidance." Reviews initiated and managed by the implementer are normally subject to quite strict guidelines in order to ensure the independence of the experts and their deliberations. Other interested and affected parties could also provide an independent technical review. For example, a technical advisory board consisting of representatives with different backgrounds such as local institutions, local and affected governments, universities, as well as representatives from industry, non-profit, and non-governmental organisations could provide review of the programme or parts of it and submit its comments to the implementer or the regulator.

Many organisations submit a comprehensive number of scientific papers to academic journals or other peer-reviewed proceedings to support critical arguments underlying the interpretation or treatment of key issues. This approach has many merits but it needs to be recognised that there always will be much key information not suitable for the standard scientific review process since data in repository development programmes often concern very detailed and specific issues that are judged not to be of general scientific interest. In fact, this is the very reason why both implementers and regulators create several other means of supporting their evidence and arguments.

3.4.2 Multiple complementary lines of reasoning

By utilising a variety of independent methods, techniques, and perspectives, scientists and engineers develop confidence that would not otherwise be possible in the reliability of the results of the models and analyses. It is important to define and carry out the analyses that support a safety case so that these multiple lines of evidence are made clear and not hidden in the potentially large and complex reports on the technical basis underlying a safety assessment, and thereby also underlying a safety case.

The multiple lines of evidence usually cited, in the safety cases and assessments produced to date, are the following:

- The evidence provided by the extensive programmes of site characterisation and research and development on the engineered barrier system; this is an integral part of the safety case, justifying the many parameters and assumptions on processes used in the quantitative safety assessment (it has also been addressed in Sections 3.2.4, 3.3.1 and 3.3.2 of this report).
- Corroborative analyses.
- The strength of geological disposal versus other concepts.
- Support from natural and anthropogenic analogues.
- Qualitative analyses.

Beyond underlying the safety assessment, such information provides evidence to support the robustness and favourable characteristics of the repository and its environment. Significant relevant evidence that is not supportive of the safety case should also be discussed and analysed. The relative weight given to various lines of evidence and reasoning depends on the stage of repository development, the information available, and the timeframes being considered in future repository evolution (Section 3.4.12).

The arguments listed are not strictly independent, but rather are complementary pieces of information for building confidence. The existence of independent evidence – for example, from various sources, across different disciplines, or applied in alternative conceptual models – that point to common conclusions supports the quality of the scientific understanding and basis for safety assessment. Other measures such as independent review of scientific work (Section 3.4.1) and effective integration of information (Section 3.4.3) are also important in this regard, even if they may not be viewed as separate or complementary evidence.

3.4.2.1 The strength of geological disposal versus other concepts

The importance of the safe management of radioactive waste for the protection of human health and the environment has long been recognised and considerable experience has been gained in this field through international collaboration. Based on this experience, it is internationally agreed that isolation and containment in deep geological formations is the best long-term waste management solution at least for high-level long-lived radioactive waste (U.S. National Research Council 1957, 2001, 2003; NEA, 1999a). An elaboration of the general concept, a summary of international views, or a comparison of the relative risks (near-term and long-term) compared to other technically feasible management schemes can be helpful in building confidence.

This is a complementary piece of information required to build confidence in a safety case in a broad sense. However, it is not an independent line of reasoning in the sense that it addresses a certain aspect of a safety case in a different and independent way.

3.4.2.2 Corroborative analyses

In addition to the analyses that assess the potential performance of the repository, the implementer often utilises alternative models to study the importance of modelling assumptions, and to confirm the fundamental understanding of important processes. This approach, which is often part of QA requirements, has been incorporated routinely in many of the analysis and modelling studies performed for current repository programmes.

The regulator may develop an independent performance evaluation capability and, therefore, may have the opportunity to conduct corroborative analyses of its own. Such analyses can provide insights to the regulator or other independent reviewers that enhance credibility and confidence in the safety case or alternatively, allow technically informed criticism of the implementer’s approaches and results – which should instigate improvements that eventually increase the credibility of the programme.

3.4.2.3 Natural and anthropogenic analogues

Support from natural and man-made analogues has long been regarded as an important means of gaining confidence in a safety case and is also discussed in the NEA safety case brochure (NEA, 2004). Analogues are systems in which processes similar to those that could occur in a nuclear waste repository have occurred, often over long time periods (decades to millennia) and/or large spatial scales (up to tens of square kilometres) – scales that are not achievable with laboratory or field experiments. There may also be analogues at a very small scale; for example, small mineral occurrences observed in nature can be used to demonstrate (in definable analogous environments) the general concept of a passive layer protecting high chromium metal materials in oxygen-rich environments over very long times. Similarly, the existence of preserved Roman nails in an oxygen-poor environment speaks to the general durability of iron-based materials in typical deep underground environments.

The concept of geologic disposal itself is based on the observation that certain geologic environments have intrinsic properties that contribute to the long-term preservation and isolation of materials placed within them by either human or natural processes. Analogue studies addressing processes in common with a proposed repository facilitate understanding of how aspects of the repository might behave by enabling comparisons of projected future behaviour with the known past behaviour of a system in which similar processes have produced characteristics that are directly observable today.

For example, observations of the past migration of radionuclides in groundwater in comparable environments provide insights into the possible future transport of radionuclides away from a repository. Information has been obtained from natural analogues (e.g. natural deposits of uranium and other minerals) and anthropogenic analogues where the movement of radionuclides in groundwater caused by past releases is being monitored. Archaeological and historical records also provide qualitative information on the degradation of materials that is relevant to the performance of the repository (e.g. the preservation of materials in Egyptian pyramids and tombs more than 5 000 years old, and the preservation of human and animal remains in Nevada rock shelters for more than 10 000 years).

However, analogues will only help confidence if they are good analogues (i.e. they are similar in the characteristics relevant to the process or location in question) and the claims made on the basis of analogues are realistic. For example, the survival of one Roman nail is a good analogue to show that metals can resist corrosion on thousand-year timescales. But it is not a good analogue to support a claim that all the steel containers in a repository will remain intact for 2 000 years if it is apparent that the vast majority of the nails have not survived. Recognition and acknowledgement of such limitations is more likely to inspire confidence than ignoring them.

There are no analogues that can fully and completely represent the total repository system, both engineered aspects and natural setting. Nevertheless, a variety of process – or material-specific analogues can be used, and typically are used, to assess how well repository models represent processes or materials of interest to evaluating potential repository performance. Knowledge gained from analogues refines performance assessment model assumptions and helps place bounds on parameter ranges, thereby improving the robustness and consistency of process models.

3.4.2.4 Qualitative analysis

An emerging trend in the safety case development is the use of qualitative analysis based on reasoned arguments that are scientifically sound. An example of qualitative analysis used in the safety case is the analysis to ensure that all the relevant FEPs have been taken into account in the safety assessment. An advantage of such qualitative analysis is its transparency as it does not require the use of sophisticated modelling tools or knowledge of highly technical information about the site.

Regulators, in reviewing quantitative safety evaluations, will look at the basis for qualitative arguments and, thus, the analyses leading to the inclusion and exclusion of features, events and processes.

Qualitative analyses are also an integral part of quantitative analyses and the uncertainty assessment (Section 3.2.3). The decision as to what to include in a quantitative analysis requires making many judgments, many of which, in turn, require reasoning that in effect represents a qualitative analysis. For example, the treatment of alternate conceptual models also typically involves expert judgment by the modeller, which is another example of qualitative analysis.

3.4.3 Integration and transparency of information and knowledge management

Effective integration of information and knowledge coming from the different fields of the programme is important. From a regulatory perspective, it is important that the implementing organisation demonstrates an ability to integrate and manage information and data. An important example is the compilation of a geosynthesis, as described in Section 3.2.4. Management structures and systems need to take into account the need to integrate information. This need is clearly recognised from the answers to the INTESC questionnaire. The information must also be documented in a way that is understandable and traceable to those within the programme and without, including regulatory agencies. An extension of this effort is the implementation of knowledge management programmes to ensure as well the integration and transfer of information and institutional knowledge through time, since the programme development can last decades.

3.4.3.1 Integration of multi-disciplinary information

The importance of clearly defining the roles and interactions of different groups in developing the safety case is recognised, but there is also a clear need to effectively synthesise information in order that the safety case has a well-founded and internally consistent technical basis. There is developing experience in using a *multidisciplinary integrated safety team* (or *safety case* team) as an important approach for ensuring integration between safety assessment, engineering (design), site characterisation and R&D, keeping a holistic view and maintaining a proper safety culture. However, there are different ways how this integration is actually achieved, and various views on how it should be organised:

- For example, a senior management team, representing all areas of the programme, might meet regularly to decide on priorities and directions. Below this team there could be more narrowly focused coordination and integration groups. For example, in addition to safety assessment teams, there could be a need for integrated teams handling design, site characterisation and environmental impact assessment. There may also be a need for integration on a "lower" (more scientific and technical) level, e.g. integration between hydrogeology and hydrogeochemistry.

- Integration and safety culture are sometimes reflected more formally in the organisational structure of the respective organisation, e.g. with a special division assigned the role of promoting the safety "doctrine" (by training, safety guides, etc.) or a "scientific integration department" responsible for ensuring the synthesis of knowledge for its use in the safety analyses.

- Alternatively, the safety *assessment* team may take a lead role in the integration of information by, for example:
  - Co-ordinating all interactions with the safety and environmental protection authorities.
  - Promoting the safety culture within the organisation, e.g. through information sessions, review of reports, participation in integration groups.
  - Including in its team activities representatives of the R&D, designers or site investigation staff, thereby building understanding of the safety relevance of R&D, repository design or site investigation issues among the respective staff and a corresponding understanding of the nature of the R&D, design and site investigation results within the safety assessment team.

- Integration between a safety assessment team and other groups can be achieved by organising interfaces between the various discipline-oriented teams involved. There is no unique and recommended structure to do this; each national implementer can define and organise the interfaces between its different teams. A complementary tool that has worked well, according to one respondent, is the use of "audit" or "review" meetings between the safety assessment team and other groups – in particular, among scientists, design engineers and safety assessors. Typically, the safety assessment team would explain how specific information is being used within the safety assessment, with an obligation on the other "specialist" group or groups for either agreement or "constructive disagreement".

It is clear that the critical aim is to have effective communication between individuals and teams so that each individual understands enough of the wider safety case context to enable them to provide the best possible contribution. The practicalities in organising integration without causing people to be "bogged down" in endless meetings as well as how to really overcome differences in attitude and perspectives between different groups is still the main challenge. It is likely that there are possibilities for further improving integration by learning from the experiences of others. It would be of interest to further share experiences on these matters.

3.4.3.2 Commitment to transparency and traceability throughout the duration of the programme

Transparency implies that lines of argument and reasoning are clearly explained and that the supporting data, assumptions and other key information are presented. Traceability requires that the sources, limitations, and interpretation of data are documented. Transparency needs to be balanced with traceability to ensure that key information is not buried indistinguishably in a surfeit of less relevant information or in a maze of circular or endless references. Experience suggests that striking the proper balance between transparency and detailed referencing is a challenge, only partly overcome by different levels of documentation (Section 2.9).

An issue related to transparency and traceability of information is that of the transparency and traceability of decisions. As new managers and technical staff join programmes, questions often arise regarding the rationale for past design decisions or for discarding certain options. If there is no longer a first-hand account available of the deliberations that led to such decisions, or if there is no transparent and traceable record of such decisions and their bases, this could cause re-examination and rework that can be costly in terms of both time and resources. This situation can be avoided by making a concerted effort to assure that the bases for decisions are well documented and that institutional knowledge is preserved throughout the long duration of the programme (see knowledge management, discussed below).

Transparency and traceability of data and decisions are also important in the interaction with the regulator and with other interested and affected parties. The decision making process should be well documented (including clear and comprehensive synthesis of the bases for decisions) and available to all throughout the programme also for auditing purposes. It has been observed time and again that deliberations organised in open, transparent and unconstrained ways are conducive to confidence building.

3.4.3.3 Knowledge management

Another emerging trend is the development of knowledge management systems. Specifically, development work is underway on automated knowledge management systems for geological disposal technology, handling the vast quantity of data (and their interpretation) involved. These systems are intended to ensure that the required knowledge is accessible to all stakeholders and that gaps can be identified and supporting R&D prioritised. Knowledge management is related to transparency and traceability in documentation, but adds a temporal and intergenerational component.

National institutions in several countries are adopting what are called "knowledge management" policies and approaches that seek to address the preservation of institutional knowledge, a challenge common to all highly technical organisations with operations continuing over decades. A repository programme, however, has particular challenges given that it may be a century or more before a decision to seal a system is made.

Knowledge management requires information technology support in terms of preserving data, information and knowledge, but it comprises more than simply automated systems (see e.g. Umeki *et al.*, 2007). Cultural and practical changes need to be made in organisations to facilitate the transfer of knowledge through the organisation at a given time as well as over time. Developing and effectively implementing a knowledge management programme also supports the idea that external parties can have confidence in the continuing safety consciousness of a programme even if, over time, there are changes in management, in key technical staff, or both.

Knowledge management is an active concern at nuclear power plants, and the IAEA provides written guidance and performs evaluations of such organisations. A similar guidance document is now in preparation to give preliminary advice to repository programmes in terms of setting up a credible knowledge management infrastructure. It is expected to be followed in about five years with a second edition that will then draw on experience gained in implementing this advice to target it more specifically for the special circumstances surrounding repository programmes.

3.4.4 Interactions among implementer, regulator and other interested and affected parties

3.4.4.1 Interactions between the implementer and regulator

As discussed in Section 3.3.3, regulators will formally review implementers' safety cases at defined stages in the development of a repository programme. At other times in the programme, implementers seek to build regulators' confidence in the safety case through more frequent, and often less formal, interactions. The success of such interaction in building the regulators' confidence will depend on the strength of the implementer's arguments and the manner in which they present them. Such interactions may also contribute to other stakeholders' confidence by showing that regulators are rigorously scrutinising the safety case – but if conducted inappropriately they could have exactly the reverse effect.

Regulators' confidence in that safety case is likely to be enhanced if the implementer:

- Shows a willingness to engage in such dialogue and, where and when appropriate, for key elements of the dialogue to be opened up to include other stakeholders.
- Demonstrates a thorough understanding of the key arguments made in the safety case, how they fit together and how the key lines of evidence support them (including an adequate understanding of work produced by various internal entities and groups – especially by sub-contractors, for example – as well as relevant work conducted by others – e.g. as reported in the scientific literature – and how it contributes to the safety case).
- Conveys confidence in the safety case, but is not arrogant or complacent.
- Is open in discussing weaknesses or open issues (and how they intend to address them, for example, by conducting further work or by adopting a more conservative approach in design) as well as strengths in the safety case.

Confidence can be eroded if the relationship between the implementer and the regulator calls into question the independence of the regulator. An independent regulator is a legal requirement but also a prerequisite for building the confidence of other stakeholders. If the implementer and regulator are, or are perceived to be, too "friendly", then this can undermine stakeholders' confidence that the regulatory review will be sufficiently rigorous. If the relationship is too "unfriendly" then dialogue is unlikely to yield useful progress and so cannot contribute to building the regulator's confidence in the implementer's safety case.

The openness with which the implementer and regulator conduct their dialogue will also have a major influence on confidence. Major meetings between the implementer and regulator behind closed doors may cause an erosion of stakeholder confidence for obvious reasons. On the other hand, the implementer and regulator need to be able to have closed-door meetings for the purposes of fact-finding, investigations and inspections. Having the public or press at such meetings could be inefficient and could cause stifling of responses to questions and work against the concept of a safety-conscious work environment where any employee can raise a safety-related concern internally or to the regulator without fear of reprisal.

Defining the types of meetings that may be held between an implementer and regulator, and specifying which types of meeting are open to external observation – and which are not – may help to preserve both the actual and perceived independence of the regulator and to contribute to confidence that the safety case is being subjected to proper regulatory scrutiny. Such a defined framework for information exchange needs also to establish clearly, for each situation, whether the regulator is delivering formal regulatory positions and decisions or not (for example, providing advisory information, interpreting regulatory language, or commenting on work in progress or plans for future work). These definitions need to strike an appropriate balance between the wishes of the implementer and others for regulatory certainty and clear and transparent expectations and guidance and, on the other hand, the need for the regulator to reserve final judgment on a safety case until the formal decision point.

One way of structuring implementer – regulator dialogue that may be particularly helpful in building confidence is through a formal issue-resolution process. Examples of these exist in various national programmes. Such a process was established between the U.S. DOE and the U.S. NRC for the duration of the pre-licensing phase. In a similar fashion, the international review team set up by the regulatory authorities in Sweden maintain a "Tracking Issues List' (TIL)", in which the implementer, SKB, provides written answers to issues brought up by the reviewers. A similar list is maintained by the Finnish regulator, STUK. In France as well, the *Groupes Permanents Déchets* (GPD) provides a forum for structured discussions among Andra, the Nuclear Safety Authority (NSA), its technical support organisation (IRSN), and a panel of national and international experts. The implementer and regulator need to agree on the exact procedure, but common features include:

- Identification by the regulator of specific technical issues requiring resolution. These will generally be issues requiring more substantive action by the implementer, since issues on which only clarification from the implementer is needed should normally be addressed in regular dialogue.
- Responses by the implementer specifically addressing the identified issues by means of additional analysis or research.
- Iteration of the process, where necessary, to address the regulator's outstanding or further questions on the issue.
- A judgment by the regulator on the extent to which it considers the issue to be resolved (e.g. issue closed; issue closed for current stage of programme but liable to be reopened in a future stage; issue closed subject to technological developments; issue unresolved but no longer significant).
- Documentation of the key points from all the above steps. The implementer and regulator will need to agree on who has access to such documentation, considering the potential benefits to confidence building of making the information widely available against any concerns about unduly constraining the frankness of discussions or the flexibility to revisit preliminary decisions (on the part of either the regulator or implementer).

Describing the rules of engagement in a publicly available document, like a "memorandum of understanding" between the organisations, for example, and abiding by these "rules of engagement" may contribute to a demonstration that independence is maintained.

3.4.4.2 Interaction with stakeholders

A geologic repository programme unfolds in a broad societal context. Every repository programme acknowledges that stakeholder involvement and consultation are keys to the success of a project that is a long-term and expensive undertaking and presents potentially substantial societal risks. Each country has its own societal and political context and, therefore, stakeholder interaction has different meanings and methods in different countries.

Experience has shown that stakeholder participation processes can be set up in such a way that regulators can take part together with other actors without endangering their independence for later regulatory actions. Different ways of involving stakeholders are actively being explored and tried or demonstrated by the Forum on Stakeholder Confidence (FSC) of the NEA and in projects supported by the European Commission (www.radwastegovernance.eu). Publications by the FSC on the topic of meaningful yet balanced stakeholder involvement include an overview of practices in NEA member countries in *Public Information, Consultation and Involvement in Radioactive Waste Management; An International Overview of Approaches and Experiences*, (NEA, 2005).

In addition, much work is being done through the Community Waste Management (COWAM) series of projects (see e.g. Dubreuil, 2004) of the European Commission, which has as its goals to:

- Empower local actors through a networking process at European level between different local contexts, countries and cultures.
- Gather and discuss the available experiences of decision-making processes at the local level within their national context in Europe.
- Set up an arena for balanced exchanges between local actors, NGOs, regulators and implementers.
- Promote new approaches to decision-making in national contexts in Europe.

The RISCOM series of projects (SKI, 2004) represent an approach where stakeholders participate to create insight, awareness and transparency among decision makers, official and unofficial stakeholders as well as the general public. The aim is that this should increase the quality of societal decision-making, including political decisions at EU, national and local levels. The INTESC participants acknowledge that important work is done in these groups. The link between these activities and the development of the safety case still has to be improved.

3.4.5 Consistency with international experience and guidance

The process for developing a repository programme and the process for building a safety case are well established, as described further below (Sections 3.4.6 and 3.4.7). Both IAEA and the NEA have been particularly active in assembling international experience and providing guidelines on the safety case and other issues related to long-term safety of deep geologic repositories. This cooperative international framework can also provide an internationally agreed-upon terminology (e.g. the NEA/IAEA definition of safety case), which contributes to transparency and therefore to confidence in safety.

Numerous technical projects and workshops by these organisations, as well as by the European Commission, aim at bringing together and documenting the best technical practices and experience in order to guide programmes, especially those at early stages of planning or development for geological repositories. The INTESC exercise confirms the success of such efforts to foster information sharing and the integration of lessons learned. Such co-operation is valuable not only for implementers who are developing safety cases, but also to inform the priorities and methods for regulatory reviews of safety cases. Increasingly, therefore, representative from both implementers and regulators participate in international projects on the safety case and in independent technical reviews by NEA and other international organisations.

A repository programme that is demonstrably in harmony with international recommendations germane to its mission, and which shares its own experiences and learns from others', shows a disposition toward learning in order to enhance safety, efficiency, and technical depth and breadth for its safety case. The public, in particular, is more likely to trust an organisation that collaborates with and learns from others, be they other nations' repository programmes or the international organisations seeking to promote safety and to enhance the technical quality of work supporting these endeavours.

3.4.6 The stepwise development and decision-making process

As is the case with good engineering practice for other long-term and complex projects, repository programmes must proceed in a stepwise fashion. Such a process is especially important for geologic repositories for high-level waste because, even compared to other large engineering projects: 1) they are first-of-a-kind, complex, and long-term projects that must actively manage hazardous materials for many decades if not centuries; 2) they are expected to hold these hazardous materials passively safe for many millennia after repository closure; and 3) they are widely perceived to pose serious risks.

The process of developing a repository programme is established and is very similar in the countries responding to the INTESC questionnaire. It usually involves different stages, such as:

- Generic R&D and concept development stage.
- Site(s) identification and characterisation (surface-based and possibly subsurface).
- Site selection (and usually further subsurface characacterisation).
- Licensing.
- Repository construction.
- Repository operation.
- Repository closure.
- Post-closure period.

Sometimes the stages are punctuated by regulatory or policy decisions; sometimes they are internal milestones set by the implementer to assess the level of confidence in the safety of the repository and to provide the opportunity to update or modify the programme as necessary. The exact milestones for which regulatory or policy decisions are required may vary from country to country. Site selection usually involves a policy (or political) decision. One or more regulatory decisions are usually required to allow repository construction, operation and closure. (See, e.g. Sections 3.3.2 for further discussion of stepwise processes.) Repository closure may be followed by a period of monitoring and institutional control (Section 3.4.11), but this is highly variably among countries.

The strength of the stepwise project is that it provides opportunities to integrate newly acquired knowledge into the programme, to evaluate the programme's status, and to allow interactions with the regulator and interested and affected parties. This has already been discussed, for example, in the preceding Sections regarding the optimisation process and the need to allow flexibility in the design (Sections 3.3.2 and 3.3.5). The stepwise approach also allows programme improvements with respect to, for instance, environmental impacts, safety, costs, or schedule. The advantages of a stepwise implementation process have been discussed quite extensively in several reports by the NEA and others (NEA 2004a, 2004b; U.S. National Research Council, 2003).

3.4.7 Iterative updates of the safety case throughout the repository programme

One of the "pillars of confidence" identified earlier (introduction of Section 3.4) was a transparent and stepwise development and decision-making process. An important aspect of such a process is that it allows the safety case to develop iteratively and to be reviewed and progressively refined as new information becomes available and system understanding improves. That is, as an organisation matures and conducts ongoing scientific and engineering work, its safety case likewise matures, expanding to provide (ideally) an ever more convincing basis for its safety evaluations. (A similar point has also been made regarding repository design; see Sections 3.3.2 and 3.3.3.) As discussed above, confidence can be further enhanced if it can be shown that updates of the safety case also incorporate the lessons and experience from the international arena.

Reassessing the safety case at given stages of repository development provides opportunities to:

- Re-confirm scenario selection and design optimisation decisions.
- Avoid a scenario in which an accumulation of apparently insignificant (or even potentially beneficial) decisions leads to safety being jeopardised.
- Ensure that the robustness of the system concept allows proposed adaptations to be carried out without unacceptable impacts upon safety.
- Check the adequacy of the safety strategy to deal with unresolved, safety-related issues.
- Incorporate progress in understanding the features and processes that affect repository safety performance.
- Guide the data collection in the next stage of development.
- Satisfy the demands for social review, which can potentially increase confidence.
- Take into account any significant change in system requirements, such as the introduction of new materials or waste types in the repository.

A critical aspect of safety case review is that the programme not only specifies new data to collect but also allows for hypothesis testing concerning repository performance. The comparison of observed results against predictions may yield useful information on modelling repository behaviour. Over time, as stages are completed, the ability of the programme to predict performance should improve. This improvement, in turn, increases confidence in the robustness of the safety case. Reviews, hypothesis testing, and updates also demonstrate a commitment to continued learning and improvement, which is another important contributor to safety (Section 3.4.9).

Re-evaluation of the safety case does not necessarily imply that earlier decisions must be revisited or that there must be a pause in programme activities, and in no case should this re-evaluation be used to unnecessarily delay decisions. The purpose of the re-evaluation is to examine the current situation and to ensure that any significant changes from the original programme goals, concept, or design are justified and take into account new knowledge and understanding of the system – and to check that cumulative incremental changes to the programme, when examined comprehensively, do not inadvertently degrade safety. How such re-evaluations and updates are addressed after a construction license has been approved is an issue that bears further discussion (Section 3.3.3).

3.4.8 Flexibility, reversibility and retrievability

Flexibility, reversibility of actions in general, and retrievability of wastes in particular, are considered confidence builders among members of the public because society at large is sceptical of technology and has a stronger desire to keep options open (U.S. National Research Council, 2001). Public acceptance of repository projects depends in part upon both the actual and the perceived degree of retrievability (Chapman and McCombie, 2003).

Flexibility is the capability and the willingness to re-evaluate earlier decisions and to redesign or change course if warranted. Reversibility is the ability to reverse the course of action or decision to a previous stage. Both flexibility and reversibility are supported by pursuing a stepwise and iterative process for all aspects of repository development (see Sections 3.3.2, 3.3.3, and 3.4.6). Because decisions are made with progressively more information as the programme develops, the likelihood of reversal is expected to decrease as the project develops. Nevertheless, reversal must remain an option for a period of time to be defined/discussed between the implementers, regulators and other potentially affected parties. A decision to reverse is evaluated with the same rigor as a decision to advance in light of current knowledge. Reversibility requires that fallback positions be incorporated into disposal policies and technical programmes.

Retrievability is the ability to remove waste containers after emplacement – although disposal means that there is no intention to retrieve the waste. There is no consensus on how long after emplacement it is reasonable or feasible to require retrievability. In some cases, retrievability is viewed solely as part of the operational safety procedures (e.g. to be undertaken if a waste package is not emplaced according to the design), whereas in other programmes retrieval is envisioned to include some time after emplacement, when interactions may have occurred with other parts of the engineered barrier system (e.g. with the clay buffer surrounding the canisters).

In most repository programmes, the retrievability option is acknowledged and in some cases, it is even mandatory. However, there can be some conflicts between the requirements of long-term isolation and retrievability. A geological repository is designed, in principle, to avoid any contact of the waste packages with the surface and to avoid human intrusion: yet retrievability implies the introduction of potentially intrusive, post-closure monitoring (see Section 3.4.11 for further discussion) or of engineering measures to facilitate retrieval. A few programmes (e.g. Andra) are now developing more detailed retrievability plans and concepts to demonstrate the feasibility of reconciling these requirements, but work in many nations is still in early stages and may benefit from further regulatory guidance and international discussions. Several regulatory organisations have declared that although there must be a possibility for retrieval, it need not be either easy or low-cost, and in any event any design changes made to facilitate longer-term retrieval may in no way compromise long-term safety. Every programme acknowledges that a retrievability option must not have an unacceptable adverse effect on safety or performance of the disposal system nor on the ability of the repository to provide safeguards against non-proliferation.

3.4.9 Institutional measures that contribute to building confidence

There are also a number of institutional measures that contribute to building confidence in the soundness of a safety case and in the safety of the associated repository. These measures may contribute quite directly to the quality of the safety assessment and its basis. Importantly they also enhance trust in the implementer or regulator and demonstrate more generally a commitment to impartial and scientifically valid methods and an openness to assess and to adjust, as needed, the disposal strategy and repository design in light of new information and technological advances that occur through its development.

3.4.9.1 Understanding the uncertainties

It is necessary to have a good understanding of the uncertainties in a safety case, and to explain how they are being managed (or why they are unimportant) in order to build and communicate confidence in the safety case. Techniques for handling uncertainties, as discussed in Section 3.2.3, are thus important. Confidence and uncertainty need not be in conflict; there will always be uncertainties (even at the final stages), but a robust safety case can still be made if uncertainties are understood and managed appropriately. In fact, if accomplished in a transparent manner, the handling of uncertainties can actually increase confidence in the implementer’s understanding of the disposal system.

3.4.9.2 Reaching internal confidence before communicating it

In a stepwise process for repository development, the safety case serves as a central basis for decision making at each phase of a disposal programme. At each such point, the implementer must be confident that the safety case being put forward will serve to support the decision-making process. This means being confident not only that regulatory criteria are shown to be met, but more generally that the safety case is scientifically and technically robust: that its structure is sound, that the relevant expertise has been brought to bear, that complex issues have been well-vetted, that the various lines of evidence are consistent, that there are strategies for addressing open questions and uncertainties, and that the conclusions are clear. In short, the internal confidence of the implementer in the safety case is a necessary prerequisite to building the confidence of regulators and other stakeholders. This includes acknowledging and accounting for the uncertainties existing at a given stage of the programme and substantiating confidence that the decision can be taken in the presence of these uncertainties.

It would be useful to identify the elements that provide the confidence – in spite of the uncertainties – to take a decision on moving to the next phase of a project: to understand, for example, on what basis an implementer decides that enough information exists to move to a formal assessment or when a safety case is deemed adequate to provide the basis for a siting decision; to gain insights into the criteria used when programmes decide "How much is enough?"; to better under the factors that allow programmes to close issues and move to a decision; etc.

Some contributions to achieving confidence are well-recognised (e.g. peer review) and have been discussed throughout this report. However, the INTESC discussions make clear that confidence and uncertainty are complementary factors and the confidence factors need to be examined in more depth.

3.4.9.3 Commitment to integrity

Integrity within the implementer organisation builds confidence in safety and is related to trust. Much has been written about trust among the implementing organisation, regulator and interested and affected parties and the differences in participating countries (e.g. FSC reports; U.S. National Research Council, 2003). Trust is one of the pillars of safety discussed earlier (Section 3.4). In short, trust is generated when the implementer is believed to have integrity and the necessary competence to carry out such a complex programme. Integrity means that the implementer says what it does and does what it says.

Technical results must be accurately and objectively reported and placed in context at each stage. Data applicability and limitations must be openly acknowledged. All relevant results, including those offered by external parties, should be incorporated in the decision making process. As discussed in Section 3.4.4, a professional relationship and dialogue between the implementer and the regulator is also perceived as a sign of integrity and is conducive to confidence building.

The implementer must also be trusted not to act capriciously or to change plans on a whim. New information or technological advances must be carefully considered and any proposed changes to designs or operational approaches should be informed by the full knowledge basis comprising existing as well as new information and understanding. Any changes in design or programme concepts should involve internal discussions and external consultations before being announced. The public also needs to know that regulatory authorities have evaluated the proposed changes and find them acceptable on safety grounds. Demonstrably following international guidelines (such as those by the IAEA and NEA) can provide some assurance that any changes in operations and plans will not be radical and that the overall concepts and goals remain reasonably consistent.

3.4.9.4 Commitment to continuous improvement and learning

An organisation that strives continually to improve and optimise systems and performance, both during operations and after permanent closure, demonstrates that it is committed to a culture that puts worker and public safety first. A phased and iterative approach to major design and operating decisions facilitates such optimisation although any changes need to be balanced against the need for stable conditions at licensing (see Sections 3.3.2, 3.3.3, 3.4.6).

During the decades of repository operation, it is prudent – and it is expected by the regulator and the public – that the implementer continues to analyse whether initial safety assumptions remain valid and also continues to improve the system. To support this learning, repository programmes usually have a performance confirmation programme that may include monitoring and a long-term science and technology development programme, as discussed in Section 3.4.11, to refine understanding and fill knowledge gaps.

3.4.10 Pilot, test and demonstration facilities

It has been suggested by the U.S. National Research Council (2003) that there is a confidence-building role that can be played by the use of pilot, test and demonstration facilities.

Test facilities provide the setting for short- and long-term experimentation aimed at improving scientific understanding. Tests may support optimisation of the repository in terms of operational processes, changes in waste types and barrier materials and designs, and changes in layout to manage thermal output. Experimentation can also be pursued during construction, operation, and closure to gain further support or evidence for the long-term safety of the repository.

It is suggested that continued testing during operations, in dedicated facilities, can help improve understanding of repository behaviour as well as allow the evaluation of design revisions needed to cope with change, for example, in the characteristics of waste due to the introduction of a new fuel cycle. Continuing test activities may provide greater confidence to both the implementer and the regulator.

Some countries, such as Switzerland, propose the implementation of a test facility that would operate in parallel with the repository, where important aspects of repository processes could continue to be investigated with extended experiments, unconstrained by the demands of waste disposal operations (EKRA, 2000). Test activities can last for many years or even decades as operations continue. Results from the test facility may lead to adjustments in the repository design or operational strategy if test results reveal issues significant for long-term repository safety.

Demonstration facilities aim at increasing technical and, especially, public understanding and confidence. They can be used to illustrate internally and also to external stakeholders what the design is, how it works, and how final closure can be achieved. They may be separate facilities (e.g. in the Bure visitors centre, the experiments performed underground are recreated in a demonstration gallery; at the Äspö HRL, SKB shows a full-scale disposal tunnel with its emplacement equipment); alternatively, they may be located in a designated part of the operational repository, but would be separated from the operational areas to allow public access without having to invoke safety measures such as special clothing and general radiological safety training.

Pilot facilities may serve similar functions as test facilities but, in addition, can allow testing of operational equipment and modes of operation by handling actual radioactive wastes. For example, in the Swiss Nuclear Legislation, the "pilot facility" is meant to provide a means to study the behaviour of wastes, the barriers and the host rock up to the end of the surveillance phase (Art. 66, Swiss Nuclear Energy Ordinance). This provides the opportunity to gain first-hand experience with operational approaches and equipment – experience that contributes to safety, in addition to allowing optimisation of the construction and operation of the full-scale facility. Pilot facilities can build confidence for both the implementing organisation and regulatory authority and can also be an educational tool for other stakeholders who are able to observe such a facility in action and thereby gain confidence in the likely operational safety of the repository. Since radioactive materials will be handled, there are special licensing challenges with using pilot facilities, and this may largely explain why no programmes are currently using this approach.

The introduction of a pilot stage in repository development is a relatively new idea for national programmes. It was proposed by SKB in Sweden in 1992 (SKB, 1992), but the original idea of a "demonstration phase", as SKB called the pilot stage – emplacing an amount of spent nuclear fuel much less than the full design capacity – has since been redefined in accordance with nuclear safety regulations; accordingly, the first active phase of repository operation is now seen as "trial operation" aiming for full operation after a safety evaluation. A pilot stage has been recommended in Switzerland (EKRA, 2000) and the United States (US National Research Council, 2003). A pilot stage may precede but then evolve quite rapidly (within a few years) to full-scale implementation, as is intended in the United States Pilot stages may also be envisioned even after full-scale operations begin, for example to test new emplacement technologies.

3.4.11 Monitoring, performance confirmation and long-term science and technology programmes

Monitoring during construction and operation of a disposal system can provide assurance that conditions assumed in safety assessment hold true. Monitoring can also be designed to include tests that purposefully challenge such assumptions. Ideally, both approaches would be designed into a monitoring system, so that the credibility of the effort is evident: that is, it is not simply an attempt to confirm what was previously assumed based on more limited data (in fact, there is awareness that the term "performance confirmation" may appear arrogant in this regard). Rather, it should represent a sincere effort to test assumptions and advance the understanding of the disposal system and the site.

A performance confirmation programme (and the parameters to be addressed) would be highly specific to the site, disposal concept, and safety case. Given the extended period for construction and operation, monitoring should not necessarily be confined to physical parameters, but should also include "monitoring" progress in science, technology, and system understanding to support continued learning (see Section 3.4.6) throughout construction and operation. Flexibility is required to be able to respond effectively by making improvements or, if necessary, taking remedial action in response to the results of performance confirmation programmes (see Section 3.4.8). A well-defined performance confirmation or monitoring programme may be helpful for taking decisions, e.g. to close a repository in programmes that foresee a prolonged "open" phase.

Performance confirmation and monitoring activities during repository operation are potentially important contributors to confidence in a safety case, but only if certain basic requirements are upheld:

- There is a need to demonstrate that any performance confirmation or monitoring activity will not degrade barrier performance. This may imply that measurements be allowed only in special galleries/demonstration premises, that measurements in the main repository continue for a limited time, or that non-intrusive monitoring technologies be developed and used.
- The parameters to be measured should be systematically identified and defined based on sound reasoning.
- A plan of action should be developed and agreed in advance to address any deviation from expected performance (including what "deviation" exactly means).

Monitoring during the post-closure period is not required in many programmes. An objective widely accepted in the international community is that long-term safety of the repository must not rely on institutional controls (such as e.g. monitoring of the repository) after it has been sealed and closed (IAEA, 2006). However, monitoring after closure can be continued to help maintain confidence in system performance. A degree of monitoring after closure may also support the continuation of non-proliferation safeguards. Such a decision could be made by the regulator at the time of the closure license application, for example, to satisfy community concerns.

The timeframes and goals for post-closure monitoring have not yet been clearly set in all programmes, and they vary across nations. The goals could include:

- Providing data for analysing actual system (and component) performance and comparing the data with assumptions or expectations, including model calculations (compliance).
- Detecting any system behaviour or failures harmful to the environment or human health (monitoring compliance).
- Safeguarding nuclear materials.
- Providing data to ensure responsibility and liability.
- Providing information for societal confidence in repository performance.

Another feature that can improve confidence in long-term safety is a science and technology research programme that continues throughout the lifetime of repository operations. The purpose of a such a programme would be to: reduce or better understand known uncertainties; provide additional evidence that the repository (and associated key processes) is behaving as predicted; test relevant new scientific discoveries made during the period of repository operations; and further develop, refine, or test aspects of the performance assessment methodology.

Like monitoring, a continued science and technology programme should represent a sincere effort to advance the understanding of the disposal system and should be aimed not only to confirm, but also to test, assumptions underlying safety. A continued science and technology programme can also foster institutional relations, and perhaps public confidence, by providing information important to stakeholders and the general public and by demonstrating a continuing investment and commitment to stewardship by the implementer.

A long-term science and technology programme can address more general issues than the repository-specific experimental work in a test facility, but its objective is not to perform open-ended science. The research programme should be focused on improving repository operation and performance and reducing the associated uncertainties. Accordingly, the studies should be evaluated based on their progress toward filling identified knowledge gaps. The monitoring, performance confirmation and continued science and technology programmes should be integrated and duplications should be avoided. The programmes should be credible, transparent, and auditable.

3.4.12 The handling of very long timescales

How to deal with generally increasing uncertainties in repository evolution and performance is a key problem to be addressed in developing a safety case. Where the consequences of calculated releases are expressed in terms of potential dose or risk, representations of the biosphere are based on assumptions that are usually simplified and not necessarily realistic (or at least, are unverifiable) hundreds or thousands of years into the future. Thus, potential doses and risks evaluated in safety assessments are not to be regarded as predictions but rather as indicators to test the capability of the system to provide waste isolation and containment, and as illustrations of potential impact to stylised, hypothetical individuals. While some hazard may remain for extremely long times, increasing uncertainties mean that there are practical limitations as to how long anything meaningful can be said about the protection provided by the system against the hazard – and these limitations need to be acknowledged in safety cases. That is, quantitative analyses for the very distant future cannot be validated in the sense of that term usually adopted in scientific arenas. This limitation is recognised in the IAEA Safety Requirements (IAEA, 2006), which state (in paragraph 2.12 of the requirements) that:

> It is recognised that radiation doses to individuals in the future can only be estimated and that the uncertainties associated with these estimates will increase for times farther into the future. Care

needs to be exercised in using the criteria beyond the time where the uncertainties become so large that the criteria may no longer serve as a reasonable basis for decision making.

These conclusions, documented in the NEA report on timescales (NEA, 2006), were reinforced by the INTESC questionnaire results and workshop. The NEA document concluded that a million years seems to be emerging as a commonly accepted time frame for recent safety assessments – although time frames covered by modelling range from 10 000 years to 100 million years. Where regulations do not explicitly specify the time frames over which protection needs to be considered, the implementer has the challenge of deciding on the level and style of assessment to be carried out over different time frames. Various factors may be considered when determining the time at which to terminate calculations of radionuclide releases, including the relevant processes, the time of peak dose, and the declining toxicity of the waste.

In considering safety (and the safety case) beyond the time frame covered by quantitative safety assessment, other qualitative arguments may be used. There can be powerful arguments – with a very credible basis – related, for example, to the expected stability of the selected geological setting. These types of arguments have been made in past safety cases, typically with good external reception. Several NEA initiatives are in fact addressing long-term stability arguments for different geological media in support of both the quantitative and qualitative statements on long-term safety (NEA, 2009).

4. CONCLUSIONS

This report documents the outcomes of the INTESC initiative, aimed at:

- Assessing the state of the art in developing safety cases (areas of agreement and disagreement).
- Identifying and understanding issues that may need further work by international expert working groups such as the RWMC and its IGSC, or perhaps other *fora* under the IAEA or the European Commission.

The report uses as a starting point the national responses to a detailed INTESC questionnaire, augmenting the responses with the outcomes of discussions at an INTESC Workshop to elaborate topics and issues that appear to be emerging and which could benefit from an international discussion.

4.1 State of the art in developing safety cases

All responding programmes are preparing safety cases (preliminary or extensive, more developed ones) in line with most of the elements of a safety case suggested by the NEA safety case brochure. Additionally, most regulations outline, at least broadly, safety case requirements that address these key elements. The need for a comprehensive and well supported safety case that provides more than simply the results of quantitative assessment is generally not new in a license application. While the name "safety case" has not always been applied consistently within the nuclear waste community, regulators have generally (and historically) required that implementers document and describe the basic evidence for the assumptions and claims made in assessment calculations, demonstrate quality assurance measures, etc.

Overall, there are similar approaches and attitudes in different programmes and similar priorities expressed from the participating regulators. Implementers appear to address issues raised by regulators. However, there are some important examples of differences in use or in interpretation and there are some developing elements of real-life safety cases that are not covered by the NEA brochure. These aspects indicate considerable progress in safety case development. This development can be divided into the following three themes:

- **Safety and assessment strategy**. There are several aspects of the safety strategy, i.e. the high-level approach for achieving safe disposal along with how the given system is analysed, that are currently evolving. There is considerable development regarding the use of safety functions, approaches to integration, the application of QA and quality control (including configuration management), and in the management and treatment of uncertainty in describing the geosphere by, for example, developing a geosynthesis and applying safety indicators other than dose or risk.
- **Relationship between long-term safety and the design, construction and operational periods.** Developing the design basis and evaluating the implications of the implementation of the design, construction work and operations are key components of the safety case. The safety case should play a central role in establishing and supporting the safety requirements on design and should demonstrate that the final design and actual construction can meet these requirements in practice. This issue is receiving increased attention since many programmes are now approaching implementation.

- **Other contributors to confidence in safety.** The INTESC questionnaire addresses many of the technical, scientific, and documentation requirements that are necessary to provide confidence in a safety case. There are several additional opportunities to enhance confidence, as discussed in Section 3.4. Most of these were not explicitly covered by the INTESC questionnaire as they are not yet routinely implemented in current safety cases, but they are being actively developed and were discussed at the INTESC workshop. Such additional contributors to confidence are judged to have the potential to play an important role in future safety cases.

4.2 Issues that merit further international attention

Most of the issues discussed in Chapter 3 are worth further consideration by international working parties such as the RWMC, and its technical working party, the IGSC. Some of these topics may also be fruitfully addressed through IAEA or EC actions. In short, these issues are:

- Development and use of safety functions (Section 3.2.1).
- Implementation of efficient QA and quality control measures (Section 3.2.2).
- Implications for the safety case from the developing trends on management and treatment of uncertainty (Section 3.2.3). (It should be noted that, on a more technical level, this issue has been and continues to be addressed by numerous projects such as the EC project PAMINA.).
- Role of geosynthesis in the safety case (Section 3.2.4).
- Implications and applicability of various design principles (Section 3.3.1).
- Approaches for using feedback from post-closure safety assessment to set design requirements (Section 3.3.2).
- Balance between flexibility and stable conditions for licensing (Section 3.3.3).
- The frequency and the extent of the safety case updates and how to incorporate new results, if any, after the construction license application (Section 3.4.7).
- Approaches to integration of information (Section 3.4.3).
- Implications and practical implementation of optimisation and BAT (Section 3.3.5).
- Reversibility and retrievability (Section 3.4.8).
- Institutional measures that contribute to confidence e.g. achieving internal confidence, integrity, commitment to continuous learning (Section 3.4.9).

Other issues discussed in Chapter 3, while of high interest, are already being addressed sufficiently through other fora and are, therefore, not a priority for additional attention by international technical working groups such as the RWMC and IGSC.

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Appendix B

INTernational Experiences in Safety Cases – INTESC

Questionnaire

TABLE OF CONTENTS

1. Introduction

The nature and purpose of the safety case has recently been described in a NEA publication (NEA, 2004). According to this publication, a safety case is "the synthesis of evidence, analyses and arguments that quantify and substantiate a claim that the repository will be safe after closure and beyond the time when active control of the facility can be relied on". The safety case becomes more comprehensive and sound as a programme progresses, and is a key input to decision-making at several steps in the repository planning and implementation process. A key function of the safety case is to provide a platform for informed discussion whereby interested parties can assess their own levels of confidence in a project, determine any reservations they may have about the project at a given planning and development stage, and identify the issues that may be a cause for concern or on which further work may be required.

2. Background to the questionnaire

Recently, there has been notable convergence in documents published by national and international in the understanding and development of long-term safety cases for geological disposal. The final draft of the IAEA safety requirements guide (DS-154), the NEA brochure on the safety case (NEA, 2004), the presentations at the Stockholm conference of 2003 (NEA, 2005), the recently released safety report on the Swiss Opalinus Clay Project in December 2002 (Nagra, 2002], and the safety cases presented at the November 2003 session of the IGSC [NEA/RWM/IGSC(2004)3] all show a significant assimilation of the principles by national organisations that were set forth in the NEA Confidence Report [NEA, 1999] and subsequent documents, such as IPAG-3 (NEA, 2002).

The Bureau of the RWMC observed at its September 2003 meeting that an important development since 1999 has been the implementation of safety cases for both the generic and the more specific phases of waste disposal, and indicated that it would be useful, both for the more- and for the less-advanced programmes, to document the progress in the field of the safety case. Desire to see an exercise in a similar style to IPAG was expressed several times and, in addition, a majority of IGSC members thought the IGSC self-evaluation raised the need to initiate an activity on "Where do we stand with respect to safety cases?" Accordingly, at the 6th IGSC meeting [NEA/RWM/IGSC(2004)19], and at the 38th RWMC meeting [NEA/RWM(2005)16], members approved in principle to set up an exercise on "INTernational Experiences in Safety Cases" – namely the INTESC [see mandate NEA/RWM(2005)7] based on the results of a questionnaire.

3. Aims of the exercise

The exercise aims:

- To analyse existing safety cases and elements, components of safety cases that are under development and to identify key concepts, including points of consensus and divergence.
- To provide a clear overview of the progress that has been made in the last decade.
- To provide a clear overview of regulatory expectations on the future safety cases.
- To improve awareness of strengths and weaknesses in present-day methodologies for developing and presenting safety cases.
- To report the state of the art to the IGSC and as an input to the forthcoming international symposium of January 2007.
- To provide a state-of-the-art report on practical experiences on safety cases for geological repositories and the lessons learnt from current practices, following the international symposium.

4. Guidance on providing responses

A number of questions and their rationale are presented hereafter. In responding to the questions, respondents should keep the following in mind:

- In order to provide sufficient detail and examples, and in order that the responses reflect the overall views and perspectives of your organisation in an integrated fashion, there is likely to be a need for consultation with persons within your organisation that are involved in other areas than your own, where these are relevant to the subject being addressed.
- Most questions are directed at both implementers and regulators, although a safety case is primarily provided by implementers. For regulators, it is asked to answer the questions in terms of what were expected in their review of the safety case in the past, and/or what will be expected in the on-going/future safety case. Responses from implementers should be based on a recently compiled safety case, and/or a safety case that is currently in an advanced stage of development. Please identify which safety case document or documents you are referring to.
- "Yes" and "no" answers are generally not sufficient. The appropriate length of the response to each question is left to the discretion of the participating organisations, but should not exceed one page. If, however, an organisation wishes to provide detailed information to support a response that runs to several pages, it may be appropriate to provide the information in appendices to the main questionnaire responses.
- Responses should as far as possible be self-contained, i.e. although references can be made to published documents, the responses should not require familiarity with these documents to be understandable.
- Some of the questions may overlap, i.e. portions of the responses could be applicable to more than one question. If this occurs, the information need only be presented once, and cross-references made between responses. Please note, however, that unique and specific information is being requested in each question. Thus, please read the questions and the corresponding notes at the end of this document carefully, and try to address the nuances in each question.

5. The questionnaire

The aim of this questionnaire is to elicit information from participating organisations on the degree to which the ideas presented in NEA (2004) are already widely implemented, or will be implemented in compiling future safety cases. Accordingly, the questionnaire is structured along similar lines to NEA (2004), and deals with:

The elements of a safety case

These comprise (1), the purpose and context, (2), the safety strategy, (3), the assessment basis, (4), the evidence, analyses and arguments that contribute to the safety case and (5), the synthesis of these evidence, analyses and arguments.

Presenting the safety case

Considerations that apply when presenting the safety case include (1), the concerns and requirements of the intended audience, (2), the explanation of the purpose and context of the safety case, and (3), other general considerations, including the need for transparency, traceability and openness.

A number of questions and their rationale are presented hereafter. Responses should be based on a recently compiled safety case, or a safety case that is currently in an advanced stage of development. Please identify which safety case document or documents you are referring to.

I. Purpose and context

The following questions are intended to place your responses in the context of the role of your organisation and stage reached in your national programme at the time if the safety case discussed in your responses.

I.1 Give the name and main role of the organisation which provided the responses.

I.2 Describe briefly the status of your national programme (the programme may, for example, be at the stage of generic feasibility studies, or be in the process of selecting a site or sites for characterisation from the surface or from underground), including your programme constraints (see Table A.3 for examples).

I.3 What decisions within your programme will be based on or affected by the conclusions of the current safety case?

I.4 Please provide a primary reference (e.g. a safety report, guidelines, regulations, standards…) and, if necessary, a small number of additional references that support your responses to this questionnaire.

II. The safety strategy

The safety strategy is considered as the high-level approach adopted for achieving safe disposal, and includes an overall management strategy, a siting and design strategy and an assessment strategy. All national programmes aim at management strategies that accord with good management and engineering principles and practice e.g. quality plan, how to adapt to stakeholders requirements-allocation of resources, co-ordination activities (see Annex 1). The siting and design strategies are generally based on principles that favour robustness and minimise uncertainty including the use of the multi-barrier concept, e.g. precautionary principle, reversibility, flexibility principles. The assessment strategy must ensure that safety assessments capture, describe and analyse uncertainties that are relevant to safety, and investigate their effects.

Management strategy

II.1 What measures have been enacted within your organisation to develop a safety culture (i.e. a "consistent and pervading approach to safety") among those engaged in all aspects of repository planning and implementation, including the development of the safety case? Give an example.

II.2 How do you ensure effective integration of information and knowledge coming from the different fields of the programme (site characterisation, design, assessments, R&D, waste characterisation…)? How do you decide on programme priorities?

II.3 Do you regard information preservation to be an important issue that is relevant to the safety case and, if so, how has this been considered in your programme? To what extent has your organisation developed an effective system of long-term record keeping that allows project decisions to be placed in a broad, historical context? Give references and an example.

II.4 If a step-wise approach to planning and development has been adopted, what is the rationale behind this approach (e.g. to allow for the involvement of stakeholders, formal referendum by Parliament or local populations on decisions, further technological developments)?

II.5 To what extent is flexibility built into the overall project plan (e.g. to allow for uncertainties in the types and amounts of waste that will eventually be emplaced, to cope with unexpected site features or technical difficulties and uncertainties that may be encountered, and to take advantage of advances in scientific understanding and engineering techniques)? What are the main challenges? What rationale for maintaining flexibility is given in the documentation of the safety case?

II.6 How does the quality assurance (QA) plan cover the different elements of the safety case? Which components of a safety case are covered by a QA?

II.7 For decisions involving expert judgement, what measures are enacted to ensure that the experts used are suitably qualified, adequately informed and take responsibility for the judgements that they make? What measures are taken to ensure that the process of their decisions is transparent and traceable?

II.8 How, if at all, does your programme apply the concept of "best available techniques" to the design of the disposal system and the construction and presentation of the safety case? What definitions and criteria are used to determine whether the "best" techniques have been used? In particular, what relation is seen by your organisation between BAT and optimisation?

Siting and design strategy

II.9 Which siting and design principles, guidelines and procedures have you developed and applied to ensure that the system is robust in terms of long-term safety (see Appendix 1, Section A1.1 for examples)?

II.10 What other siting and design principles are developed and applied that are relevant to the safety case, including e.g. the need to facilitate monitoring and possible waste retrieval?

II.11 Which guidelines or criteria for waste conditioning and waste acceptance have you developed that are relevant to the safety case, e.g. prohibition of liquid waste forms, use of stable waste matrices use of a long-lived waste, maximum heat output from waste packages?

Assessment strategy

II.12 Give a brief description of your strategy for the management and treatment of uncertainty in your assessments, including any scheme that is adopted for different timescales or for the categorisation of uncertainties (e.g. as scenario, model and data uncertainties). (Note: your response may overlap with that for the following questions; please use forward and backward referencing where appropriate)

II.13 Do you adopt a probabilistic and/or deterministic approach for the analysis of scenarios or assessment cases and what is the rationale behind your choice?

II.14 What are the criteria or procedures whereby some FEPs or parameter combinations are excluded from detailed consideration and others are included (including e.g. the use of expert elicitation and peer review)?

II.15 How are the particular scenarios for human intrusion selected and analysed? As a specific question in this regard, how are risks to the intruder considered in your safety case? How is the approach for human intrusion the same or different from that used for other types of FEPs?

II.16 If conservative model assumptions and pessimistic parameter values are used for the treatment of some uncertainties, what rationale is used for the selection of uncertainties to be treated in this manner?

II.17 What kinds of analyses are carried out to explore parameter sensitivity and the impact of uncertainties in parameter values?

II.18 Which alternative conceptual models are developed and applied where uncertainties exist at a conceptual level?

II.19 If a stylised approach is used for the treatment of some uncertainties, what rationale is used to justify this approach and for the selection of uncertainties to be treated in this manner?

II.20 Do you analyse any "what if?" scenarios or cases (i.e., scenarios that are not physically impossible for the site yet lie outside the range of possibilities supported by scientific evidence) and what is the rationale for their analysis?

II.21 What is the rationale behind any "cut-off" times for calculations of dose and/or risk and what is the overall timescale of concern in developing the safety case (this may extend beyond the "cut-off" times for calculations of dose and/or risk, with safety discussed in terms of alternative safety indicators or more qualitative arguments)? Please refer to your Timescales answers if appropriate.

II.22 What strategy has been developed to account for diverse sources of information and opinion in safety assessment analyses and in the safety case, including possibly contradictory opinions of technical experts?

III. The assessment basis

The assessment basis is the collection of information, and analysis tools supporting the safety assessment. This includes an overall description of the disposal system (that consists of the chosen repository, components and its geological setting with associated safety functions), the scientific and technical data and understanding relevant to the assessment of system safety, and the assessment methods, models, computer codes and databases for analysing system performance. The quality and reliability of a safety assessment depends on the quality and reliability of this assessment basis. According to NEA (2004), a discussion of the assessment basis in any detailed presentation of the safety case should include evidence and arguments to support the quality and reliability of its components.

The system concept

With each answer, please give references and an illustration.

III.1 How is the role and relevance to safety (i.e. the safety function) of each component of the disposal system described in the documentation of the safety case? What principles and requirements guide the approach to selecting barriers (e.g. multi-barrier principle, analysis of safety functions)? How are the barriers or functions identified and prioritised?

III.2 How is the biosphere defined in the safety case? Does the treatment of the biosphere consider its possible safety functions as well as being a source of potential disruptions?

Scientific and technical information and understanding

III.3 Which arguments are given for the adequacy of scientific understanding of key features of the disposal system (including multiple lines of arguments, where available)?

III.4 What measures (approaches and practical example) have been enacted to ensure that all relevant scientific information is taken into account in describing the system; its evolution and its performance; and that no significant features, events and processes (FEPs), interactions and associated uncertainties have been overlooked?

Methods, models, computer codes and databases

III.5 What is the process by which scientific understanding of the system is handled in order to obtain the accurate models and databases that will support the safety case?

III.6 What is the source of the waste/radionuclide inventory considered in developing the safety case, what assumption underlie this information and to what extent is the information subject to uncertainty?

III.7 What types of evidence support the applicability of models and associated databases within your safety case (including, e.g. laboratory and field measurements and observations at various scales, natural analogues and expert elicitation)?

III.8 How, if at all, do your assessment basis and safety case utilise data, results, and technical guidance from international sources such as, for example, the NEA's FEPs and thermodynamic databases, IAEA's biomass project, assessment methodologies published by other national programs, or other technical guidance on specific aspects of safety assessments?

III.9 How, and to what extent, does the safety case take account of the duration and nature of the construction and operational period and any pre-closure open period in analysing post-closure safety? (Refer to your responses to the timescales questionnaire if appropriate.)

III.10 What roles do detailed mechanistic models of specific processes or combinations of processes play in the safety case (e.g. direct use in radiological consequence analysis, justification of simplifying assumptions, and derivation of parameter values)?

IV. Evidence, analyses and arguments

Most national regulations give safety criteria in terms of dose and/or risk, and the evaluation of these indicators, using either mathematical analyses or more qualitative arguments, for a range of evolution scenarios for the disposal system, appears prominently in all safety cases that are intended for regulatory review. Robustness of the safety case is, however, strengthened by the use of multiple lines of evidence leading to complementary safety arguments that can compensate for shortcomings in any single argument. Complementary types of evidence and arguments in support of a case for safety include general evidence for the strength of geological disposal as a waste management option, evidence for the intrinsic quality of the site and design, safety indicators complementary to dose and risk, and arguments for the adequacy of the strategy to address and manage uncertainties and open questions.

Evaluation of performance/ safety indicators

IV.1 What methodologies have been developed for checking the reliability or plausibility of the results of key assessment calculations?

IV.2 Do any scenarios, probabilistic realisations or assessment cases give rise to doses and/or risks at or above acceptance limits and, if so, what if any arguments are made to counter these unfavourable findings?

IV.3 Does the safety case make use of safety and performance indicators in addition to dose and risk and how are the measures or "yardsticks" with which they can be compared in order to judge safety derived?

Strength of geological disposal as a waste management option

IV.4 Which arguments does your safety case present for building confidence in the strength of geological disposal in general as a waste management option?

Feasibility of implementation as planned

IV.5 Has it been demonstrated that the system can be implemented with existing technology or are new technological development required?

IV.6 How do you assess the possibility of defects in waste and container fabrication, repository construction, operation and closure and other aspects of implementation, and how is the possibility of defects treated in safety assessment? Please give an example.

The management of uncertainties and open issues in future project stages

IV.7 Have uncertainties, and assessment methodology, open siting and design issues been identified that must be addressed in future project stages? If yes, which ones? How are they identified and prioritised?

IV.9 What strategy has been developed to deal with remaining uncertainties and open issues in the course of future project stages (including, e.g. RD&D and site characterisation to better characterise or reduce uncertainties and design optimisation to avoid uncertainties or mitigate their effects)?

Complementary evidence and lines of argument

IV.10 What additional complementary evidence and lines of argument are cited to support the final conclusions or recommendations of the safety case (Annex 1, Section A1.2 for examples)?

IV.11 What roles do natural analogues and other observations from natural systems (e.g. isotope diffusion profiles within the host rock) play within the safety case?

V. Synthesis

In general, a safety case will conclude that there is adequate confidence in the possibility of achieving a safe repository to justify a positive decision to proceed to the next stage of planning or implementation. This is a *statement of confidence* on the part of the author of the safety case – typically the developer – based on the analyses and arguments developed and the evidence gathered. The audience of the safety case must decide whether it believes the reasoning that is presented is adequate, and whether it shares the confidence of the safety case author. To this end, a synthesis of the available evidence, arguments and analyses is made. According to NEA (2004), this should highlight the grounds on which the author of the safety case has come to a judgement that the planning and development of the disposal system should continue.

V.1 In the documentation of the safety case, please give a reference, if available, to a clear statement made of why the authors of the safety case have sufficient confidence that the proposed system is safe (or that a safe system is ultimately achievable) to recommend proceeding to the next project stage?

VI. Presenting the safety case

The emphasis placed on particular lines of argument and analyses and other aspects of the style of presentation must take account of the interests, concerns and level of technical knowledge of the intended audience and the stage where the safety case is according to the step by step decision making process. The audience may include the regulator, political decision-makers or the public, as well as technical specialists within the implementing organisation itself. Multiple levels of documentation may thus be required, but these products must remain consistent amongst one another. According to NEA (2004), there is only one safety case, but it may be cast in different "language" at different levels of detail for various audiences.

In any description of the safety case, a clear statement of purpose and context is required, and consideration must be given to factors including transparency,[1] traceability[2] and openness.

Concerns and requirements of the intended audience

VI.1 What different levels of documentation and/or argumentation are available to address the concerns and requirements of different audiences? How is the documentation of the safety case organised to provide transparency and traceability?

VI.2 What, if any, is the role of other types of media in addition to printed documents in presenting the safety case to different audiences (e.g. computer graphics, videos)?

VI.3 What documentation has the relevant regulator developed (or does it plan to develop) on how it will review a safety case? Which technical aspects of the safety case are addressed? Are there particular requirements also on the format and presentation of the safety case?

Purpose and context

VI.3 How are the context and purpose of the safety case described in the safety reports, including any programmatic and practical constraints that have affected the development of the safety case (Appendix 1, Section A1.3 for examples)?

VI.4 If previous safety assessments have been completed in the waste management programme, how are they described in the safety report to provide context? In particular, how are the lessons learnt from earlier safety assessments (and from their review by safety authorities and others) described and used?

VI.5 Does the documentation of the safety case make reference to the contents of other national or international safety cases or peer reviews (e.g. in order to place results in perspective)?

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1. ***Traceability*** in PA refers to an unambiguous and complete record of the decisions and assumptions made, and of the models and data used in arriving at a given set of results. This is an important element of quality assurance and, in principle; complete traceability can be achieved, even though at high cost in terms of time and resources.
2. ***Transparency*** refers to the PA being clearly reported, so that the audience can gain a good understanding of what has been done, what the results are, and why the results are as they are. This is a more subtle, and audience-dependent, requirement. The IPAG has set out nine points of guidance on promoting transparency to technical audiences and reviewers.

REFERENCES APPENDIX B

Nuclear Energy Agency (1999), *Confidence in the Long-term Safety of Deep Geological Repositories: its Communication and Development*, OECD, Paris, France.

Nuclear Energy Agency (2002), *Establishing and Communicating Confidence in the Safety of Deep Geologic Disposal – Approaches and Arguments*, OECD, Paris, France.

Nuclear Energy Agency (2004), *Post-closure Safety Case for Geological Repositories: Nature and Purpose*, OECD, Paris, France.

Nuclear Energy Agency (2005), *Geological Repositories: Political and Technical Progress, Workshop Proceedings, Stockholm, Sweden, 7 10 December 2003*, OECD, Paris, France.

IGSC (2004), Summary Records of the 6^{th} Plenary Meeting of the IGSC, OECD/NEA Integration Group for the Safety Case (IGSC), NEA/RWM/IGSC(2004)19, Paris, France.

IGSC (2004), Observations regarding the Safety Case in Recent Safety Assessment Studies, Proceedings of the Topical Session at 5^{th} IGSC Plenary Meeting, OECD/NEA Integration Group for the Safety Case (IGSC), NEA/RWM/IGSC(2004)3, Paris, France.

International Atomic Energy Agency (2005), Geological Disposal of Radioactive Waste, IAEA Safety Standards Series, Draft safety Requirements DS154, IAEA, Vienna, Austria (to be published).

Annex 1

EXPLANATORY NOTES AND EXAMPLES

A1.1 Examples of principles, guidelines and criteria to ensure robustness

Robust systems are, according to NEA (2004), characterised by a lack of complex, poorly understood or difficult to characterise features and phenomena, ease of quality control and an absence of, or relative insensitivity to, detrimental phenomena arising either internally within the repository and host rock, or externally in the form of geological and climatic phenomena. They are also characterised by a lack of uncertainties with the potential to compromise safety. Examples of the various principles, guidelines and criteria can be identified that aim to ensure robustness by minimising unfavourable phenomena and uncertainties and/or the effects of uncertainty on the evaluation of safety are given in Table A1.1.

Table A1.1 **Examples of the various principles, guidelines and criteria that can be identified and aim to ensure robustness by minimising unfavourable phenomena and uncertainties and/or the effects of uncertainty on the evaluation of safety**

Principles
Inclusion of ample reserves of safety in the system concept (particularly during the early stages of development).
Adoption of multiple safety provisions, in which either uncertainties are avoided or safety can be demonstrated in the presence of remaining uncertainties (this includes the multi-barrier concept, and the concept of multiple safety functions, in which over-dependence on any single safety provision is avoided).
Adoption of a flexible strategy for design development and improvement in order to ensure efficient use of the safety potential of the host rock (e.g. “design-as-you-go”).
Other engineering principles and practice to promote robustness, such as the backfilling of access routes and the use of markers as a measure to guard against future inadvertent human intrusion, the physical separation of waste into sets of packages of limited size to limit the effects of a single package performing poorly, and the use of institutional surveillance (for a limited time).
Other sound engineering principles and practices for the design, construction and operation of the repository.
Guidelines
Guidelines related to the characteristics of a site (e.g. a site that is structurally simple and/or simple with respect to processes and events – including geological events and possible inadvertent human intrusion).
Exclusion guidelines/criteria for a site and for zones within a site (e.g. recent volcanism, exclusion zones around geological features with unfavourable properties, regional zones of weakness).
Guidelines/criteria related to waste conditioning (e.g. prohibition of liquid waste forms, use of a stable waste matrix, and use of a long-lived container).
Guidelines related to tunnel excavation (e.g. drilling methods to minimise damage).
Guidelines related to the design basis (e.g. a minimum depth for the repository may be specified; a site may be sought that is larger than the minimum necessary; the possibility for retrievability and monitoring may be incorporated in the design.
Procedures
Peer-review procedures for decisions regarding siting and design.
Quality-assurance procedures for site characterisation, waste and container fabrication, repository construction and operation.

A1.2 Examples of complementary evidence or lines of argument

Examples of complementary evidence or lines of argument to support a safety case are:

a) The principles, guidelines and procedures that have been adhered to in order to in order to achieve a robust system (see Table A1.1 for examples).

b) Specific connections that are identified between safety and the roles of the various barriers within the multi-barrier concept.

c) The fact that all *identified* safety-related issues which are important for the decision under consideration at the current development stage have been addressed.

d) The consideration that has been given to all relevant data and information, together with their associated uncertainties.

e) The fact that all models and databases that were utilised have been adequately tested.

f) The use of a well-defined and rational assessment procedure, such that the effects of uncertainties on the conclusions of the assessment, in terms of safety, are minimised.

g) The fact that results have been fully disclosed and subjected to quality-assurance and review procedures.

h) The existence of independent evidence, obtained, for example, by comparing assessment results with independent studies performed for similar disposal concepts (in particular, the results of sensitivity analyses within these studies).

A1.3 Examples of programmatic and practical constraints

A number of factors constrain the way in which development proceeds. These may be divided broadly into:

- Programme constraints that apply to a waste-management programme as a whole.
- Practical constraints that apply at a particular stage in repository development.

Some examples of these two classes of constraints are presented in Table A1.3, taken from NEA (1999).

Table A1.3 **Examples of programme and practical constraints affecting the development of the safety case for a deep geological repository** (from NEA, 1999)

Programme constraints
• The legal requirement that any repository for domestically produced radioactive waste should be located in that country. • The licensing framework requiring a safety case to be made at defined points within a repository-development programme. • The strategy to pursue, in addition to the domestic option, the possibility of international disposal options. • The strategy either to reprocess spent nuclear fuel or to pursue direct disposal. • The strategy to investigate one or more host-rock options. • The strategy to examine more than one design option (e.g. alternative canister materials). • The time constraints on repository implementation, which may be affected, for example, by the capacity available for interim storage. • The strategy to implement a repository in stages, beginning with an initial “demonstration repository” for a portion of the waste to be disposed. • The legal requirement to provide for some degree of retrievability in the repository design.

Table A1.3 **Examples of programme and practical constraints affecting the development of the safety case for a deep geological repository** (from NEA, 1999) (Cont'd)

Practical constraints
• The development status of waste-management technology (e.g. canister-fabrication technology). • The means for acquisition of both general understanding and specific data, including laboratory facilities (e.g. underground laboratories in generic and site-specific geological settings), experimental methods and research models for the interpretation of data. • The availability of data (e.g. from site characterisation) and performance-assessment tools at each particular development stage. • The externally controlled programme funding. • The manpower available to the organisation, including the availability of experienced project staff. • Schedule issues, including externally-set deadlines. • The manner in which acceptance requirements are formulated.

Appendix C

COMPILATION OF ANSWERS TO THE INTESC QUESTIONNAIRE

Johan Andersson, JA Streamflow AB

TABLE OF CONTENTS

1. INTRODUCTION

The INTESC project aimed to gather and analyse international experience in safety cases [see NEA/RWM(2005)7].

A questionnaire addressing these objectives was distributed and refered to Appendix B. Answers were received from 17 organisations (see Table 2.1) representing both implementing organisations and regulatory authorities in 10 countries. Some organisations cooperated and provided joint answers.

This appendix compiles the answers to this questionnaire. The compilation is structured in the same way as the questionnaire, with five sets of questions under the themes:

- I: Purpose and context.
- II: The safety strategy.
- III: The assessment basis.
- IV: Evidence, analyses and arguments.
- V: Synthesis.
- VI: Presenting the safety case.

Some detailed questions in the questionnaire may, however, be combined under a single heading.

The compilation is generally divided into a short introductory observation section followed by a compilation of answers given. For simplicity, in the latter the different respondents are identified by their organisation acronyms even if it is understood that answers are given by staff and may not necessarily represent the full official standpoints of the organisations. It needs to be understood that the level of complexity in answers varies between respondents. It could well be that confidence arguments are made, which have not been listed by the questionnaire respondents, as they are more or less taken for granted. If an organisation is not mentioned in connection to a specific procedure, this does not necessarily mean that this procedure is not favoured by this organisation. It just reflects that the point was not made on the questionnaire answer.

2. PURPOSE AND CONTEXT

Answers have been received from 19 organisations in 11 different countries. Most of the respondents are implementing organisation, but regulators or organisations working on behalf of regulators from four countries also provide answers. Table 2.1 provides an overview of the purpose and context of the Safety Cases and their related reviews, as well as references to the main documents.

There is a wide range of programme development represented in the answers. Most of the reported Safety Cases have been prepared of an actual license application or are being prepared for a coming license application. However, many concern earlier stages of development and concern more generic feasibility or are prepared to guide further R&D. Furthermore, several respondents refer to uncompleted – or even planned – Safety Cases. Generally, the progress of the cited Safety Case reflects the status of the national programme, with more generic examples from programmes at the stage of generic feasibility studies, and more specific ones for programmes in the process of selecting a site or sites for characterisation from the surface or to license an underground repository.

The responses mainly concern HLW and spent nuclear fuel projects. However, there are also answers from ILW repository projects.

Most regulatory answers concern existing regulations on the Safety Case or regulations under development, but experiences from previous reviews are also addressed. With few exceptions, the regulatory answers do not address whether the existing safety cases presented by the related implementing bodies fulfils the regulatory requirements.

Compilation of answers

Tables 2.1 and 2.2 summarise the responses to questions I.1 to I.4 in the questionnaire.

Table 2.1 **Participating organisations, main role and decisions related to the safety case**

Country and organisation	Main role
Belgium Ondraf/Niras	Implementing organisation
Canada CNSC	Regulatory authority
Canada OPG	Implementing organisation
Finland Posiva Oy	Implementing organisation
France Andra	Implementing body The French National Agency for Radioactive Waste Management
Germany BfS Colenco GRS – Braunschweig (GRS-Bs)	Implementing body (BfS). Colenco and GRS contributed mainly to the questions dealing with the more specific aspects of the safety case as indicated in the text.

Table 2.1 **Participating organisations, main role and decisions related to the safety case**

What decisions within your programme will be based on or affected by the conclusions of the current safety case?	**Country and organisation**
Confirm deep disposal option – decision to go for siting will be asked.	Belgium
N/A	Canada CNSC
Required for EA approval as a necessary step towards Construction Licence for the Deep Geological Repository of (DGR) for LILW at the Bruce site. Further site characterisation and safety case development will take place before the application for a construction license.	Canada OPG
The answer is mainly based on the Safety Case to be prepared for the construction license application for the final disposal facility to be submitted in 2012. The operation license application in order to take the final disposal facility into operation in 2020 will be submitted in 2018. Answers also relate to previous steps in the Finnish programme, including site identification surveys to select sites for preliminary investigations and safety assessment(1986-1992), detailed site investigations and safety assessment (1992-1999), selection of Olkiluoto in the municipality of Eurajoki as the site for the final disposal facility (1999) followed by Government decision in favour of the project in December 2000 and Parliament ratification in May 2001 as well as planning and initiating the construction of an underground characterisation facility, ONKALO, which will form part of the final disposal facility. The construction of and installations in the ONKALO are to be carried out between 2004 and 2011 together with characterisation and investigations to support the application of construction licence.	Finland Posiva Oy
After publication, Dossier 2005 Argile, was first reviewed by the regulatory authority, by the National evaluation council and by an international review team, followed by a national public debate. Based on this, on 28 June 2006, the new 2006 French Programme Act was first adopted by the National Assembly on 12 April, and adopted by the Senate on 31 May, then second and final reading and adoption by the National Assembly on 15 June 2006. According to the new French Act, reversible waste disposal in a deep geological formation and corresponding studies and investigations shall be conducted with a view to selecting a suitable site and to designing a repository in such a way that, on the basis of the conclusions of those studies, the application for the authorisation of such repository be reviewed in 2015 and, subject to that authorisation, that the repository be commissioned in 2025.	France Andra
In the former German Democratic Republic short-lived low- and intermediate-level radioactive waste was disposed of in the Morsleben Repository for Radioactive Waste (Endlager für radioaktive Abfälle Morsleben – ERAM), a former rock salt and potash mine. Since German unity the Morsleben facility has the status of a federal repository and BfS became the responsible operator of the repository. The license for operating the ERAM does not include decommissioning of the repository. Therefore a license application for the decommissioning of the repository according to the Atomic Energy Act is prepared by BfS. The safety case supports this license application.	Germany BfS Colenco GRS – Braunschweig (GRS-Bs)

Table 2.1 **Participating organisations, main role and decisions related to the safety case** (Cont'd)

Country and organisation	Main role
Germany GRS- Cologne	GRS-Cologne supports the work of the German regulatory authorities in all fields concerning safety aspects of final disposal of radioactive wastes.
Japan NUMO JAEA	Implementing organisation (NUMO) JAEA, Japan Atomic Energy Agency, is legally in charge of research and development of geological disposal of vitrified high-level radioactive waste to provide scientific and technical basis to support both the implementing organisation, i.e. NUMO, and the regulatory bodies, i.e. Nuclear Safety Commission (NSC) and the Nuclear and Industrial Safety Agency (NISA).
Sweden SKB	Implementing organisation

Table 2.1 **Participating organisations, main role and decisions related to the safety case** (Cont'd)

What decisions within your programme will be based on or affected by the conclusions of the current safety case?	**Country and organisation**
A review and update of the German safety criteria is being carried out. The revision of the safety criteria as well as the development of supporting guidelines is carried out by the Final Disposal Department of GRS Köln with the support of a number of experts from Germany and abroad. Safety cases have been devloped and will be needed, but coming decisions in Germany appear not to primarily depend on safety cases. A moratorium on exploration of the Gorleben salt dome as a final disposal site has been in effect since 1 October 2000. The Coalition Parties have planned to solve the issue of final disposal during this term in office. However, such a solution and the associated essential programme decisions cannot be based on a Safety Case because such a case is currently not available. Court decisions have acknowledged that the license application of Konrad (LILW) disposal site contains all the elements of a safety case necessary for the final the licensing step, but lawsuits have been pending against the plan approval. On 8 March 2006 the Upper Administrative Court of Lower Saxony in Lüneburg has turned down these law suits. The court excluded the possibility of an appeal against its decisions. This exclusion has been confirmed by the Federal Administrative Court. The applications decommissioning of the Morsleben facility are orientated on the ideas developed during the criteria revision and therefore also on (NEA, 2004) and WS-R-4. It has, however, to be acknowledged that the plan application deal with the decommissioning activities relating to old practise and deviate, therefore, from what would be expected from a new repository built.	Germany GRS-Cologne
The HLW disposal programme is in the process of selecting a site. The "Specified Radioactive Waste Final Disposal Act" specifies that the siting process shall consist of three steps. Firstly, Preliminary Investigation Areas (PIAs) for potential candidate sites are nominated based on site-specific literature surveys focusing on long-term stability of the geological environment. Secondly, Detailed Investigation Area(s) (DIAs) for candidate site(s) are then selected from PIAs following surface-based investigations, including boreholes, carried out to evaluate the characteristics of the geological environment. Thirdly, detailed site characterisation, including underground research facilities, leads to selection of the site for repository construction. Taking into account the technical achievement of generic feasibility study over last twenty years, which was integrated in JNC H12 as a safety case, the Japanese programme for geological disposal of HLW stepped into an implementing phase with the promulgation of the Act. Following the Act, NUMO was established in October 2000. NUMO announced the start of open solicitation of volunteer municipalities for PIAs with publication of an information package on December 19, 2002 and has been at the first stage of the siting process. The H12 safety case will be a basis for NUMO to provide its safety case specific to individual volunteered sites when applied. The present R&Ds carried out by NUMO, JAEA and other R&D organisations are focused on further increase in the confidence of H12 safety case from various aspects, e.g. demonstration of site investigation techniques and engineering feasibility, development of more reliable assessment models and databases, etc.	Japan NUMO JAEA
Preparatory step for a safety case in support of a licence application of a repository for spent fuel nuclear fuel in the Swedish crystalline basement rock. Feedback to the final stage of the ongoing site investigations, to repository layout and design and to R&D issues.	Sweden SKB

Table 2.1 **Participating organisations, main role and decisions related to the safety case** (Cont'd)

Country and organisation	Main role
Sweden SSI SKI	Regulatory authorities
Switzerland Nagra	Implementing organisation
United Kingdom EA	Regulatory authority
United Kingdom Nirex	Implementing organisation
USA USDOE-YMP	Implementing agency for the U.S. Department of Energy, Office of Civilian Radioactive Waste Management (OCRWM), Yucca Mountain Project (YMP), national spent fuel and high-level radioactive waste repository.

Table 2.1 **Participating organisations, main role and decisions related to the safety case** (Cont'd)

What decisions within your programme will be based on or affected by the conclusions of the current safety case?	**Country and organisation**
A safety case addressing long-term safety will be needed to support a decision whether or not to proceed with construction of an encapsulation plant and a final repository.	**Sweden** SSI SKI
Decision by the Swiss Government (theFederalCouncil) of June 2006 to approve Project Opalinus Clay confirms that, in principle, construction of a deep geological repository for SF/HLW/ILW is feasible in Switzerland. Federal Office of Energy in charge of preparing site selection procedure for deep geological repositories. Nagra is presently preparing the technical basis for applying this procedure once it is approved by the Federal Council. The site selection process will be conducted under the lead of the Federal Office of Energy	**Switzerland** Nagra
Generic Performance Assessment is used as the basis for certain advice that Nirex gives on the packaging and conditioning of ILW. It might be taken as a partial demonstration that Nirex Phased Geological Repository Concept can provide appropriate long-term performance at an appropriate site.	**United Kingdom** EA
In the United Kingdom, there is currently a period of consultation regarding the options for long-term radioactive waste management, being undertaken on behalf of Government by an independent Committee on Radioactive Waste Management (CoRWM). In order to be able to continue to provide advice on the conditioning and packaging of wastes to waste producers, Nirex has developed a generic phased geological repository concept. This questionnaire is answered with respect to this concept, i.e. a generic viability study. Advice will be given to waste producers on packaging of waste as part of the Letter of Compliance process, on the basis of the results of the generic performance assessment. This allows waste to be packaged now with confidence that it is packaged in a way that is consistent with the disposal concept. The safety case will also inform any future site selection process.	**United Kingdom** Nirex
Programme is preparing to submit a license application for the Yucca Mountain Project (YMP), national spent fuel and high-level radioactive waste repository to the national regulator (US Nuclear Regulatory Commission or NRC) in 2008, to allow construction to start approximately three to four years later. A safety case currently in preparation will be basis for licensing decision.	**USA** USDOE-YMP

Table 2.2 **Main references used on response**

Belgium: Ondraf/Niras

- Ondraf/Niras, Safety Assessment and Feasibility Interim Report 2 (SAFIR 2), NIROND 2001-06 E (December 2001).
- Ondraf/Niras, Technical overview of the SAFIR 2 report, NIROND 2001-05 E, December 2001.
- NEA (2003), *SAFIR 2: Belgian R&D Programme on the Deep Disposal of High-level and Long-lived Radioactive Waste – An International Peer review*, Nuclear Energy Agency, OECD, Paris, France.
- With regard to the preparation of the Safety and Feasibility Case 1 (2013) no open references can yet be provided.

Canada: CNSC

- Regulatory Guide G-320, Assessing the Long-term Safety of Radioactive Waste Management, Canadian Nuclear Safety Commission (2006).
- Available on the CNSC website (www.nuclearsafety.gc.ca) by following the links 'Regulatory & Licensing Information/Regulatory Documents/Current Regulatory Documents.

Canada: OPG

- The safety case is currently under development. A number of supporting reports to the safety case will be prepared prior to submission of the EA Study Report. A paper on the Safety Case is being prepared for submission to the NEA Symposium on "Safety Cases for the Deep Geologic Disposal of Radioactive Waste: Where Do We Stand?", to be held 23-25 January 2007 in Paris. Primary references for the present response are:
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Czech Republic: RAWRA

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- Test case for modelling approaches evaluation, 2002.
- Sensitivity study on near field and far field performance in the conditions of reference repository, 2004.
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Table 2.2 **Main references used on response** (Cont'd)

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Japan: NUMO, JAEA

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Sweden: SKB

- SKB Technical report TR-06-09: "Long-term safety for KBS-3 repositories at Forsmark and Laxemar – a First Evaluation. Main Report of the SR-Can project".

Sweden: SSI, SKI

- N/A

Switzerland: Nagra

- Nagra has comprehensively documented Project Opalinus Clay, including the safety case, in a hierarchy of reports. At the highest level, there are three key technical project reports, which are primarily aimed at a technical audience (Swiss safety authorities, the Swiss scientific and technical community, technical bodies such as implementers and regulators in other countries, but also the technically interested non-specialist reader). These three reports include a safety report, which is divided into two parts: (i) a report addressing long-term safety, and (ii) a report on models, codes and data that serves as a technical back-up for the main report:
  – Nagra (2002a), *Project Opalinus Clay: Safety Report*, Nagra Technical Report 02-05, Nagra, Wettingen, Switzerland.
  – Nagra (2002b), *Project Opalinus Clay: Models, Codes and Data for SA*, Nagra Technical Report 02-06, Nagra, Wettingen, Switzerland.
- The other two top-level reports are a project report providing a synthesis of geological information on Opalinus Clay and on the geology of northern Switzerland and, more specifically, the Zürcher Weinland region, and a project report describing the design, construction, operation and closure of the proposed facilities.
  – Nagra (2002c), *Projekt Opalinuston - Synthese der geowissenschaftlichen Untersuchungsergebnisse. Opalinus Clay für abgebrannte Brennelemente, verglaste hochaktive sowie langlebige mittelaktive Abfälle*, Nagra Technical Report 02-03, Nagra, Wettingen, Switzerland.
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– Table 2.2 **Main references used on response** (Cont'd)

Switzerland: Nagra (Cont'd)

- Another important reference report to support the safety case is the FEP Management Report:
  - Nagra (2002f), *Project Opalinus Clay: FEP Management for Safety Assessment*, Nagra Technical Report 02-23, Nagra, Wettingen, Switzerland.
- The project reports, in turn, are backed up by more detailed technical "reference reports".

United Kingdom: Environment Agency (EA)

- Current regulatory guidance is set out in:
- Disposal Facilities on Land for Low and Intermediate Level Radioactive Wastes: Guidance on Requirements for Authorisation, Environment Agency, Scottish Environment Protection Agency, Department of the Environment for Northern Ireland, 1997.
- A copy of this document is appended to this response. We are currently embarking on a review of this document and will in due course produce revised guidance for deep geological disposal. It is envisaged that separate guidance will be produced for near-surface radioactive waste disposal.

United Kingdom: Nirex

- Nirex, Generic Post-closure Performance Assessment, Nirex Report N/80, 2003

USA: USDOE-YMP

- In preparation. An early version of a document that spells out the plans for the safety assessment was published in 2001: "Total System Performance Assessment-License Application Methods and Approach," and is available on the internet at: http://www.ocrwm.doe.gov/documents/osti/31229_osti/31229.pdf

3. THE SAFETY STRATEGY

According to the NEA Safety Case brochure, the safety strategy is considered as the high-level approach adopted for achieving safe disposal. It includes an overall management strategy, a siting and design strategy and an assessment strategy.

3.1 Management strategy

Judging from answers all national programmes aim at management strategies that accord with good management and engineering principles and practice e.g. quality plan, how to adapt to stakeholders requirements, allocation of resources, co-ordination activities.

Safety culture is of key regulatory concern and organisations take several actions to ensure a safety culture. Effective integration of information and knowledge coming from the different fields of the programme is, for example, ensured by a high-level overall integration team. Key safety issues govern programme priorities. All programmes make provisions for storing information in some type of document management systems. Actions for very long-term management and preservation of the information are still being developed.

Most programmes apply a stepwise approach to decisions. All programmes declare a flexible approach to design and focus of the safety case work. Most programmes are subject to formal quality assurance (QA), with safety assessment QA plans being part of the overall quality management system of the organisation. Experts are selected on the basis of references and expert decisions are usually documented. Data clearance procedures are applied. It also appears generally accepted that the BAT principle should be as is the optimisation principle, due consideration should be given to economical and other societal factors i.e. taking into account what is reasonably achievable, but otherwise this concept is still subject to interpretation.

3.1.1 Safety culture

Means to ensure a safety culture is of key regulatory concern. The basic responsibility for developing a safety culture rests with the implementer. Organisations take several actions to ensure a safety culture including:

- A multidisciplinary integrated safety team.
- Integration groups or specific divisions aiming at spreading safety culture within the organisation.
- Safety functions etc. as a means to guide design, siting and R&D.
- Guidance documents on safety philosophy (see also QA programmes and plans).
- QA programme, QA plan and management structure.
- Stepwise planning and implementation.
- Automated knowledge management system on geological disposal technology handling the vast quantity of material involved, helping ensure the required knowledge is accessible to all stakeholders and that gaps can be identified and supporting R&D prioritised.
- Use of external experts and review as well as ensuring regular communication with regulator and other stakeholders.

Compilation of answers

Safety culture of key regulatory concern although SSI/SKI note that the basic responsibility for developing a safety culture rests with the implementer. Similarly, UK/EA remarks that it is important that both the developer and the regulator ensure an effective safety culture is promoted within each organisation. As a regulator, we would expect to scrutinise the way in which any developer addresses this issue. The Environment Agency is developing a set of principles that will guide all of its activities in radioactive substances regulation. GRS-Cologne notes that the draft safety requirements demand a number of planning principles including the establishment of a safety concept relying on multiple safety functions, testing of components which are not yet state of technology, and the application of management principles and QA procedures.

Organisations take several actions to ensure a safety culture including:

- *An integrated safety team:* At Ondraf/Niras, one team is responsible for all safety related matter and this team also co-ordinates all interactions with the safety and environmental protection authorities. This team has also as an objective to promote the safety culture within the organisation, e.g. through information sessions, information distribution on legal and regulatory matters, review of reports, participation in integration groups. SKB integrated the R&D staff in the safety assessment project, thereby building understanding of the safety relevance of R&D issues among the R&D staff and a corresponding understanding of the nature of the R&D results within the safety assessment team.
- *Integration groups or specific divisions aiming at spreading safety culture within the organisation*: Ondraf/Niras has created integration groups to manage the interfaces between the poles and ensure multidisciplinary integration. People responsible for safety evaluations are participating in all interaction groups to bring into the discussion the safety aspects. Posiva devoted considerable amount of organisational discussion of long-term safety to the development of the Posiva Safety Concept (or "safety strategy") since the time of TILA-99. Andra created a special division in 2002 whose specific activities include: increasing awareness and providing training in environmental and safety-related issues for the purposes of anticipation and prevention, formalising the safety "doctrine" by providing safety guides and updating them as operating feedback is acquired to build up a solid and consistent base and source of improvement for the entire agency, keeping close watch over operational safety to reduce the number of incidents and ensure more effective analysis of operating feedback, for the installations that are currently under operation, and guaranteeing environmental preservation at all times by identifying all the paths to progress in environmental management plans aimed at feeding the continuous progress initiative. SKB has built teams that address specific subjects from the point of view of repository design, site understanding and long-term safety assessment. In particular hydrology issues and hydrological modelling are addressed in this integrated fashion. The BfS safety philosophy has been intensively discussed internally and external discussion has been started. Nagra recognise the importance of clearly defining the roles and interactions of different groups of personnel in developing the safety case. (see also the answers to questions regarding integration, Section 3.1.2)
- *Safety functions etc. as a means to guide design, siting and R&D:* The tool of safety functions (long-term safety and operational safety) has been developed to integrate in all S&T work (design, assessment basis, safety assessments) the elements of safety and – together with the safety strategy – steer and prioritise R&D needs. BfS has intensively discussed the safety philosophy internally and external discussion has been started. The Safety Concept was developed to serve as a common conceptual model for Posiva "core tasks" in the period preceding the submission of the application for construction license. It

has been used both as an instrument in training activities and as a framework for setting priorities in RTD programmes. NUMO/JAEA notes that in order to fulfil the expanded requirements when dealing with a range of repository concepts and with a variety of volunteer sites, major extension of the existing background H12 assessment is required. SKB developed safety relevant requirements on the host rock prior to the onset of site investigations. The requirements have been used in ensuring i) that the site investigation programme encompasses all relevant aspects of long-term safety and ii) in preliminary evaluations of the suitability of the host rock at the candidate sites from the point of view of long-term safety.

- *Guidance documents on safety philosophy (see also QA programmes and plans):* A document describing Ondra/Niras' safety strategy for deep disposal is under development as a basis for the development of the SFC 1, and has to be considered as a guidance element for all work in the disposal programme. During the last years, BfS developed a safety philosophy, which sets out and explains from its own point of view the reasons for the fundamental approach and safety objectives for a repository in deep geological formations.

- *QA programme, QA plan and management structure:* OPG commitment to developing, constructing, operating, decommissioning, and closing the DGR facility in a manner that protects workers, the public and the environment, and ensures compliance with applicable regulatory requirements is stated in the Project Quality Policy for the DGR. NUMO/JAEA notes that a specific aspect of maintaining a safety culture concerns the development of appropriate guidelines for quality assurance (QA) or, more generally, quality management (QM). SSI/SKI notes that also the regulatory organisations have during several decades in various ways improved their own work format. This includes e.g. development of review strategies, gradually improved utilisation of external experts and expert groups, more detailed planning of research projects as well as development and implementation of a revised quality assurance programme. UK/EA notes that safety culture would normally include accreditation to appropriate standards, and commitment to appropriate principles and policies across the organisation. It is likely that management systems will ensure due attention to such principles and policies. USDOE-YMP has a formal Safety Conscious Work Environment (SCWE) is in place and receives active support from all levels of management. It is based on nuclear industry practices.

- *Stepwise planning and implementation:* This aspect is specifically noted by OPG and NUMO, but is certainly part of most other programmes as well (see Section 3.1.4). NUMO has taken a stepwise formulation of siting factors and criteria as an approach for selection of the site for final repository. In order to maintain flexibility without losing focus and make the siting and repository development work more systematic, NUMO has developed a formalised tailoring procedure termed the NUMO Structured Approach (NSA). The NSA provides a methodology for developing repository concepts in an iterative manner, which couples management of immediate issues with consideration of longer-term developments. The NSA also guides the interaction of the key site characterisation, repository design and performance assessment groups. NUMO safety case has been incorporated in the framework of such repository concept development.

- *Knowledge management system:* JAEA has initiated a project to develop a "next generation" Knowledge Management System (KMS) on geological disposal technology. This will utilise advanced electronic information management technology to handle the vast quantity of material involved. Autonomic systems will perform many of information processing functions, helping ensure the required knowledge is accessible to all stakeholders and that gaps can be identified and supporting R&D prioritised. In a departure from conventional structuring by technical discipline, the prototype KMS utilises a safety case structure. An element of the KMS is a well-planned and structured training programme to be complemented by specially designed expert systems conditioned by the accumulated experience of retiring staff members. The KMS is expected to help pervade safety culture not only in JAEA but in all users, including the implementer and the regulator.

- *Use of external experts and review as well as ensuring regular communication with regulator and other stakeholders*: OPG uses external experts both for the primary analysis and for peer review, in order to ensure that international experience is effectively used. OPG also has regular communication with CNSC, public and other stakeholders. SSI/SKI notes that the Swedish authorities has contributed by input through the periodic RD&D reviews, and through the common reviews of safety reports such as the SR 97 and SR-Can interim report. In recent years, the Swedish regulators have devoted more and more attention to the review of quality assurance issues.

3.1.2 Integration

Effective integration of information and knowledge coming from the different fields of the programme are important from a regulatory perspective. It is important that the implementing organisation should be able to demonstrate an ability to integrate and manage information and data. Management structures and systems need to take account of the need to integrate information. Recurrent preliminary safety assessments are seen as an important tool for prioritising the programme.

Listed examples of approaches for ensure effective integration of information and knowledge coming from the different fields of the programme include:

- Recognising that safety assessment forms an inseparable set with engineering (design) and research studies on site characterisation and phenomenological evolution of the repository.
- Requirement management system.
- High-level overall integration team.
- Focusing on major phenomena controlling repository evolution – rather than on academic disciplines – use of multiple expert groups
- Communication of main findings.
- International peer review.
- Separation between long-term R&D and more immediate development programme.
- Knowledge management and QA.

It also should be noted that there is substantial overlap between this question and the question about safety culture (see Section 3.1.1).

Listed examples of how to decide on programme priorities include:

- Key safety issues govern programme priorities.
- Iterative process in planning safety case, site characterisation and design.

Compilation of information

According to SSI/SKI effective integration of information and knowledge coming from the different fields of the programme are important from a regulatory perspective. Recurrent preliminary safety assessments are seen as an important tool for prioritising SKB programme. The Swedish regulators also have the opportunity to give general recommendations concerning SKB programme priorities and such recommendations have included pointing out areas where complementary work may be needed or pointing out areas where SKB reporting appear to be vague or undefined. According to the UK/EA, it is important that the implementing organisation should be able to demonstrate an ability to integrate and manage information and data. Management structures and systems need to take account of the need to integrate information. It is important that there is good technical co-ordination between different parts of the repository programme. GRS-Cologne notes that the draft safety requirements demand the integration of site characterisation, geoscientific long-term prognoses, repository design details, technical and mining-related design, emplacement method, backfilling method, sealing of the shaft), characterisation and long-term prognosis of the technical barriers, waste data, safety analyses into a safety case. GRS-Cologne provide recommendations to the regulator BMU concerning future directions of regulatory research based on the results of previous regulatory research activities (which include review of safety cases and research performed abroad) as well as on needs arising from other regulatory activities (e.g. the development of criteria and guidelines or activities in licensing procedures) or from questions concerning the German programme in general.

Listed examples of approaches for ensure effective integration of information and knowledge coming from the different fields of the programme include:

- *Recognising that safety assessment forms an inseparable set with engineering (design) and research studies on site characterisation and phenomenological evolution of the repository.* Andra notes that the safety assessment is not an autonomous domain of the repository feasibility study. It forms an inseparable set with engineering (design) and research studies on site characterisation and phenomenological evolution of the repository. The organisation set up within Andra and, in particular, the co-ordination authority between different units working together on the project, is a guarantee of this constant interaction. The NUMO Structured Approach (NSA) guides the interaction of the key site characterisation, repository design and performance assessment groups.
- *Requirement management system.* NUMO develops a Requirements Management System (RMS) to help implement the NSA. This RMS will allow the justifications, supporting arguments and knowledge base used for every decision to be clearly recorded and will highlight when such decisions may need to be revisited, for example due to changing boundary conditions or technical advances. Integration of information and knowledge coming from the different fields of the programme will be performed through the RMS in NUMO. Note: many other organisations develop RMS – but this was not listed in responses.
- *High-level overall integration team*: Ondraf/Niras has a programme integration team, with the programme manager/co-ordinator, the scientific co-ordinator, a member of the board of directors, and with the co-ordinators of the three poles is responsible for decisions on programme priorities (new S&T work to be launched) and for approval of new studies and R&D work. The OPG DGR programme is directed by a senior management team (Implementation Team), representing all areas of the programme, which meets regularly (every two weeks) and decides on priorities and directions. Posiva present management structure is a matrix enhanced by a number of specific co-ordination and integration groups and the so-called TKS Group (RTD Group) consisting of top management and senior advisers the duty to see to it that the RTD work is integrated and prioritised to correspond to the defined company strategy. To ensure closer links between the engineering and safety teams Andra created a "scientific integration department" responsible for ensuring the synthesis of knowledge for its usage in the safety analyses. Particular care was devoted to the quality of the interfaces between units through the "HLLL Argile" project management. In addition to the co-ordination at the Agency's steering committee, dialoguing was encouraged at all the organisation's levels. Nagra makes extensive use of "audit meetings" between the safety assessment group and staff from the science and technology group (e.g. geologists)

where typically the safety assessment group would explain to the staff from the science and technology group how specific scientific information is being used within safety assessment. (See also the SKB answer in Section 3.1.1).

- *Focusing on major phenomena controlling repository evolution – rather than on academic disciplines – use of multiple expert groups*. Andra notes that the scientific teams evolved from an organisation initially based on the various academic disciplines required to study the repository (geology, geomechanics, geochemistry, etc.) to a more transversal approach centred on the major phenomena controlling the repository's evolution (behaviour of the materials, transfers, etc.). It is an important concern of BfS to bring together different expert groups such as geoscientists and safety assessors to develop data bases and models supporting a safety case.
- *Communication of main findings*: Ondraf/Niras communicates the context of each R&D study (i.e. the safety statement it should eventually substantiate) in-house and with the external contractors. (Evidently the case for most other organisations as well but not listed in the answers).
- *International peer review*: RAWRA notest that as a base, in 2004 IAEA WATRP mission approved and optimised the Czech nation programme of geological repository development.
- *Separation between long-term R&D and more immediate development programme*: Posiva now makes a clear distinction between the pure research and development activities on one hand and the time-bound activities aiming at producing certain well-defined outcomes within a prescribed period on the other hand.
- *Knowledge management and QA*: the JAEA Knowledge Management System is intending to manage all scientific and technical data, information and knowledge on the geological disposal programme by structuring them according the general safety case concept. Nagra makes use of knowledge management, where regular assessments of what needs to be done within designated fields are made by staff assigned to each field, as an integral part of Nagra QM system. USDOE-YMP addresses integration through organisational structure, management expectations, and most importantly, a formal system for requesting and supplying and documenting data and design information across organisational boundaries.

It also should be noted that there is substantial overlap between this question and the question about safety culture (Section 3.1.1). In fact, JAEA/NUMO, SKB and Nagra also refer to their answers there.

Listed examples of how to decide on programme priorities include:

- *Key safety issues govern programme priorities:* The OPG programme priorities are decided by early identification of key safety issues, early formulation of the key arguments in the safety case to help ensure the required work underpinning the safety case will be in place planning of regulatory submissions and ensuring required 'pieces' will be in place. At SKB, the conclusions form the current safety case assessment entail important input to decisions on programme priorities at this stage. Nagra adhere to the principle that no statement in the line of arguments in the safety case may be made without foundation, justification and documentation.
- *Iterative process in planning safety case, site characterisation and design.* The OPG development of the DGR design and the safety case, and their relation to the site characterisation work, is planned as an iterative process. Andra notes that research and design work is by nature an interactive activity between the engineers in charge of engineering, the research programmes, and those in charge of safety assessments. The repository architectures

proposed within the framework of the Dossier 2005 are the results of these exchanges and take particularly into account what was learned from the previous safety assessments (especially the Dossier 2001). At BfS, decisions on programme priorities depend on an iterative cycle of site characterisation, data ascertainment, design planning, and performance assessment. (In fact such iterations are also important in the SKB work planning, but not listed in the answer).

3.1.3 Preservation of information

There is usually a regulatory requirement for a well-managed record management system for the recording of detailed information on all aspects of the project affecting the safety case. In fact, all programmes make provisions for storing information in some type of document management systems. These systems are usually part of the organisations quality management systems.

Actions for very long term, i.e. at least many hundreds of years, management and preservation of the information are still being developed by most organisations. However, for existing facilities some organisations already now store information in national archives and makes provisions for long-term preservation of information, including specifying the meaning of the symbols used, preparing glossary for the future and reproducing key documents on permanent paper handled using gloves to avoid any risk of pollution. It is also noted that in some societies, institutional control is generally seen as a positive attribute, i.e. when there is a tradition of carrying responsibilities over many generations. A good analogue might be temples and places of worship. Their maintenance over many generations – and the social systems supporting them – indicates that the extended commitment would not be a novelty in this environment.

Compilation of answers

SSI/SKI note that a well-managed record management system, RMS, is a prerequisite for later archive activities. SSI regulations SSI FS 1997:1, "Regulations on Filing at Nuclear Plants" contains requirements on archives in nuclear installations. UKEA notes that information preservation is very important. Current regulatory guidance is that an implementing organisation should: "… set up and maintain a comprehensive system of records for the recording of detailed information on all aspects of the project affecting the safety case". GRS-Cologne considers information preservation relevant for the development of the Safety Case by the implementer. The proposal for the revision of the German safety criteria is, however, not prescriptive with regard to the concrete measures to be undertaken by the implementer on this issue.

All programmes make provisions for storing information in some type of document management systems. These systems are usually part of the organisations QM systems. Ondraf/Niras initiated the development of a knowledge management system, in order to structure, map and better preserve all information available and being generated. OPG system of governance includes records and document management procedures requiring proper filing. All technical reports, licensing submissions and regulatory correspondence are filed in a controlled documents system for permanent retention, currently in both paper and electronic form. However, specific aspects are still under development for the DGR programme. RAWRA has preserved all information from the beginning of the programme in e-form and hard form. For the preservation of information, Posiva has defined a document management system has been defined as a part of QA and covers both electronic documentation and paper archives. It also defines the times over which different documents must be preserved. During the development of the safety case, Andra records all technical notes and reports that have been established to support the Dossier 2005. BfS have recorded the data on which the safety assessments are based in a data base including information about the origin of the data and the log of all modifications during the development of the safety case. NUMO/JAEA note that information preservation has been regarded as an important issue related to the safety case as the safety case will be iteratively updated and used as a key input for decision making at each step of the long-term implementation of the repository programme. The method of the preservation will be incorporated in the NUMO Structure Approach and in the JAEA Knowledge Management System. At SKB preservation of information from projects developed from a few years back is obtained through the following of project management routines required by a more encompassing management system. For the licence application for a final repository, a compilation of older decisions and the history behind the present design will be given in a systems analysis report. Nagra follows a well-defined project documentation process as part of Nagra QM system. USDOE-YMP has elaborate record keeping systems are in place, with off-site storage by an independent contractor specialising in this type of activity to keep duplicates of all records. For realising knowledge management at GRS-Cologne, a knowledge model was adopted containing the different stages of specification of the knowledge goals, knowledge identification, acquisition, development, use, dissemination, preservation, and assessment of the knowledge system.

Actions for very long-term management and preservation of the information are still being developed. Posiva notes that for some documents, there is no end point defined for preservation, but how this can be guaranteed for the longer term (over periods exceeding a few hundreds of years) is still to be defined. Andra seeks to preserve its repository records as long as possible, while providing for the risk that they will be lost after a statutory monitoring period. As an example, for the "Centre de la Manche", which is under monitoring phase after closure, two types of records on permanent paper have been foreseen: (i) copies of a detailed tree-structure record for managing the "Centre" and potentially using the site in the future (one stored at the Centre and the other in the French National Archives), (ii) a single volume aimed at decision makers and the general public. Andra has specified the meaning of the symbols used and provided a glossary for the future. It has also clarified the archive architecture and produced an abstract of each section in layman's terms. These two records have been reproduced on permanent paper and handled using gloves to avoid any risk of pollution. BfS notes that it is of central importance that the data on the repository and on the risks associated with the repository are handed down at least for a period of 500 years. Inadvertent human intrusion should be prevented within this period. NUMO/JAEA notes that the Government (i.e. Ministry of Economy, Trade and Industry – METI) should preserve relevant information (not yet specified) on the final repository forever as far as the nation can survive. This covers the timescale for the life cycle of a repository, e.g. up to a century. Furthermore, in Japan (and some other Eastern societies), institutional control is generally seen as a positive attribute as there is a tradition of carrying responsibilities over many generations. A good analogue might be temples and places of worship. Japanese wooden temples that are over 1 000 years old – continuously maintained with rebuilding work constrained to original specifications and still used for their original purpose (e.g. Horyuji temple, a UNESCO world heritage site, contains a range of wooden buildings which have been continuously maintained for 14 centuries). Such structures – and the social systems which support them – indicate that the extended commitment required by the Act would not be a novelty in this environment. In 2006, the Swedish Government gave SSI and SKI the task to investigate possible addition to the existing Nuclear Activities Act, regarding responsibility issues after closure of a repository for nuclear waste, including the planned repository for spent fuel. The USDOE-YMP record keeping systems procedures require updating of media for non-paper records at specified intervals.

3.1.4 Stepwise approach to decisions

Most programmes apply a stepwise approach to decisions. Many countries actually have formalised the steps in regulations or other government decisions. In many cases, the implementer also adds steps in addition to the legally required ones.

Examples of decisions steps include:

- Early studies and consultation with potential host communities and with major stakeholders to create and maintain local support.
- Regular evaluation of R&D programme.
- Decision to go for surface based site characterisation.
- Decision to go underground.
- Construction licence application.
- Trial operation.
- Routine operation.
- Closure or decommissioning.

The purpose of implementing a stepwise approach to decision is generally to ensure timely progress to implementation as well as to define the control procedures and mandates of the authorities. It may also be argued that the nature of the technical and scientific issues involved in the development and safety evaluation of a final repository concept requires a stepwise approach, simply since they are too complex to address in any other way. It is also means that decisions regarding the timing of future events (such as repository backfilling and closure) do not need to be taken now but can be left to future generations, thus allowing them some choice.

At each stage, there are usually opportunities for public input, e.g. via ongoing consultation as well as by participation in EIA and licensing hearings. However, the degree of stakeholder involvement varies between steps and between programmes.

Compilation of answers

Ondraf/Niras applies a stepwise approach, although there are no legal requirements for this. As the disposal programme runs over several decades before a decision on construction of a facility can be taken, a stepwise approach allows that the progress made and interim conclusions can be presented to the decision makers at regular intervals. Stakeholder involvement also requires a stepwise approach, because a series of decisions will have to be prepared.

OPG has adopted a stepwise approach. The initial stages prior to entering the regulatory process involved providing studies and consulting with the host community and with major stakeholders to ensure community support via both a host community agreement and a community poll. The next stage is to obtain EA approval for the project. This is a Federal requirement. Also the following Canadian regulatory process is stepwise and there are three stages of regulatory review prior to operation: EA, site preparation/construction licence application, and operating licence application. At each stage, there are opportunities for public input via ongoing consultation as well as by participation in EA and licensing hearings.

RAWRA notes that the base for a stepwise approach is the State Concept of Radioactive Waste and Spent Fuel Management approved by Czech Government in 2002. More steps have been effectuated with respect to public, under RAWRA management, outside formal control.

Posiva notes that the programme for spent fuel disposal in Finland was defined as stepwise procedure from the very beginning in 1983 when the Government formulated it for the first time. The purpose of the Government decision then was to ensure timely progress to implementation as well as to define the control procedures and mandates of the authorities.

Andra notes that stepwise approach of their work is based on an assessment system provided by the Waste Act of 1991 and ordered by Andra trustee ministries or implemented by the initiative of the

Agency itself. To that effect, the Act created an independent National Review Board to inform and advise the government on the interim progress at the technical and scientific levels. A siting phase initiated in 1993 through a consultation mission led by Mr. Bataille identified four candidate sites (two of them were combined into one area). Beginning in 1994, Andra started preliminary geological and geophysical surveys and drilled exploratory boreholes in these three different areas of France. In 1996, three applications, backed by these preliminary studies, were filed by Andra to obtain construction and operating licences for underground laboratories so that in situ R&D programmes could be pursued. By the end of 1998, the French government took a twofold political decision concerning the Andra projects: 1) it authorised the construction and operation of an URL at the Eastern site, and 2) it did not authorise work at the other sites and started a new siting process with another consultation mission in order to find a new site with outcropping granite. After the decree formalising the Eastern site decision (August 1999), Andra began its in situ R&D Programme for the Meuse and Haute-Marne area. The construction of the URL started in September 2000, after the authorisation to sink two shafts was granted by the government on 7 August 2000. To prepare for the 2006 comprehensive assessment by the French government and Parliament required by the Waste Act, Andra set out to produce an intermediate milestone report in 2001 for the Projet HAVL Argile, the Dossier 2001 Argile leading up to the final Dossier 2005 Argile, which is a conclusive study and is an essential input to the future political decision-making process in France. At the request of Andra trustee ministries, a peer review was organised between October 2002 and February 2003 to assess Andra programme in the Dossier 2001 Argile with respect to international practices. The review was organised by the OECD/NEA; it included international experts from either Andra counterparts or safety authorities' research or technical support organisations.

In contrast, BfS notes that the current legal framework does not consider a stepwise approach for repository development. Nevertheless, as part of the licensing procedure performed by the licensing authority (the competent Ministry of the concerned Federal State) a public hearing has to be organised where BfS has to comment upon questions raised by the public and demonstrate to the licensing authority that all legal requirements are met. GRS-Cologne notes that the Plan Approval Procedure (i.e. licensing procedure, "Planfeststellung") required by the German Atomic Energy Act for federal installations for the safekeeping and final disposal of radioactive waste, generally lasts for the whole duration of a project and a stepwise approach is not explicitly implemented. Nevertheless, it is the opinion of GRS-Cologne that such an approach could be applied within a plan approval procedure if the stakeholders would commit themselves on a voluntary basis. A legally binding commitment to a stepwise approach *might*, however, require changes in legislation. *In the most recent GRS draft for safety requirements, a stepwise approach with focus on repository optimisation is foreseen. In the ongoing discussion it should be clarified whether and, if so, by which legal or other means, such an approach can be established.* GRS-Cologne also believes that, if the exploration of Gorleben were continued and/or alternatives for HLW/SNF disposal were investigated (cf. I.2, I.3) it would be necessary for an effective continuation of the German programme to implement such a stepwise approach including the effective involvement and information of regulatory bodies and other stakeholders on exploration results and interpretations.

NUMO/JAEA note that a stepwise approach is legally adopted in the Specified Radioactive Waste Final Disposal Act. In accordance with the Act, NUMO will promote the implementation of the repository programme in a step-by-step manner, with thorough evaluation of information and extensive public involvement at each stage from the beginning of selecting a repository site, licensing, repository construction, operation and closure, and post-closure institutional control. Furthermore, in Japanese society, decision making is generally a gradual, stepwise process. Reversing a decision can be difficult and hence there is a desire for staged processes where a very high degree of confidence can be built up before each individual decision step. This is especially the case if it involves precedence, like a "first of its kind" facility.

According to SSI/SKI, a stepwise approach in a project is implemented and can be regarded as unavoidable in the Swedish context, since separate safety evaluations will according to SKI regulations (SKI FS, 2002:1 and SKI FS, 2004:1) be required before construction, trial operation and routine operation and finally closure or decommissioning. The formal stepwise licensing following these stages is however only part of a gradual development of the Swedish programme. Opportunities for a stepwise development is also made possible in earlier stages by the Swedish authorities' review of the SKB R&D programmes every third year and the government decisions associated with the RD&D programme reviews.

SKB notes that it is a legal requirement that an R&D programme is submitted every three years, and that it is evaluated by safety authorities and approved by the Government after broad consultation process. This enforces a stepwise implementation of the Swedish programme. Furthermore, the nature of the technical and scientific issues involved in the development and safety evaluation of a final repository concept requires a stepwise approach, simply since they are too complex to address in any other way.

A stepwise approach to repository implementation is foreseen in Switzerland's Nuclear Energy Law. The several licences that are required for implementing a repository and for its eventual closure define major steps. The stepwise approach is also foreseen in Swiss regulations (HSK R-21 – HSK & KSA, 1993). Even before licensing, however, Nagra has defined several milestones with corresponding safety reports.

According to the UK/EA, it is very likely that a stepwise approach will be followed to any development, but the approach has not yet been determined.

Nirex regards a stepwise approach as fundamental to the planning and development of a repository. The Nirex stepwise process is based on important, clearly-defined decision points (e.g. choice of long-term waste management option, selection of a site, start of repository construction, start of waste emplacement, backfilling, sealing and closure of the repository). This process allows stakeholder involvement and allows the repository development programme to proceed in a steady and measured way. In particular it means that decisions regarding the timing of future events (such as repository backfilling and closure) do not need to be taken now but can be left to future generations, thus allowing them some choice.

USDOE-YMP notes that a stepwise approach is built into the regulatory framework to allow an orderly decision process. A technology development programme is in place to assure that if there are new developments that could enhance safety and efficiency, they will be seriously considered even during the operational phase.

3.1.5 Flexibility

All programmes declare a flexible approach to design and focus of the safety case work. The main rationale for maintaining flexibility is to provide room for inclusion of results from technical developments, changing and partly unknown waste amounts and inventories, new R&D results and more detailed site understanding during the long process ranging from site selection, site investigation, underground construction and repository operation to repository closure and decommissioning. Even after licensing, there will be a need for some performance confirmation programme to update the safety case by doing tests and analyses to assure that with new information coming from tests and observations the basis for the safety case is still sound.

However, in light of the need for flexibility, a main challenge from the regulatory perspective is to evaluate whether or not the programme in question has reached sufficient maturity at the stage of licensing. At the time of licensing one should expect a well developed understanding of what are the critical issues, in order to minimise the risk of entirely new and very significant issues (or a new significance of an old issue) appearing after a license has been given. One of the ways to ensure the control of uncertainties is to direct design choices toward solutions offering the greatest robustness, that is, those less sensitive to the effect of external factors or the lack of knowledge. An upstream integration of safety in the design allows also taking into account the other requirements of a project (cost, constructability, etc.) without conflicting with the repository's global safety.

It should also be noted that some organisations develop knowledge and requirement management systems in order to ensure well founded decisions when they finally have to be made. These systems are designed to handle advances in science and technology while flexibly responding to (changing) requirements of end-users and other stakeholders.

Compilations of answers

The main rationale for maintaining flexibility is to provide room for inclusion of results from technical developments, changing and partly unknown waste amounts and inventories, new R&D results and more detailed site understanding during the long process ranging from site investigation, underground construction and repository operation. Ondraf/Niras maintains its flexibility mainly by taking into account the possibility of changes (e.g. in waste inventory, in materials, in site characteristics) before going to a process of optimisation of the disposal system. According to OPG, the stepwise approach to DGR planning and implementation allows for iteration of design and safety assessment to take account of new information from site characterisation. Furthermore, at each stage of regulatory review prior to operation (EA, Site Preparation/Construction Licence application, and Operating Licence application), new information will be considered for its effect on the Safety Case. According to RAWRA repository geometry, barriers system and site features still remain flexible and shall be optimised with periodic safety evaluations. Andra overall project plan follows an iterative process giving an opportunity to adapt design options to new knowledge, but controls that the evolution of the repository's components are adapted to all the repository's life phases and would not be unfavourable to safety. BfS notes that the development of the technical concept for closure of ERAM was a stepwise iterative approach. Currently, flexibility within the project plan is mainly due to the rather simple concept for backfilling and closure that results in robust system behaviour. Thus, possibly undiscovered site features or unexpected technical difficulties are less important for the results of safety assessment. NUMO/JAEA notes that great flexibility is essential due to volunteering approach to selecting repository site. The NSA, and its supporting requirement managament system, allows for uncertain boundary conditions and provides a method for ensuring that NUMO will find an optimum solution based on sate-of-the-art understanding of the issues involved at the time when the decision finally has to be made. The supporting R&D plan should emphasise flexibility to respond to both changes in the repository programme (e.g. caused by inherently unpredictable changes in socio-political boundary conditions) and to the rapid advances in fundamental science and technology. The JAEA knowledge management system is designed sufficiently to be flexible to respond to changing requirements of end-users (e.g. defined in RMS of NUMO) and to optimise R&D programme. According to SKB, the main rationale for maintaining flexibility is to provide room for inclusion of results from technical developments, new R&D results and more detailed site understanding during the decade-long time period remaining before repository operation. At every stage, at least one functioning option should be identified, that can then be improved and optimised in the subsequent step. According to SSI/SKI, the experience from ongoing work suggests that a high degree of flexibility is needed, since the perceived importance of various issues often has changed as more and more information have become available (from e.g. site investigations and development of engineered barriers) For Nagra, the rationale for maintaining flexibility given in the documentation of the safety case is that it allows new findings to be taken into account, and to cope with changes in the programme constraints (e.g. an extension of the existing nuclear power programme). The UK/EA considers that flexibility is important but the future process remains to be defined. For example, changes to design may be required to accommodate some of the more challenging waste streams. At the current generic stage of the Nirex repository programme, there is necessarily considerable flexibility built into the overall project plan. This includes flexibility regarding siting (the assessments are currently generic and representative of a range of geological settings in the United Kindgom). There is also flexibility regarding the disposal inventory. In the United Kingdom, the national radioactive waste inventory is updated every three years and Nirex assessments are then updated to reflect any changes. Nirex operates a formal change control process to address any safety-significant changes. The USDOE-YMP notes that the regulatory prescribed performance confirmation programme will continue to update the safety case by doing tests and analyses to assure that with new information coming from tests and observations the basis for the safety case is still sound. Legislation has decreed the amount of waste to be disposed of at Yucca Mountain before another repository becomes available, but this is being revisited in the national lawmaking bodies.

Posiva notes that the repository can be started only after sufficient maturity has been reached in the design and development of the technology and a reasonable level of confidence can be shown in the safety case. Some issues may still be left for confirmation during the construction period, while for granting the operational license, any significant safety issues cannot remain unsolved. A main challenge will be on the decision making as the decision to go ahead will always be a collective expert judgement. Andra notes that one of the ways to ensure the control of uncertainties is to integrate safety already in the phases the farthest upstream from the design phase in order to direct the choices toward solutions offering the greatest robustness, that is, those less sensitive to the effect of external factors or the lack of knowledge. An upstream integration of safety in the design allows also taking into account the other requirements of a project (cost, constructability, etc.) without them conflicting with the repository’s global safety. Similarly, SSI/SK find it a main challenge from the regulatory perspective to evaluate whether or not the programme in questions has reached sufficient maturity at the stage of licensing. At the time of licensing, one should expect a well developed understanding of what are the critical issues, in order to minimise the risk of entirely new and very significant issues (or a new significance of an old issue) appearing after a license has been given.

3.1.6 Quality assurance

Formal QA is usually a regulatory requirement and should concern all activities affecting the safety case.

Most programmes are subject to formal QA, with safety assessment QA plans being part of the overall quality management system of the organisation. Safety assessment QA plans may, for example, cover routines for project management, reviews, improvements, FEP handling, documentation of knowledge of processes of importance for long-term safety, and of handling of these processes in the assessment, data clearance process (selection of input data and discussion and quantification of input data uncertainty), adequacy of codes, system for storing/archiving of all the files, checking PA calculations and maintenance of PA computer programmes.

Some programmes do not (yet) apply formal QA, but certainly take measures to ensure quality in their work.

Compilation of answers

According to CNSC site characterisation should be carried out under a formal site characterisation plan that includes quality assurance/quality control (QA/QC) protocols to verify the data. All software used in an assessment should conform to accepted quality assurance (QA) standards. According to SSI/SKI formal QA of the safety assessment work may not be needed until license applications, but SKB was recommended to if necessary revise the QA strategy for the preliminary assessment SR-Can to ensure sufficient clarity, rigour and traceability. The UK/EA notes that the relevant regulatory guidance is that the developer shall establish a comprehensive quality assurance programme for all activities affecting the safety case. This shall include supporting activities such as research and assessment. According to GRS-Cologne, the proposal for the revision of the German safety criteria requires the development and application of a comprehensive quality assurance programme which has to cover all phases of disposal (planning, design, construction, operation, closure). The proposal is, however, not prescriptive with respect to the details of this programme.

Most programmes are subject to formal QA. Ondraf/Niras S&T work conducted in the disposal programmes, as well as the development of the SFC 1 is part of Ondraf/Niras ISO9001 certification. OPG DGR programme is covered by OPG quality management system. All areas of the programme contributing to the Safety Case, including design, site characterisation, and safety assessment – including software – are covered by the Project Quality Plan (PQP). Posiva notes that all activities related to the development of safety case are subject to QA. According to the principles defined in the ISO 9001 standard, Andra has defined processes regrouping activities, which contribute to the same finality and are oriented toward a customer's satisfaction. This organisation allowed inciting engineers in charge of the studies to identify possible ways of improvement. They involved especially the management of the project's configuration and the control of the scientific data. A general document management procedure is related to project management (on the establishment of management plans, controlling reviews, etc.). NUMO has developed its own QMS to ensure high quality of all its technical activities, documents and databases. The QMS will be integrated within the RMS. The QMS with relevant documents is also respectively developed in JAEA for each technical activity in particular for developing the "assessment basis", such as data acquisition and analysis in site characterisation, laboratory measurements, and provision of dataset for repository design and PA. The QMS are being integrated in the JAEA KMS. SKB QA plan for the SR-Can assessment covers, *inter alia*, routines for project management, FEP handling, documentation of knowledge of processes of importance for long-term safety, and of handling of these processes in the assessment, selection of input data and discussion and quantification of input data uncertainty and model documentation. The site characterisation and site modelling activities and the result thereof are covered by separate QA plans. At Nirex, all elements of the production of a safety case are covered by the QA plan. This includes demonstrating that all those involved in producing the safety case (whether Nirex staff or contractors) are suitably qualified for the role. Nirex has formal company management procedures and instructions determining the level of checking and review appropriate for calculations in support of a safety case and formal procedures covering the review of all documents prior to publication. Nagra Project Opalinus Clay was developed within the framework of the Nagra Quality Management (QM) System. The QA plan included specific quality assurance measures (defined in specific quality assurance guidelines) concerning e.g. data clearance, project documentation, adequacy of codes, checking PA calculations and maintenance of PA computer programmes. USDOE-YMP notes that any item of feature that is deemed "important to safety or waste isolation" is covered under the full QA programme. GRS-Cologne applies a certified process-orientated QA system according with DIN EN ISO 9001:2000.

Some programmes do not apply formal QA, but certainly take measures to ensure quality in their work. RAWRA ask reviewers to participate in the project evaluation. BfS notes that the QA of the safety analysis (models, codes and data) has been performed by standard procedures. All final documents produced for the safety case are subject of quality specifications, which are controlled by specialist departments of BfS. An overall check of consistency and plausibility of data, models, arguments and conclusions for the safety case was performed by an external evaluator. However, no formal QA-plan has been implemented in addition to these measures. For the realisation of the closure measures, however, a formal QA will be implemented.

3.1.7 Qualification of experts

Regulators generally require that 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, including the use of expert judgement. Traceability of scientific and technical decisions should be reported including relevant description of expert judgement behind choices of strategies, models and parameters used in the safety case. Formal expert panel elicitations could be a tool for strengthening confidence in judgements of uncertainty, in situations with an insufficient data basis. Formal and independent reviews carried out on behalf of the implementer are also seen as important (or even required in some countries).

Experts are selected on the basis of references (publications, experiences in other programmes…) and they are provided with all the basic and more detailed information they need to do their job (e.g. information sessions). Expert decisions are documented, e.g. by putting their name on the reports or conclusion/recommendations they deliver, in meeting minutes or technical notes written for the preparation of the judgements. At least in cases the experts responsibility of the judgements made are ensured by requiring that the experts involved review the parts of the documentation of the safety case that is influenced by their input. Decisions and judgements are reviewed, e.g. by workshops or peer review teams. Data clearance procedures are applied. Formal expert judgement elicitations are applied on some programmes, but have much more limited application in other programmes.

Compilation of answers

According to CNSC 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, including the use of expert judgement. SSI/SKI expects traceability of scientific and technical decisions to be reported including relevant description of expert judgement behind choices of strategies, models and parameters used in the safety case. SSI guidance (SSI, 2005) recommends the use of formal expert panel elicitations as a tool for strengthening confidence in judgements of uncertainty, in situations with an insufficient data basis. According to SKI regulations SKI FS 2004:1, a required measure is that primary safety review as well as independent safety review is carried out. According to the UK/EA, it would be the responsibility of the developer to demonstrate that experts are suitably qualified. A process of regulatory and peer review would enable any defects in a safety case to be challenged GRS-Cologne notes that the proposal for the revision of the German safety criteria does not contain requirements concerning decisions involving expert judgement. It is, however, expected that the regulatory guideline about assessing post-closure safety will require formal procedures about the guidance, use and documentation of subjective decisions especially in the development of scenarios. The extent to which these requirements should be prescriptive is still being debated.

Experts are selected on the basis of references (publications, experiences in other programmes…) and they are provided with all the basic and more detailed information they need to do their job (e.g. information sessions). Ondraf/Niras select experts, both national and international, based on qualifications and on demonstrated capability within the radioactive waste management area. OPG chose experts from technical research institutes and from universities. In particular cases, the experts are approved by RAWRA Council. Andra was granted an organisation and its own procedures to ensure the quality of the Dossier 2005, with quality being defined according to the ISO 9001 standard. SKB has developed an expert database where the qualifications and roles of all participating experts are documented in a structured manner. The Nagra company policy required that the work was conducted by personnel sufficiently qualified for their work and with access to the necessary tools, and that they were fully aware of the expectations and take full responsibility for their work. The experts chosen were asked by Nagra to take account of the views of the scientific and technical community as a whole, and not simply to present their own personal opinions; and to interact with others in their own field and in other relevant fields.

Expert decisions are documented. Ondraf/Niras ask experts to put their name on the reports or conclusion/recommendations they deliver. OPG documents decisions within the controlled document system. BfS document the decisions in the minutes of the meetings. Technical notes were written for the preparation of the judgements and for the documentation of the decisions. NUMO will record all important decisions for the repository programme with the considerations for the decision making including associated expert judgements, requirements and arguments forming the basis for the requirements in the RMS. Nagra recorded all meetings with experts, and entered the records into the project documentation system. SKB ensures the experts responsibility of the judgements made by requiring that the experts involved review the parts of the documentation of the safety case that is influenced by their input.

Decisions and judgements are reviewed. OPG uses workshops or peer review teams to ensure judgements are not narrowly informed and represent an emerging consensus. RAWRA notes that an expert group is involved in the programme and technical issues are judged by reviewers. NUMO has organised advisory committees of domestic and international experts to support NUMO technical activities. SKB has an independent review group reviewing all major documents in the safety case. SKB also requires that the experts involved review the parts of the documentation of the safety case that is influenced by their input.

For assigning values to model parameters a data clearance procedure, which is integrated in the knowledge management system of Ondraf/Niras, is applied. NUMO has been developing the methodology that enables expert judgements to support decisions [e.g. ESL (evidential support logic), MAA (multi attribute analysis)]. In the JAEA KMS, expert systems are being developed to support decisions in the technical activities for developing a safety case.

Nirex uses a formal group elicitation methodology where expert judgement is being used to quantify the uncertainty in some quantity. In an elicitation session, suitably qualified experts take part in a facilitated procedure designed to help them quantify the uncertainty in the parameter as a probability density function (PDF). Before tackling the parameters in question, the facilitator will train the experts in the estimation of probabilities and explains the requirement to avoid bias. In addition to the roles of facilitator and experts, the customer for the data would also be present, as could a number of observers. To further ensure transparency and traceability, a formal write-up of the elicitation meeting is produced, documenting the decisions made, and the technical discussions leading up to them. In recent Nirex elicitations, an audio recording of the entire meeting has also been made, to assist in the process of documenting the outcome. For the future, Posiva plans enhanced documentation planned for the expert elicitation process. The USDOE/YMP notes that the regulator, the US Nuclear Regulatory Commission, has published guidelines on how to do formal expert judgement elicitations in this context.

3.1.8 Application of BAT

Many programmes do not formally require application of Best Available Technology (BAT). The need is there to show that the technologies being applied are sufficient to meet the safety and other criteria that do apply to the repository.

Other programmes need to apply BAT or at least discuss its implications. BAT would apply both to siting and design, but the interpretation of the “best” appears subject to interpretation. However, much is of the interpretation, and how to separate between BAT and optimisation, is still left for judgement.

It appears generally accepted that the BAT principle should be applied as is the optimisation principle, due consideration should be given to economical and other societal factors i.e. taking into account what is reasonably achievable. The use of optimisation and BAT could be seen as an attitude of doing as good a job as reasonably possible in creating a safe repository. As in other areas, where BAT and optimisation are applied, the words "reasonably possible" means that due consideration should be given to economical and other societal factors. Furthermore, in most programmes there is still more focus on demonstrating existence of technical solutions, but not to irrevocably freeze them. As a result, and although safety is a major criterion, optimisation has not necessarily been accomplished to the end. Depending on the progress made in knowledge, ways of improvement are possible and could be developed in later phases of the projects.

Regarding site selection, the question whether "the best" site (from the point of view of long-term safety) or a site that offers "sufficient" safety should be sought is still under debate in many countries. However, it may be noted that in Finland it was argued, and accepted, that the selected site (Olkiluoto) was at least as good a site as the other site alternatives studied. In Sweden, authorities accept the voluntary participation in SKB site investigations on part of the municipalities as a societal boundary condition.

Given the stepwise developments, regulatory decisions about BAT could only be made at the time of a license application. The developer would then not be in a position to finally claim optimisation and use of BAT until much of the iterative development work has been finalised. At earlier stages, the discussion of optimisation and BAT is rather a framework for discussing feedback to remaining development needs.

Compilation of answers

Many programmes do not formally require application of Best Available Technology (BAT). Ondraf/Niras notes that at the moment, the concept of BAT is not formally used in the Belgian programme. Claims of long-term safety submitted to support a licence application may be evaluated by the CNSC using factors that include nationally and internationally accepted best practices. Although OPG notes that application of "best available techniques" is not a requirement. RAWRA has not yet applied BAT. BfS notes that the design of repository – a former salt mine – the amount of waste and the disposal technique applied before 1991 had to be accepted as a given fact for the safety case because of the special historic circumstances. According to GRS-Cologne the proposal for the revision of the German safety criteria require optimisation of radiation protection during the post-operational phase and this is reached when proof has been furnished that the protection objective has been fulfilled and the repository has been designed in line with the state of the art in science and technology, and when the applicant has demonstrated that the planning principles… have been observed. It can be observed that this is not a requirement for best available technique but for a balanced decision according to the state of science and technology. According to USDOE-YMP the BAT concept is implicit in the design of the engineered system and the operational approaches, but it is not a required aspect of the repository programme. The need is to show that the technologies being applied are sufficient to meet the safety and other criteria that do apply to the repository.

Posiva notes that according to the General Safety Requirements (STUK-B-YTO 195, 1999) the planning shall take account of the decrease of the activity of spent fuel by interim storage and the utilisation of best available technology (BAT) and scientific knowledge. A part of the Environmental Impact Assessment carried out in 1997-1999 was devoted to assessment of alternatives and in that context it was argued that geologic disposal by the KBS-3 concept (or its variant) was the best method to deal with spent fuel in Finland and Olkiluoto was at least as good a site as the other site alternatives studied. Apart from the choice of the concept and site, the thinking is that BAT principle should be applied in the same way as the optimisation principle, i.e. taking into account what is reasonably achievable.

Andra notes that the studies to support the Dossier 2005 were conducted within the feasibility stage. The purpose of feasibility is to focus on the existence of technical solutions, but not to irrevocably freeze them. Feasibility, therefore, appeals to the notion of confidence in the assessment over long time scales. This confidence is based on the quality of the technical argumentation in all its aspects: confidence not only in the repository concept, in the data, the models, the analyses, but also in the approach itself, which organises all these technical data into a consistent set, that is, the "safety case" or "safety dossier". The feasibility assessment is thus based on one of the best controlled technologies, but it is still possible to implement another one. As a result, and although safety was a major criterion in the definition of the architectures and their development, their optimisation was not necessarily accomplished to the end. Depending on the progress made in knowledge, ways of improvement are possible and could be developed in later phases of the project.

NUMO has developed repository design philosophy to embody "good engineering practice" and "design factors" to optimise repository concept for a given siting environment. The application of the BAT to the development of repository concepts has been under discussion in this context in NUMO and JAEA, but has not been specified in the programme yet.

According to Swedish regulations (SSI FS, 1998:1) "application of best available technique in connection with final disposal means that the siting, design, construction, operation and closure of the repository and appurtenant system components should be carried out so as to prevent, limit and delay releases from both engineered and geological barriers as far as is reasonably possible. When striking balances between different measures, an overall assessment should be made of their impact on the protective capability of the repository." According to SSI/SKI, the use of optimisation and BAT could be seen as an attitude of doing as good job as reasonably possible in creating a safe repository. As in other areas, where BAT and optimisation are applied, the words "reasonably possible" means that due consideration should be given to economical and other societal factors. One example of such societal boundary conditions in the Swedish programme is the voluntary participation in SKB site investigations on part of the municipalities. A problem in the interpretation of this concept in the particular application of spent nuclear fuel disposal is that there is no obvious existing and comparable application available to set the standard. A possible basis for comparison is the ongoing development of disposal concepts in other countries (even if none of these countries at that time will have a spent fuel repository in operation). A decision whether or not the KBS-3 concept comply with the principle of "best available technique" have to be made after the evaluation of the application that SKB is expected to submit in 2009. SKB notes that the development of a repository system is carried out in steps, with safety evaluations at appropriate points of the development. According to SKB, this means that the developer is not in a position to finally claim optimisation and use of BAT until much of the iterative development work has been finalised. At earlier stages, the discussion of optimisation and BAT is rather a framework for discussing feedback to remaining development needs.

In the United Kingdom, the regulation of radioactive waste discharges and disposals is governed by two optimisation concepts which, taken together, are regarded as the equivalent of BAT. These concepts are best practicable environmental option (BPEO) and Best Practicable Means (BPM).

Nagra notes that the relevant Swiss regulation HSK R-21 (HSK & KSA, 1993) does not explicitly mention BAT. However, there is a paragraph related to optimisation ("safety enhancing measures"): "Even if compliance with Protection Objectives 1 and 2 is demonstrated, the radiological consequences from the repository have to be reduced by appropriate measures as far as feasible and justifiable with current status of science and technology. However, owing to the uncertainties involved in determining potential radiation exposure, no quantitative optimisation procedure is required." Regarding site selection, the meaning of BAT should be further discussed. Specifically, the question whether "the best" site (from the point of view of long-term safety) or a site that offers "sufficient" safety should be sought is still under debate.

3.2 Siting and design strategy

According to the NEA Safety Case brochure the siting and design strategies are generally based on principles that favour robustness and minimise uncertainty including the use of the multi-barrier concept, e.g. precautionary principle, reversibility, flexibility principles.

Generally, the applied siting and design principles aim at a repository solution that would ensure safety and compliance with general dose/risk criteria. Some regulators accepts that this is achieved by adequate design of multiple engineered barriers, or favourable site characteristics, or both, whereas others require that the principles of BAT and optimisation are applied both to design and siting, i.e. these regulations require demonstration both of the selection of appropriate design and the selection of appropriate sites. While several barriers are required, strict application of the multi-barrier-principle may not be required, since it could be ambiguous how this principle should apply for a sealed repository. Furthermore, EIA principles usually require a report on both alternative design and site.

Final adjustment of layout adaptation will be done according to the quality of the rock that is found in advancing the construction steps. Post closure monitoring is planned by most organisations but this is not necessarily seen as key component of the safety case. Most allow for retrievability but only few programmes take actions on revising disposal concepts to dramatically facilitate this. Other programmes are against such actions.

3.2.1 Safety related siting and design principles

Generally, adequate siting and design are needed for ensuring safety. Some regulators accepts that this is achieved by adequate design of multiple engineered barriers, or favourable site characteristics, or both, whereas others requite that the principles of BAT and optimisation are both to design and siting, i.e. these regulations require demonstration both of the selection of appropriate design and the selection of appropriate sites. While several barries are required, strict application of the multi-barrier-principle may not be required, since it could be ambiguous how this principle should apply for a sealed repository. Furthermore, EIA principles usually require a report on both alternative design and site. It may also be noted that according to the AkEnd committee in Germany a “repository concept based on a favourable overall geological setting” for which “the geological barriers and the shaft barrier shall form the main barrier” while “the [other] technical barriers have a supplementary function” is considered the preferred option.

Generally, the applied siting and design principles aim at a repository solution that would ensure safety and compliance with general dose/risk criteria.

Several siting principles have been listed by respondents, including:

- Stability and longevity, such that a deep repository is neither strongly affected by societal changes nor by the effects of long-term climate alterations on the ground surface.
- Site characteristics contributing to multiple passive barriers.
- Site characteristics favourable to EBS and high retention (e.g. low hydraulic conductivity and fracture frequency).
- Avoidance of detrimental phenomena.
- Possible to characterise, e.g. sites that are simple and describable by calculation tools.
- Locating the repository at a site where the host rock can be assumed to be of no economic interest to future generations.
- Low population density.
- International guidance (e.g. IAEA).

- Acceptance by local municipality and pre-published procedures for site evaluation and acceptance.
- Siting predetermined or decided politically.

However, other principles have possibly also been applied. Furthermore, the adequacy of some of the principles listed above could possibly be questioned in some programmes. It may also be noted that given the importance of site characteristics in many programmes, site characterisation activities need be given major consideration in the overall development.

The following design principles have been listed by respondents:

- Searching for robustness, e.g. by application of multiple barriers providing multiple safety functions.
- Design with demonstrable safety functions.
- Ensuring operational safety
- Application of well-known techniques
- Searching for long-term isolation and containment in the EBS or isolating rock zone surrounding the repository.
- Locating the repository at a sufficient depth to provide protection against any surface or near-surface processes and human activities.
- Flexibility as regard detailed solutions.
- Passive barriers.
- Consideration of thermal and other functional requirements.
- Final adjustment of layout adaptation will be done according to the quality of the rock that is found in advancing the construction steps.
- Compartmentalisation and solidification of wastes.
- QA procedures for EBS fabrication, repository construction and operation.
- Costs kept within a reasonable bandwidth.
- Development of formal design requirement management systems.
- Application of Multi-Criteria Analysis (MCA) for taking due account of the safety functions and more specifically of the safety reserves the different designs can provide.
- Preservation of information.
- Retrievability.
- Environmental impact.

As noted under siting principles, other design principles have possibly also been applied. Furthermore, the adequacy of some of the principles listed above could possibly be questioned in some programmes. It may also be noted that the design in some cases was already given when a safety case was developed.

Compilation of answers

Generally, adequate siting and design are needed for ensuring safety. The CNSC expects that he applicant demonstrates that the waste management system will maintain its integrity and reliability under extreme conditions, disruptive events, or unexpected containment failure, including inadvertent human intrusion. According to the CNSC, this is achieved by adequate design of multiple engineered barriers, or favourable site characteristics, or both. According to SSI and SKI, the principles of BAT and optimisation are applicable to all steps, including siting, of the development of the repository system that may affect the repository's long-term protective capability. The SKI regulation SKI FS 2002:1 requires that the safety, after the sealing of the repository, should be maintained by a system of barriers. The barriers utilised for providing the long-term safety (SKI FS, 2002:1) need to contribute to containment and/or retention of radioactive substances, either directly or indirectly by protecting other barriers, but the regulation does not explicitly require the application of the multi-barrier-principle, since it could be ambiguous how this principle should apply for a sealed repository. Instead, the SKI regulation requires that the barrier comprise several barriers so that a necessary level of safety is maintained in spite of a single deficiency in a barrier. The SKI regulation SKI FS 2002:1 state that the repository site and repository depth should be chosen so that the geological formation provides adequately stable and favourable conditions to ensure that the repository barriers perform as intended over an adequate period of time. It is also stated that the repository site should be located at a distance from natural resources that are or may be exploited. Furthermore, the Swedish Environmental Code requires a report on both alternative design and site for a nuclear installation. According to the UK/EA, there is no currently agreed national approach to siting in the United Kingdom. Relevant regulatory guidance on the design states that the facility shall be designed, constructed, operated and be capable of closure so as to avoid adverse effects on the performance of the containment system. GRS-Cologne notes that criteria revision is being undertaken in accordance with the principles of the Recommendations of the AkEnd. A "repository concept based on a favourable overall geological setting" for which "the geological barriers and the shaft barrier shall form the main barrier" while "the [other] technical barriers have a supplementary function" is considered the preferred option. The committee has also formulated criteria whose non-fulfilment leads to the exclusion from the site selection procedure and also suggests that areas to be considered have to fulfil several "minimum requirements" relating to permeability, size, depth and long-term stability.

Several siting principles have been listed by implementing respondents, including:

- Stability and longevity, such that a deep repository is neither strongly affected by societal changes nor by the effects of long-term climate alterations on the ground surface. NUMO and JAEA notes that particular consideration is given to the long-term stability of the geological environment, taking into account the fact that Japan is located in a tectonically active zone. The safety concept assumes that major disruptive events can be excluded by site selection. The SKB siting aim at the placing of the repository at depth in a long-term stable geological environment which means that the waste is isolated from the human and near-surface environment.
- Site characteristics contributing to multiple passive barriers. To OPG the natural characteristics of the site proposed for the DGR play an important role in the performance of the DGR. For NUMO and JAEA, geological environments having favourable characteristics for the disposal system provide the basis for repository design. The Nagra siting and design principles aim to ensure robustness in terms of long-term safety. They focus on multiple passive barriers, stability and longevity. (See also design principles).
- Site characteristics favourable to EBS and high retention (e.g. low hydraulic conductivity and fracture frequency). Within investigated granitic sites, SKB aim at selecting candidate repository areas with favourable properties for safety, in particular low hydraulic conductivity and fracture frequency (similar answer by Posiva). To support the NUMO and JAEA safety concept, R&D activities have focused on understanding natural system attributes that favour EBS performance, including relative tectonic stability, low groundwater flux, favourable geochemistry and a low risk of disruptive events. Safety assessment has been conducted for a defined repository system, taking alternative future evolutions of the system into account in order to illustrate the robustness of its intrinsic safety features.
- Avoidance of detrimental phenomena (listed by Nagra, NUMO and JAEA).

- Possible to characterise, e.g. sites that are simple and describable by calculation tools (listed by RAWRA, but surely agreed by many others).
- Locating the repository at a site where the host rock can be assumed to be of no economic interest to future generations. By regulation, RAWRA excluded sites with potential raw materials accommodation. The Posiva site selection process was designed to ensure that the future utilisation of natural resources was not compromised, that groundwater flow conditions were favourable for disposal and that the repository would be located in stable bedrock. SKB note that by locating the repository at a site where the host rock can be assumed to be of no economic interest to future generations, the risk of human intrusion is reduced. According to Nagra a site should be chosen so that any foreseeable resource conflict is avoided and so that there is no conflict with future infrastructure projects that can be conceived at present, in order to minimise the likelihood of future inadvertent human intrusion.
- Low population density. Posiva considered the most suitable areas for repository siting were considered to be those with a low population density.
- International gudiance (e.g. IAEA). Ondraf/Niras has used the international recommendations on siting of deep disposal (IAEA Technical Report Series No. 177, IAEA Safety Series n°54; IAEA Safety Series n°60) and the EC work.
- Acceptance by local Municipality and pre-published procedures for site evaluation and acceptance. Selection of the Bruce site resulted from an approach to OPG by the local municipality. (True for other programmes as well!). NUMO decision to proceed with a volunteering approach was driven by the recognition of the great importance of public acceptance. NUMO developed the stepwise siting procedure and following the NSC guideline, NUMO published the “Siting Factors for the Selection of Preliminary Investigation Areas” in 2002, which discusses how the factors that determine site suitability are determined. These factors are effectively the criteria that will be used to determine the acceptability of a volunteer – or to compare volunteers if there are too many of them to go through to the Preliminary Investigation (PI) stage. The siting factors provide guidance and constraints for safety case development, specifically focused on geological stability in the early stage of repository programme. Siting factors for the later siting stages will be developed and have a similar role for future safety case development. Based on the constraints given by the siting process, NUMO has adopted an approach that aims to maximise the flexibility to tailor repository concepts to the diversity of suitable siting environments which may be found and to encourage involvement of local communities in decision making.
- Siting predetermined or decided politically. BfS notes that siting was predetermined.

Furthermore, USDOE-YMP notes that a formal siting guidelines publication was promulgated as a regulation, and the proposed repository was evaluated against those guidelines leading to a formal decision by the Secretary of Energy, the U.S. Congress, and the President, designating Yucca Mountain as the national repository for high-level waste and spent nuclear fuel in 2002. It may also be noted that given the importance of site characteristics in many programes, site characterisation activities need be given major consideration in the overall development. OPG notes that site characterisation activities have been given major consideration in the overall development of the DGR. The technical approach to address these topics is defined in a Geoscientific Site Characterisation Plan (SCP).

The following *design principles* have been listed by respondents:

- Searching for robustness, e.g. by application of multiple barriers providing multiple safety functions. Posiva applied the multi barrier principle to enhance the robustness of the system in case of defect in a single barrier. Radionuclides released from a defective canister undergo retention, retardation and dilution by other barriers in particular slow release from the spent fuel, slow aqueous diffusive transport in the buffer and slow transport in the geosphere. Andra applies the robustness principle and notes that it means that the characteristics of the repository components must be such that they can guarantee maintaining their functionalities against reasonably imaginable disturbances despite residual uncertainties. Generally, the concepts retain the solutions which are as robust as possible against external disturbances and uncertainties. The system is long-term safe in a robust way (BfS, GRS-B and Colenco). Long-term safety ensured by the robustness of the post-closure safety case is a key design factor for NUMO. Due to Japan's complex geology, an engineered barrier system (EBS) with sufficient margins in its isolation functions to accommodate a wide range of geological environments and their potential future states was developed in H12 (NUMO and JAEA). However, in NUMO strategy for iterative development of the basic repository concept as the process of site selection and characterisation progresses each of the identified "design factors", not only long-term safety, is examined in order to assemble a repository design option. SKB applies the use of multiple barriers (canister, buffer and host rock) providing multiple safety functions (isolation and retardation broken down into a number of lower level functions). (Similar answer by Nagra).

- Design with demonstrable safety functions. Andra selects the repository concepts so that their safeness can be checked as easily as possible and without calling for complex demonstrations subject to caution, but notes that demonstrability is a relative notion and that the simplicity of a check is not a goal in itself. One design principle of BfS is that safety can be demonstrated. SKB have selected materials so that their long-term properties are verifiable.
- Ensuring operational safety, i.e. both conventional and radiological safety of construction, operation, closure and decommissioning (listed by NUMO and JAEA, but certainly applies to most all other respondents as well).
- Application of well-known techniques. One design principle by BfS is that well-known techniques are applied. Design factors considered by NUMO include: engineering feasibility/ quality assurance; fundamental feasibility of construction and operation to defined quality levels; engineering reliability: practicality of implementation in view of boundary conditions (e.g. emplacement rate) and robustness with regard to operational perturbations. The SKB engineered barriers are made of naturally occurring materials that are stable in the long term in the repository environment.
- Searching for long-term isolation and containment in the EBS. In the Posiva case the safety of the disposal is based mainly on long-term isolation and containment of radionuclides in the copper iron canisters.
- The barriers are passive, i.e. they function without human intervention and without artificial supply of matter or energy (noted by SKB).
- Locating the repository at a sufficient depth to provide protection against any surface or near-surface processes and human activities: Posiva (as well as SKB) will locate the repository at sufficient depth to provide protection against any surface or near-surface processes and human activities.
- Consideration of thermal and other functional requirements. Posiva notes that as part of the repository design, dimensioning analyses should include thermal analyses covering the thermal evolution of the repository system, thermo-mechanical analyses and thermo-hydro-mechanical analyses to study the behaviour of the EBS system in transient phases. Furthermore, Posiva rock suitability criteria considers respect distances to fracture zones

with potential of causing larger movement than 0.1 m in case of postglacial earthquakes, respect distance to major water-conducting fracture zones, groundwater salinity, rock mechanical properties, thermal properties etc. The repository is designed by SKB so that temperatures that could have significant detrimental effects on the long-term properties of the barriers are avoided. Canisters deposition holes must follow respect distances from major deformation zones and must not be intersected by too large fractures.

- Flexibility as regard detailed solutions and allowing for new techniques. A flexible strategy (horizontal/vertical, two disposal stores) in the design proposal has been applied, by RAWRA. In the phase of the evaluation of basic design alternatives BfS included the use of new techniques. The NUMO structured approach provides a procedure to develop repository concept considering advances in technology, science as well as changing requirements from stakeholders.
- The final adjustment of layout adaptation will be done according to the quality of the rock that is found in advancing the construction steps. Posiva has established a method for evaluating the suitability of the site during the course of its construction by comparison of the anticipated conditions with those subsequently measured underground. The final rock volumes and position of tunnels and deposition holes will be designed following pre-determined rock suitability criteria. However, the final adjustment of layout adaptation will be done according to the quality of the rock that is found in advancing the construction steps.
- Compartmentalisation and solidification of wastes. According to Nagra a repository design, where in the case of intrusion only a small part of the repository is affected, is beneficial. This can be achieved by compartmentalisation; i.e. each SF/HLW waste package forms an isolated compartment with no hydraulic shortcut to the next one and waste emplacement tunnels are widely spaced.
- QA. SKB currently develops QA procedures for canister fabrication, repository construction and operation.
- Preservation of information. Nagra notes that measures must be taken to ensure that information regarding the purpose, location, design and contents of the repository are preserved so that future generations are made aware of the consequences of actions they may choose to take that might affect the performance of the disposal system.
- Costs kept within a reasonable bandwidth. One design principle applied by BfS is that the costs for closure of the repository will be kept within a reasonable bandwidth. NUMO considers socio-economic aspects, i.e. factors contributing to costs and acceptance by all key stakeholders.
- Development of formal design requirement management systems: With respect to design principles, DGR Conceptual System Requirements are under development by OPG. This document will direct development of all aspects of the engineering components of the DGR. The RMS and KMS developed by NUMO and JAEA respectively, have similar objectives.
- Application of Multi-Criteria Analysis (MCA): In preparation of the SFC 1, Ondraf/Niras is currently developing a formal design requirement management system. For the selection of the reference design (supercontainer design) a Multi-Criteria Analysis (MCA) was conducted taking due account of the safety functions and more specifically of the safety reserves the different designs can provide.
- Retrievability, i.e. ease of waste package retrieval after emplacement (NUMO).
- Environmental impact: extent of all environmental impacts associated with repository implementation (NUMO).

As noted under siting principles, others design principles have possibly also been applied. Furthermore, the adequacy of some of the principles listed above could possibly be questioned in some programmes. Finally, it could be noted that the design of the repository and particularly the position of the emplacement chambers within the former mine were already given when BfS, GRS-B and Colenco developed the safety case.

3.2.2 Monitoring and retrievability

Some regulations require post closure monitoring and may also see that some facilities, such as surface impoundments for tailings, may need to rely on institutional controls for a more extended period of time. In contrast, other regulations have no requirements explicitly connected to monitoring or retrieval. If provision were to be made for waste retrieval, it would be very important to consider the overall safety implications. It is implied that such measures should have a minor or negligible influence on repository safety to be permissible.

Post closure monitoring is planned by most organisations. However, this is not necessarily seen as key component of the safety case. Some see retrievability as an important argument leaving future generations the ability to make decision about the repository process (reversibility). Most allow for retrievability at least during the operational phase and note that it is usually possible also in the post closure phase. Among respondents there is generally no action taken on revising disposal concepts to dramatically facilitate waste retrieval, although some note that retrieval is easier during early parts of the post close phase.

Compilation of answers

CNSC recognises that in spite of design optimisation, some facilities, such as surface impoundments for tailings, may need to rely on institutional controls for a more extended period of time. Any intention of relying on institutional controls to ensure long-term safety should be documented and justified in the long-term assessment. In contrast, SSI/SKI have no requirements explicitly connected to this. However, a paragraph in SKI FS 2002:1 states that measures adopted to facilitate monitoring and retrievability should be analysed and reported. It is implied that such measures should have a minor or negligible influence on repository safety. Furthermore, the Act on Nuclear Activities clearly implies that repository should be constructed for final disposal rather than storage. In the United Kingdom, there is a regulatory requirement for monitoring to address the changes caused by construction and waste emplacement. There is no regulatory requirement to facilitate waste retrieval, although this approach is advocated by Nirex and has been considered by the Committee on Radioactive Waste Management. If provision were to be made for waste retrieval, it would be very important to consider the overall safety implications. GRS-Cologne notes that no requirement for retrievability is made. It is however required that, if any provision for retrievability will be implemented, this must not compromise post-closure safety.

Retrievability is at the moment not a formal requirement for a repository for HLW and spent fuel, but is seen by Ondraf and Niras as an element of flexibility.

The Posiva disposal is planned so that no monitoring of the disposal site is required to ensure the long-term safety. Best available technology will be applied. The retrievability of the waste is maintained.

Regarding the reversibility, beyond the ability of removing already emplaced waste packages, Andra concept of reversibility means (i) the possibility of gradual and “flexible” operation of the repository process, leaving future generations the ability to make decision about the repository process; and (ii) the ability to make evolving the repository design during the repository process.

Accordingly, the repository process is broken down into successive stages by allowing for an observation period, before deciding to keep the installation as it is, to go ahead on to the next stage or backwards to the previous stage.

NUMO and JAEA note that NSC and NISA require retrievability until the repository is closed. NSC also requires monitoring at each step from the beginning of the site characterisation up to decommissioning of the repository. These requirements should be considered in siting and design principles.

SKBs final approach to monitoring has not been established. The safety case is, however, not based on any (potential) information form monitoring of a sealed repository. The KBS-3 method does allow retrieval. However, no particular measures are taken to facilitate retrieval.

The Nagra repository concept conforms to the recommendations of EKRA and the Swiss Nuclear Energy Law, and involves an extended period of monitoring, during which retrieval of the waste is relatively easy, and the emplacement of a representative fraction of the waste in a pilot facility to test predictive models and to facilitate the early detection of any unexpected undesirable behaviour of the system should this occur. Thus, opportunities are provided for review and possible reversal of decisions, including the retrieval of emplaced wastes.

According to USDOE-YMP monitoring will be conducted during operations, and after permanent closure. Retrieval is to be possible during operations, but need not be possible after permanent closure of the repository.

3.2.3 Guidelines or criteria for waste conditioning and waste acceptance

While regulators may comment on waste conditioning and waste acceptance requirements developed by the implementer a final thorough and comprehensive evaluation will not be done until a license application has been submitted. The regulators may impose additional conditions if a license is given.

All programmes with heat producing waste have some thermal requirements. These are generally defined as maximum allowed heat output or maximum allowed temperature (in a specified repository environment). Examples of other listed requirement include, a solid waste form, each of the waste packages must have a well-defined radionuclide and material inventory that is known with reasonable accuracy, and design of waste canisters and arrays of waste canisters to ensure nuclear sub-criticality.

Compilation of answers

SSI and SKI note that detailed requirements such as maximum allowed thermal output for each canister are currently being developed by the implementer SKB. They will be commented on by the regulators in the context of safety assessment review, but a final thorough and comprehensive evaluation will not be done until a license application has been submitted. Additional conditions may be imposed by the regulators if a license is given. For operational waste, waste acceptance criteria for disposal in the SFR repository are sometimes being revised and developed by SKB and reviewed by the authorities, but this is considered outside the scope of this questionnaire response. UK/EA expects waste producers to assess the suitability of any waste products for ultimate disposal. For importation of any radioactive waste Swiss law require an importation licence. GRS-Cologne notes that according to the draft safety requirements the applicant has to specify requirements for the respective types of radioactive waste to be emplaced.

Thermal requirements are put on waste packages for heat producing waste, i.e. containing HLW and spent nuclear fuel. Ondraf and Niras note that HLW waste packages are designed to respect thermal limitations, e.g. number of spent fuel assemblies placed in a disposal container. RAWRA requires that the temperature on the interface canister/filling shall not exceed 90°C. Posiva thermal dimensioning is done adjusting the heat power per canister and the spacing of the deposition holes and tunnels SKB limits the maximum heat output from the waste packages to 1 700 Watts. Nagra has defined the maximum thermal power of waste packages. USDOE-YMP notes that the heat output from waste packages will need to meet criteria set for container surface temperature and for rock wall heating. GRS-Cologne notes that either the radionuclide concentration within the waste package has to be limited or the emplacement density of the waste packages has to be adapted in a way that temperature limits resulting from the design requirements for the repository and the host rock are kept, taking into account the planned configuration in the repository.

Several require a solid waste form. Ondraf/Niras' system of waste acceptance criteria specify that the end-product of waste processing and conditioning should be a solid waste form (excluding free liquids), and has to be compatible with the disposal environment). The USDOE-YMP waste acceptance criteria specify only solid wastes and that all commercial spent nuclear fuels and defence-related borosilicate glass wastes will be accepted. RAWRA requires waste to be solidified, containing no liquids and dangerous substances. GRS-Cologne notes that waste is to be disposed of in solid or solidified form. No self-inflammable or potentially explosive waste packages must be emplaced.

The basic principle of Atomic Energy Commission of Japan for conditioning of high-level radioactive waste from a reprocessing plant is to solidify it into a stable form. The Act defines "specified waste" as HLW from reprocessing and this is where all NUMO efforts are concentrated. The planned development programme for a first HLW repository is based on an assumed capacity of 40 000 waste packages each containing 150 litres of vitrified waste, corresponding to reprocessing of all spent fuel expected to be produced up to 2020. The specification of an inventory of at least 40 000 waste packages is seen as a sensible goal (covering a major part of the wastes produced by the current generation of nuclear power plants). A 40 000 package inventory is thus used as a planning basis, but flexibility for optimised utilisation of a suitable site is explicitly considered.

Nagra requires design of waste canisters and arrays of waste canisters for spent fuel to ensure nuclear sub-criticality (in conjunction with a requirement for minimal burnup of the spent fuel). Nagra also notes that criticality is mainly an issue in the context of disposal of spent fuel. Nagra also requires that each of the waste packages must have a well-defined radionuclide and material inventory that is known with reasonable accuracy. GRS-Colgne notes that criteria require the emplacement concept and the admissible proportion of fissile material in the waste to be specified in a way that the waste packages remain sub-critical.

OPG will require overpacking packages showing signs of deterioration so that they can be handled safety and so that retrievability is ensured for sufficient period. No liquid wastes or explosive materials are stored on an interim storage basis and will not be received at the DGR. OPG notes that the DGR will receive low- and intermediate-level waste, which is not expected to generate significant heat.

Andra has established with the collaboration of waste producer a "knowledge report" describing the level of knowledge from the producer point of views for many parameters (activity for 144 radionuclides for which the life period is over six months, thermal power, mechanical properties..) per each primary waste. Those reports helps in establishing the waste inventory model (MID), which groups wastes primary into reference waste packages in view of focusing the repository development, the safety analysis on to a similar and reasonable number of family of wastes.

Nirex has developed the Generic Waste Package Specification (GWPS) which defines and justifies the standards and specifications that should be used as the basis for the design, assessment and production of waste packages to ensure compatibility with long-term waste management plans, including disposal in the Nirex Phased Geological Repository Concept (PGRC). Certain guidelines or criteria in the GWPS are relevant to the post-closure safety case, including the use of solid grouted wasteforms, the need to exclude free liquids from and minimise voidage in wasteforms. Limits are also imposed on gas generation, maximum heat output and the fissile material content of waste packages.

Nagra has also prepared a number of documents containing detailed waste specifications (and assessments of operational and long-term safety) to support applications to import various reprocessing wastes (vitrified HLW, long-lived ILW).

3.3 Assessment strategy

According to the NEA Safety Case brochure, the assessment strategy must ensure that safety assessments capture, describe and analyse uncertainties that are relevant to safety, and investigate their effects.

In fact, uncertainty assessment is a key component of most safety assessments. Approaches taken essentially follow those listed in the brochure, but the approach of using function indicators as a tool for scenario selection is possibly a new development. In most assessments deterministic and probabilistic calculations are seen as complementary and both approaches are adopted. Actually applied FEP exclusion criteria generally concern low likelihood to occur, if they would have trivial impact or if regulatory provisions exclude them. Most regulators, but not all, accept a separate treatment of future human action scenarios. Many, but not all assessments consider the risk of the intruder. Conservative assumptions are acceptable to handle situations where knowledge is lacking or phenomenon is poorly understood. Model evaluation should include sensitivity analyses as well as uncertainty and importance analysis to show which parameters control the variability in model output. Most implementers apply some alternative models, but possibly, the depth of consideration of alternative models is a matter of argument between implementer and regulator.

Regulators generally accept stylised approaches for assessing aspects of scenario analysis, for assessing future human actions and for assessing the biosphere evolution. However, the extent of stylising is still a matter for interpretation. Most consider “what-if” cases, usually postulating loss of barrier function(s). However, their rationale, as well as the view whether they lie outside the risk contribution slightly varies between respondents. Several examples of handling diverse opinions are applied.

3.3.1 Management and treatment of uncertainty

Management and treatment of uncertainty is a key regulatory concern. A formal uncertainty analysis of the predictions to identify the sources of uncertainty is needed. A consistent and structured way of describing and handling of uncertainties is required. The developer will need to demonstrate that the safety case takes adequate account of all relevant uncertainties, and the regulatory guidance does not specify the approach that must be followed.

Uncertainty assessment is a key component of most safety assessments. However, it is still an issue under development in some programs. It may also be noted that appropriate site selection, in particular in terms of the long-term stability of geological environments, and repository design based on reliable technology are keys to minimise uncertainties in the long-term performance of the system. Nevertheless, uncertainty can never be completely eliminated. In this regard, multiple lines of arguments independent from safety/performance assessment are essential to enhance confidence.

Cited examples of handling scenario and system uncertainty include:

- Broad range of scenario selection, including assessment of highly unlikely "what-if" cases to explore the robustness of the system.
- Comprehensive assessment of FEPs through a structured and systematic approach, including QA and internal review or bias audit groups.
- Using safety functions as a tool for a structured approach to scenario selection.

Main examples of handling model uncertainty include:

- Structured and quality assured approach for assessing and documenting scientific understanding of processes and their modelling in the safety assessment in special process reports or knowledge reference documents
- Formulation of alternative conceptual models – selection of conservative assumptions.
- Applying both detailed mechanistic models and more simple assessment or insight models as well as alternative modelling approaches.

Cited examples of quantifying data uncertainty include assessing and documenting data and data uncertainties systematically according to established routines and reviews. Uncertainty is quantified both as probabilistic distributions and by providing best estimate and conservative values. A few organisations apply formal elicitation in which measured values are supplemented by the judgement of suitably qualified and experienced experts on the basis of various research data, and can take into account any scarcity of data, uncertainty or bias from measurements. Sensitivity analyses with deterministic models and uncertainty analyses (probabilistic analysis) are the cited means of assessing the impact of data uncertainty.

Compilation of answers

CNSC expects a formal uncertainty analysis of the predictions to identify the sources of uncertainty. This analysis should distinguish between uncertainties arising from input data; scenario assumptions; the mathematics of the assessment model; and the conceptual models Posiva notes that in accordance with the Government Decision on the safety of the disposal of spent nuclear fuel (Government of Finland, 1999), a safety assessment shall include uncertainty and sensitivity analyses and complementary discussions of such phenomena and events which cannot be assessed quantitatively. The SKI guidance (SKI FS, 2002:1) suggests that evaluation of uncertainties is a key component of safety assessment work. A consistent and structured way of describing and handling of uncertainties is required. The SSI guidance (SSI, 2005) on cut-off times and presentation of the risk analysis reflects the fact that the value of quantitative risk calculations for compliance demonstration will decrease as uncertainties increase with time. A different level of ambition is required the first 1 000 years, the time including a full glacial cycle (i.e. about up to 100 000 years) and times up to 1 million years. According to the UK/EA the treatment of uncertainty is central to the establishment of a post-closure safety case. The developer will need to demonstrate that the safety case takes adequate account of all relevant uncertainties, and the regulatory guidance does not specify the approach that must be followed. GRS-Cologne notes that in the draft safety requirements it is demanded that the implementer – in the course of stepwise repository development and optimisation – establishes a consistent uncertainty management. He should, as part of the safety case at each step, present statements on the uncertainties not resolved so far, their relevance for safety, and approaches for their further treatment e.g. by further R&D work or by robust repository design. At each step, identified uncertainties have to be accounted for in the long-term safety demonstration. It has to be distinguished between scenario, model and parameter uncertainties, being aware that such a categorisation is always somewhat arbitrary, subjective and dependent on the chosen modelling and assessment approaches.

No distinction will be required between so-called subjective and so-called stochastic uncertainties. Nevertheless, the implementer is asked to provide a clear discussion of the sources of each uncertainty and to analyse their sensitivity with regard to performance and safety. For uncertain parameters or assumptions amenable to quantification, either conservative choices are to be made or reasonable probability density distributions are to be derived. In either case, decisions have to be justified and to be documented in a traceable manner. For each likely or less likely scenario to be considered in assessment calculations, a probabilistic uncertainty analysis has to be carried out.

Uncertainty assessment is a key component of most safety assessments. OPG recognise uncertainty in the long term in the safety case by development of a range of quantitative and qualitative arguments for safety. Andra takes provisions, by choice of a very stable geological medium and by compartmentalisation of the repository into zones to prevent interactions between various kinds of waste, which would allow overcoming uncertainty consequences. Uncertainties are systematically investigated and their potential effects are examined, particularly in qualitative safety analyses. Uncertainty assessment is a key aspect of the SKB SR-Can work. Nirex notes that a systematic and adequate treatment of uncertainties in a performance assessment is essential and in the United Kingdom the regulatory guidance would tend to favour a probabilistic approach. Nirex has tended to fulfil this requirement by conducting PSA studies and by considering a range of scenarios. Nagra investigated the impact of uncertainties in Project Opalinus Clay by considering a range of possibilities for system evolution sufficiently wide to cover all reasonable future evolutions. These were analysed by the use of alternative conceptual models and by the use of alternative parameter sets, leading to a large number of assessment cases. NUMO and JAEA take a bounding approach, involving selecting a set of scenarios for possible evolution of the system, applying a range of possible alternative conceptual models and selecting conservative data. The general methodology internationally developed has been used, with specific features depending on the Japanese disposal system. They also note that appropriate site selection, in particular in terms of the long-term stability of geological environments, and repository design based on reliable technology are keys to minimise uncertainties in the long-term performance of the system. Nevertheless, uncertainty can never be completely eliminated. In this regard, multiple lines of arguments independent from safety/performance assessment are essential to enhance confidence.

However, it is still an issue under development in some programs. Ondraf/Niras notes that as this aspect was not treated in a systematic and satisfactory manner in SAFIR 2, this is seen as one of the major challenges in the preparation of the SFC 1 (work in progress). In the actual stage of the programme, RAWRA has not adopted any obligatory strategy for treating uncertainty. By regulation, no restrictions exist in this point.

Cited examples of handling *scenario and system uncertainty* include:

- Broad range of scenario selection, including assessment of highly unlikely “what-if” cases to explore the robustness of the system: OPG assesses a range of scenarios including a less likely scenarios and “what-if” scenarios. Posiva illustrates significance of barrier functions by means of bounding and “what if” analyses. SKB uses bounding calculation cases to explore the robustness of the system to the effects of alternative ways of selecting scenarios, including unrealistic scenarios that can put an upper bound on possible consequences. BfS/GRS-B/Colenco makes a pessimistic definition of the scenarios, e.g. with respect to time and rate of brine inflow into the mine. Nagra arranged cases into discrete groups dealing with the reference scenario, release of radionuclides via the gas pathway, “what-if?” situations to illustrate the robustness of the system, design/system options and different (stylised) possibilities for future human actions and for the characteristics and evolution of the biosphere. GRS-Cologne notes that the choice of scenarios with highly speculative character, namely of those assuming direct human intrusion, will be guided in the guidelines which are presently being developed. In H12, scenarios are classified into the Base Case scenario, Perturbation scenarios and Isolation Failure scenarios. Some of the Isolation Failure scenarios are evaluated as a what-if type scenario. Assessment cases are defined in each scenario category (NUMO and JAEA).

- Comprehensive assessment of FEPs through a structured and systematic approach, including QA and internal review or bias audit groups: SKB generally handles system uncertainty through the proper management of FEPs in the SR-Can FEP database according to established routines. Influences between processes are handled, in the Process reports, by systematically going through a set of defined physical variables that could mediate influences and by the systematic treatment of boundary conditions for each process. In Project Opalinus Clay, Nagra established a bias audit group with a number of well-defined tasks (e.g. to minimise the possibility that some important FEPs might have been overlooked, to ensure that all relevant scientific understanding was taken into account in the definition of assessment cases, to ensure that the information and computer codes used in the safety assessment were appropriate, etc.). GRS-Cologne notes that uncertainties concerning potential future evolutions of the repository system are addressed by requiring a well-structured procedure for the development of scenarios in order to ensure that a comprehensive set of reasonable scenarios will be considered. The procedure should make use of national and international FEP databases and ensure the traceability of every decision made during the development process. In Nirex approach any FEPs not considered within the base scenario must either be screened from the assessment basis (with a justification for their irrelevance or insignificance) or considered within a variant scenario. However, consideration within a variant scenario does not necessarily imply explicit representation of a specific FEP, many FEPs have a similar impact on system performance. NUMO and JAEA acknowledge the provision of a comprehensive FEP (features, events and processes) as a starting point to develop scenarios for performance assessment.
- Using safety functions as a tool for a structured approach to scenario selection: SKB handles scenario uncertainty is through a structured and logical approach based on: the use of safety function indicators in order to focus the selection on safety relevant issues; QA measures to ensure that all FEPs have been properly handled in the assessment; and independent internal reviews.

Main examples of handling *model uncertainty* include:

- Structured and quality assured approach for assessing and documenting scientific understanding of processes and their modelling in the safety assessment in special process reports or knowledge reference documents: Andra made up knowledge reference documents in order to provide a complete view of the scientific understanding on the following studied components: geological medium, engineered materials, packages, etc. They describe the state of knowledge, correlatively identify the lack of knowledge and thus contribute in determining the sources of uncertainty and orienting the actions to reduce them. Once a good level of knowledge is reached on each component and the global architecture is defined, the evolution of the repository over space and time is described as finely as possible. The systematic work led to a list of uncertainties (on phenomenology, models, data, component characteristics...). SKB essentially handles conceptual uncertainty for internal processes in the Process reports. For each process, the knowledge base, including remaining uncertainties, is described and, based on that information, a handling of the process in the safety assessment is established. GRS-Cologne notes that the conceptual, mathematical and numerical models (including codes) to be used in the assessments shall be developed according to established quality assurance procedures. Verification, validation and confidence building shall be carried out according to the state of the art in science and technology.

- Formulation of alternative conceptual models – selection of conservative assumptions. GRS-Cologne notes, that if there are doubts concerning modelling assumptions or with regard to the presence and/or nature of processes, alternative assumptions shall be explored. If possible, conservative assumptions should be used and/or the robustness of the system against such uncertainties should be demonstrated. (For other respondents, see responses in Sections 3.3.5 and 3.3.7). In H12, deterministic analyses are performed using an altered model from the model, which is used at the reference case (NUMO and JAEA).
- Applying both detailed mechanistic models and more simple assessment or insight models as well as alternative modelling approaches: OPG applies a suite of assessment models, both simple and detailed. According to Posiva employing of relatively simple deterministic models facilitates comprehensive uncertainty analyses. BfS employed two contractors using different codes and, as a consequence, partially different models. Nagra employed both detailed mechanistic models and more simple assessment or insight models as well as alternative modelling approaches (e.g. in the case of spent fuel dissolution, where two different process models were employed to generate time-dependent fuel dissolution rates as input to the assessment model).

Cited examples of quantifying data uncertainty include:

- Assessing and documenting data and data uncertainties systematically according to established routines and reviews. SKB handles data uncertainties according to established routines described in the data report. Quality assurance is obtained through the use of a template for data uncertainty documentation, through clearly defined roles for participating experts and generalists and by the use of external reviews prior to finally establishing input data for the assessment. Similar to SKB, Nagra handles data uncertainties according to established routines described in the safety report.
- Nirex quantifies uncertainties in data in terms of "probability density functions" (PDFs) that give the relative likelihood of different parameter values. The PDFs can be based solely on measured values, or, more usually, are generated at a formal elicitation in which measured values are supplemented by the judgement of suitably qualified and experienced experts on the basis of various research data, and can take into account any scarcity of data, uncertainty or bias from measurements.
- Data uncertainties are quantified considering both as probabilistic distributions or by providing best estimate and conservative values. Posiva quantification is based on systematic combinations of the best-estimate and conservative parameter values. RAWRA usually adopts the conservative approach in data application, and probabilistic method is used for sensitive data application as migration parameters.

Sensitivity analyses with deterministic models and uncertainty analyses (probabilistic analysis) are the cited means of assessing the impact of data uncertainty. OPG performs sensitivity analyses, and uses both probabilistic and deterministic treatments. BfS/GRS-B/Colenco varied single parameters deterministically in order to investigate the influence of the specific parameters. A global uncertainty and sensitivity study is performed by assigning a distribution function to every parameter and performing a probabilistic safety analysis. In H12 deterministic analyses are conducted using varied parameters from those used at the reference case analysis (NUMO and JAEA).

3.3.2 Probabilistic/deterministic

From a regulatory perspective deterministic and probabilistic calculations are seen as complementary, even in cases where the acceptance criteria are in terms of risk. However, the approach used should be justified with respect to the assessment context, and should provide results in a form consistent with the form of the acceptance criteria.

In most assessments deterministic and probabilistic calculations are seen as complementary and both approaches are adopted. Probabilistic methods provide a mathematical means of handling the wide range of uncertainties and spatial variability in input data. Since the impact of a parameter can be completely different under different conditions (non-linearity of the system), deterministic variation of single parameters may not be sufficient and a probabilistic assessment can be more appropriate than choosing a "conservative" parameter set. Deterministic cases can provide a clear illustration of the impact of individual uncertainties and design variations. They could also be more efficient when presenting the results to various stakeholders.

Compilation of answers

The CNSC is willing to accept either or both approaches, but the approach used should be justified with respect to the assessment context, and should provide results in a form consistent with the form of the acceptance criteria. SSI regulations (SSI, 1998) specify a risk target for the design of the repository. SSI guidance does not, however, require a strict probabilistic approach to the risk analysis. The UK/EA does not specify any particular approach. In a major safety case for a deep geological facility, it is likely that deterministic and probabilistic approaches would be used where appropriate. According to GRS-Cologne a probabilistic approach is required in order to fully explore the parameter space. Complementary deterministic analyses might be useful in order e.g. to clarify where the "best belief" concerning the conceptualisation is situated in relation to the manifold of realisations, to identify local sensitivities, to investigate realisations with high consequences etc.

To Ondraf/Niras deterministic and probabilistic calculations are seen as complementary and both approaches are adopted. The deterministic approach present advantages when interpreting the results in terms of compliance and when presenting the results to various stakeholders. Probabilistic calculations are a tool for evaluating some type of uncertainties (combined parameter value uncertainty) and sensitivities. Similar answers are given by Posiva, OPG and BfS, GRS-B and Colenco. However, BfS, GRS-B and Colenco also point out that since the impact of a parameter can be completely different under different conditions (non-linearity of the system), deterministic variation of single parameters is, however, not sufficient. The parameter space of the reference scenario is covered by probabilistic calculations in a way that includes selected alternative scenarios. This approach is preferred to the practice of choosing a "conservative" parameter set. To SKB probabilistic calculations are used essentially as a means of handling data uncertainty and spatial variability in the modelling of radionuclide transport and dose. The probabilistic approach is used to address most of the uncertainties in Nirex post-closure assessments of the radiological risk from the groundwater pathway. Statistical analysis of the results of a probabilistic calculation can be used to explore the sensitivity of the performance measure e.g. risk to the uncertain model parameters and is also consistent with current regulatory guidance in the United Kingdom, as an important regulatory requirement is the calculation the expectation value of risk for comparison with the regulatory risk target.

In accordance with the French Safety Rule RFS.III.2.f, Andra mainly adopted the deterministic approach. This is implemented at two different stages; first for the definition of the SEN (normal evolution scenario) and SEA (altered evolution scenario), and then during the scenarios modelling computation and analysis itself. In addition to this main deterministic approach, a preliminary probabilistic study has also been carried out taking into account the simultaneous variation of several parameters. The purpose is to back up the lessons learnt with the deterministic studies and assess the effects of joint variations of several parameters according to probability density functions adopted for each one.

NUMO and JAEA note that a deterministic approach was taken in the H12 approach with some complementary probabilistic calculations. The deterministic approach is mainly adopted as the assessment results can be more transparently interpreted. However, the NSC is discussing on the application of risk-based safety regulation which is based on the disaggregated approach. The discussion on the likelihood of scenarios to be considered in the assessment would be needed more explicitly in the future safety assessment.

The emphasis in Nagra Project Opalinus Clay was on the one-by-one ("deterministic") analysis of assessment cases, since this approach was considered to give a clear illustration of the impact of individual uncertainties and design variants. Probabilistic calculations were, however, also used to explore systematically the consequences of different combinations of parameters that fall within the ranges of uncertainty. In a major safety case for a deep geological facility USDOE-YMP finds it likely that deterministic and probabilistic approaches would be used where appropriate.

3.3.3 FEP Exclusion criteria

From a regulatory perspective the approach and screening criteria used to exclude or include scenarios should be justified and well-documented. Actually applied FEP exclusion criteria generally concern low likelihood to occur or if they would have trivial impact. Methods to make such judgements include expert judgement and screening calculations. Furthermore, FEPs with a positive effect on the safety are excluded when their conceptualisation is very complicated compared to their benefit. Other cited reasons to exclude FEPs are: regulatory provisions exclude them, they are outside the bounds or scope of the safety case or shown to be of no importance by e.g. previous assessments, accepted knowledge, review or audits.

However, some in some assessments the methodology of subsuming replaces that of screening, unless the FEP is considered to be immaterial to the system performance. Subsuming of scenario representations involves considering a specific scenario representation in relation to a more general case. If the specific scenario representation has a conditional risk, which is similar to or lower than the general case it can be subsumed into the general case.

Compilation of answers

From a regulatory perspective the approach and screening criteria used to exclude or include scenarios should be justified and well-documented (CNSC). According to SSI/SKI sufficient justification is needed for the exclusion of FEPs from detailed consideration and expert elicitation and peer review are examples of methods for providing a higher level of assurance that the exclusion is reasonable. Similarly, the UK/EA would require the implementer would to present relevant arguments, which would be reviewed by the regulators. According to GRS-Cologne special consideration should be given to the categorisation of FEPs and resulting scenarios with regard to their relevance for safety functions and their likelihood of occurrence.

Applied FEP exclusion criteria generally concern low likelihood to occur or if they would have trivial impact (CNSC, RAWRA, BfS, NUMO and JAEA, SKB, SSI and SKI, Nagra). Methods to make such judgements include expert judgement and of screening calculations (OPG, Ondraf and Niras, SKB, Nagra, USDOE-YMP). Andra notes that a qualitative safety analysis (QSA) methodology was developed for detailed consideration of FEPs in the Dossier 2005 Argile. A first objective is to identify whether the uncertainties are correctly covered. If some of the uncertainties are not, it must be confirmed that they would have little impact on the repository, or that they refer to very unlikely situations. Furthermore, FEPs with a positive effect on the safety are excluded when their conceptualisation is very complicated compared to their benefit (BfS, SKB, Nagra). Other cited reasons to exclude FEPs are: if regulatory provisions exclude them (Nagra, USDOE-YMP), outside the bounds or scope of the safety case (BfS, SKB, Nagra) or already shown to be of no importance by e.g. previous assessments, accepted knowledge, review or audits (Ondraf/Niras, Posiva, BfS, GRS-B, Colenco, SKB). In H12 FEPs were also screened based on based on suitable site selection or on suitable design (NUMO and JAEA).

In previous studies, Nirex screened scenarios using expert judgement. However, in the current Nirex approach, the methodology of subsuming replaces that of screening, unless the FEP is considered to be immaterial to the system performance. The overall aim is to apply a principle of caution to subsume scenario representations at the highest possible level (for example, into the base scenario whenever appropriate) and hence to treat explicitly only those scenario representations which cannot be subsumed. Subsuming of scenario representations involves considering a specific scenario representation in relation to a more general case. If the specific scenario representation has a conditional risk which is similar to or lower than the general case it can be subsumed into the general case. For example, any variant scenario with a conditional risk less than or equal to the base scenario can be subsumed into the base scenario. This will always be conservative, regardless of the probability of occurrence for the variant scenario, as the base scenario is taken to have probability one.

3.3.4 Scenarios for human intrusion

Most regulators, but not all, accept a separate treatment of future human action or human intrusion scenarios. The purpose of these scenarios is rather to illustrate the impact on the repository's protective capability after the human disturbance and to provide a basis for exploring possible measures. Reasonable efforts should be made to limit the dose from a high-consequence intrusion scenario, and to reduce the probability of the intrusion occurring, but the impacts need not be factored into the overall risk estimates Furthermore, it may be noted that the Swedish regulations, issued by the SSI do not require reporting of risk to the intruder.

Many, but not all assessments consider the risk of the intruder. Some have more focus on the potential impacts on long-term safety due to the fact that a direct pathway from the repository to the biosphere would exist for some time period.

A stylised approached, compared to other scenarios, is usually adopted. However, the word "stylised" may be interpreted differently (see also Section 3.3.8). It may mean accepting a different (higher) risk limit for these scenarios, whereas others note that future human action scenarios need to be stylised, in the sense that the actual mode and likelihood of penetration are not known. It is also suggested that quantitative assessments of risk based on evaluations of frequencies of human activities observed in the recent past are not intended to be predictions of future human behaviour and of its consequences. Rather, by basing them on current technology and behaviour, they provide present-day society with an understandable basis for deciding whether the wastes would be sufficiently isolated and contained. It may also be noted that some organisations still discuss the approach to take with their regulator.

Compilation of answers

According to the CNSC disruptive, events usually cannot be integrated directly into the normal evolution scenario where barriers are assumed to remain intact for their entire design life. Such events, even those that can be predicted to occur once or more during the assessment period, may have to be assessed separately and included in the interpretation of the normal evolution scenarios. Reasonable efforts should be made to limit the dose from a high-consequence intrusion scenario, and to reduce the probability of the intrusion occurring. The SSI and SKI require that future human action scenarios should be reported separately and should not be included in the risk calculations. There is no requirement on the reporting of risk to the intruder. The purpose of these scenarios is rather to illustrate the impact on the repository's protective capability after the human disturbance and to provide a basis for exploring possible measures. In contrast, in current the UK/EA guidance, the approach for human intrusion FEPs is similar to that for other FEPs (based on an estimate of annual individual risk), although the current guidance was written before the advice in ICRP 81. GRS-Cologne notes that according to the developing guidelines treatment is restricted to those activities which unintentionally influence or shortcut the isolation capability. A number of reference scenarios are given by the guideline the derivation of which was based on present-day standards in Germany concerning e.g. drilling and mining. The emphasis lies not on risk to the intruder but on consequences to the environment. Presently, no numerical limits or targets are given for the assessment results and this issue is still under discussion.

Many (e.g. OPG, Andra, BfS, GRS-B, Colenco, NUMO, JAEA, Nirex) but not all (SKB, Nagra, USDOE-YMP) assessments consider the risk of the intruder. Andra also assessed consequences to the individuals of a hypothetical critical group exposed in the medium or long term, directly or not, to contaminated water. Nirex also considered a second scenario representation (the "site occupier scenario") concerning the distribution of spoil from the exploratory drilling operations onto the land surface in the vicinity of the borehole site, with the potentially exposed group defined to be individuals who occupy the site after the end of drilling activities and make use of the land for growing food.

H12 (NUMO and JAEA) as well as Nagra also focuses on the potential impacts on long-term safety due to the fact that a direct pathway from the repository (or, in the most extreme case, from a spent fuel canister) to the biosphere would exist for some time period. This is the only aspect assessed by SKB. USDOE-YMP focuses on the potential dose receptor prescribed by regulation and do not consider the intruder.

A stylised approached, compared to other scenarios, is usually adopted. OPG applies a stylised treatment since this is a disruptive event. RAWRA considers this an emergency scenario of a low probability and a higher limit is applied. According to Posiva this is an unlikely disruptive event that has to be assessed in accordance with the regulatory Guide YVL 8.4 (STUK, 2001). Based on feedback from Andra experience, analysis of situations taken into account internationally, and the recommendations of basic safety rule RFS III.2.f, Andra has identified human intrusion as being beyond the scope of the normal evolution scenario and its sensitivity analyses. With respect to the Basic Safety rules, it is supposed to take place as soon as the repository memory is lost, i.e. 500 years. BfS notes that the resulting risks for human intrusion and for natural evolutions (including future near surface human actions) are evaluated differently. The protection objectives given for natural evolutions need not strictly be met by human intrusion scenarios. Rather than attempt to assess the overall impact of societal/technical/scientific change on the likelihood of inadvertent intrusion, the present NUMO and JAEA discussion assumes the continuation of the current social, technical and scientific environment into the future and a stylised drilling scenario has been taken for the assessment of human intrusion. Such a stylisation on human intrusion is significantly different from the approach to other types of FEPs. SKB notes that the future human action scenarios are by necessity more stylised than most of the naturally occurring phenomena that could affect the repository. USDOE-YMP applies a stylised treatment of human intrusion.

According to Nagra, the cases considered in the evaluation of the effect of human intrusion on the general population were judged to span a reasonable range of possibilities, although they may be seen as stylised, in the sense that the actual mode and likelihood of penetration are not known. The results illustrated the robustness of the system even in the face of human intrusion cases (Nagra, 2002a).

Nirex notes that risks from human intrusion may be evaluated by considering the range of scenarios that may be associated with human actions and identifying the relevant potentially exposed groups at risk from exposure to radiation for each scenario and that the probability of each scenario occurring can be evaluated by estimating the probabilities of the events which give rise to the scenario. However, given the difficulty in predicting future human behaviour the approach is to develop scenarios based on current technology and patterns of behaviour in the locality of the site or, in the absence of suitable information, at similar locations. The modes of intrusion considered are those that might occur given present economic needs and technology and the current pattern of resource exploitation. Thus quantitative assessments of risk are based on evaluations of frequencies of human activities observed in the recent past. Such assessments of risk are not intended to be predictions of future human behaviour and of its consequences. Rather, by basing them on current technology and behaviour, they provide present-day society with an understandable basis for deciding whether the wastes would be sufficiently isolated and contained.

Some still discuss approach. Human intrusion is a subject of detailed discussions between Ondraf, Niras and FANC & AVN, in view of the development by the safety authorities of a regulatory framework and guidance for disposal (both surface and deep disposal).

3.3.5 Conservative assumptions – rationale

From a regulatory perspective conservative assumptions are acceptable to handle situations where knowledge is lacking or phenomenon is poorly understood. However, it needs to be demonstrated that the net effect of all assumptions leads to overestimation of dose/risk. Furthermore, a movement away from conservative assumptions as more information becomes available is expected, since unduly conservative modelling approach might not be so appropriate when considering optimisation.

Implementers have similar views. Generally, conservative assumptions are applied where knowledge is lacking or phenomenon is poorly understood. However, it is noted that the degree of conservatism is a compromise between, e.g. comprehensibility of the conceptualisation and demonstration of safety.

Compilation of answers

From a regulatory perspective conservative assumptions are acceptable to handle situations where knowledge is lacking or phenomenon is poorly understood. However, it needs to be demonstrated that the net effect of all assumptions leads to overestimation of dose/risk. Furthermore, a movement away from conservative assumptions as more information becomes available is expected, since unduly conservative modelling approach might not be so appropriate when considering optimisation. According to the CNSC, a conservative approach should be used when developing computer code and models; assumptions and simplifications of processes to make them more amenable for inclusion in computer models should not result in under-estimation of the potential risks or impacts. The net effect of all assumptions should be a conservative representation of long-term impacts and risks. SSI and SKI notes that the use of conservative assumptions at a certain level is unavoidable since the safety case would otherwise have to be unreasonably complex (this would decrease the transparency). However, during the course of a repository development project one would in certain areas expect a movement away from conservative assumptions as more information becomes available. According to the UK/EA, the implementer would need to present relevant arguments. An unduly conservative modelling approach might not be so appropriate when considering optimisation. GRS-Cologne notes that no specific guidance is given except for the general advice that conservative choices have to be substantiated and justified. Posiva, as well as RAWRA, note that regulatory guidance requires that conservative or pessimistic assumptions be applied throughout the modelling.

Generally, conservative assumptions are applied where knowledge is lacking or phenomenon is poorly understood (OPG). NUMO and JAEA notes that conservative assumptions in H12 have been made in the case where realistic model descriptions were found to be inappropriate because of uncertainties arising from insufficient understanding of the relevant phenomenon. Similarly, conservative parameter values have been used in the case where they are not supported by reliable data and a good understanding of the processes or feature being represented. The use of pessimistic data and model assumptions is primarily governed by difficulties of defending any other approach, due to either lack of data or understanding (SKB). Nagra uses conservative assumptions to deal with phenomena for which the models, codes or data for reliable, detailed modelling are unavailable, but for which the potential impact can be (conservatively) bounded. The USDOE-YMP restricts such assumptions to parameters that do not greatly influence outcomes, and/or to parameters that are difficult to defensibly quantify in terms of PDFs. However, BfS, GRS-B and Colenco note that the degree of conservatism is a compromise between, e.g. comprehensibility of the conceptualisation and demonstration of safety.

Depending on the knowledge acquired for each phenomenon or material Andra divides models into four different types, "best estimate model", "conservative models", "pessimistic models" and "alternative models". A conservative model addresses a case in which it is possible to demonstrate that its use, all things being equal otherwise, tends to overestimate the repository's impact, compared with the results that would be obtained by taking into consideration all the relevant phenomena in the chosen parameter variation range. A parallel classification is defined as regards parameter values.

Nirex notes that it is often necessary to make a number of simplifying assumptions, either because insufficient data are available or the modelling capability cannot represent some feature of the system in full detail. The aim is to address issues as realistically as possible, whilst erring on the side of caution. Therefore, some simplifications involve taking a conservative view, i.e. assumptions are made such that radiological risk will tend to be over- rather than under-estimated. Conservative assumptions are often the best way of addressing issues without introducing unnecessary complexity into the models. This approach is used to address some uncertainties in Nirex assessments of the groundwater pathway. This approach of making conservative assumptions can sometimes lead to models, which although robust from a safety point of view, are physically unrealistic. Also, it is important to note that the probability that all parameters in a system take their most pessimistic values is, in general, negligible, so that a calculation that assumes this would give a significant overestimate of the consequence and therefore provide a poor basis for making decisions.

3.3.6 Analyses carried out to explore parameter sensitivity and the impact of uncertainties

From a regulatory perspective model evaluation should include sensitivity analyses as well as uncertainty and importance analysis to show which parameters control the variability in model output. This is a key component of safety assessment work.

Listed methods to explore parameter sensitivity and the impact of uncertainties include:

- Structured parameter variations as well as single parameter "what-if" cases.
- Monte Carlo simulations followed by e.g. rank regression of results.
- Formal sensitivity techniques such as Iterated Fractional Factorial Design.
- "Insight calculations" using simplified models.

Compilation of answers

According to CNSC model evaluation should include sensitivity analyses to show whether the model output responds as expected to variations in the model input parameter values. Model evaluation should also include uncertainty and importance analysis to show which parameters control the variability in model output. Also to SSI and SKI, this is a key component of safety assessment work. According to the UK/EA, it is up to the implementer to develop and justify an approach. The impact of uncertainties needs to be understood – and sensitivity studies offer one approach to achieve this aim. According to GRS-Cologne, probabilistic uncertainty analyses are required to explore the full parameter space. GRS made in the past good experiences with using global (probabilistic) methods for sensitivity analyses but the criteria and guidelines are not prescriptive on that issue.

Listed methods to explore parameter sensitivity and the impact of uncertainties include:

- Structured parameter variations as well as single parameter "what-if" cases (OPG, RAWRA, Posiva, Andra, BfS, GRS-B, Colenco, NUMO, JAEA, SKB, Nagra).
- Monte Carlo simulations followed by e.g. rank regression of results (Andra, BfS, GRS-B, Colenco, NUMO, JAEA, SKB, Nagra, Nirex) USDOE-YMP conducted a variety of statistical and other specially designed modelling tests.
- The impact of parameter uncertainties on consequences can be demonstrated by comparing a calculation with best estimates for particular parameters with worst case estimates. In this context, a worst case estimate usually means that a parameter is given the worst credible value i.e. there is a low probability of the actual value being worse. "What if?" calculations can be carried out to investigate the effects of specific values of some parameters. Conceptual model uncertainty can also be addressed in this way, by performing "What if?" calculations for a small number of alternative conceptual models for the system i.e. to ascertain whether the uncertainty matters.
- Formal sensitivity techniques such as iterated fractional factorial design will eventually be performed by OPG. Nirex notes that it is sometimes helpful to consider variations in a particular parameter systematically in order to understand the impact it has on long-term safety. This can be achieved by conducting deterministic sensitivity studies.
- "Insight calculations" using simplified models (Nagra).

It should also be noted that there is substantial overlap with the question on uncertainty handling (see Section 3.3.1). Therefore, answers given here may not be complete.

3.3.7 Alternative conceptual models

Regulators generally require assessment of alternative conceptual models if there are uncertainties in the underlying conceptual model. Furthermore, at least some regulators require the alternative models to be a substantially different and to be composed of a self-consistent set of properties and geometries.

Most implementers apply some alternative models and generally, the identified alternatives are propagated through the safety assessment. It is often the case that only the more conservative one is folded into the assessment system model. However, some define "alternative models" to handle uncertainties where a model, if chosen, does not have an unequivocal effect on the impact, or a model that appears more comprehensive than the selected reference model but has been less thoroughly validated. Possibly, the depth of consideration of alternative models is a matter of argument between implementer and regulator.

Furthermore, before site investigations take place the large uncertainties that may be associated with the geological environment make qualitative arguments in the safety case may be more meaningful than quantitative PA calculations at this stage. These qualitative assessments would then be used to scope uncertainties and identify data requirements for the site investigation programme and to provide strategy and guidance for the development of the repository concept and safety case at later stages.

Compilation of answers

CNSC acknowledges that investigation of uncertainties in the underlying conceptual model would require assessment of alternative conceptual models. According to SSI and SKI, alternative conceptual models are tools to characterise and explore uncertainties, which should be considered for addressing a variety of issues. The implementer needs to have a strategy for how, when and why alternative conceptual models should be developed during the course of a repository development programme. Furthermore, the alternative models must be a substantially different and must be composed of a self-consistent set of properties and geometries. If alternative conceptual models cannot be ruled out, the UK/EA would expect them to be addressed using a justified approach. According to GRS-Cologne, if there are doubts concerning modelling assumptions or with regard to the presence and/or nature of processes, alternative assumptions shall be explored.

Most implementers apply some alternative models. Ondraf/Niras considers the potential impact of complexation by mobile organic molecules. OPG judges it likely that alternative geologic conceptual models will be considered, such as with respect to assumptions about the presence of major fractures. Posiva considers a different approach, related to definition of deformation zones and their orientation and also applies both porous media and DFN concepts in the groundwater flow modelling. Andra introduced the notion of “alternative” model in the Dossier 2005 Argile. The given definition was that an alternative model designates a model that is not considered to be closest to the “phenomenological” but is offered as an alternative, although it cannot be classified on a “phenomenological”, “conservative “ or “pessimistic” scale. Examples might include a model that, if chosen, does not have an unequivocal effect on the impact, or a model that appears more comprehensive than the selected reference model but has been less thoroughly validated. To consider the hypothesis that gaseous hydrogen has an inhibiting effect on radiolytic dissolution, a sensitivity study was conducted using an alternative model, based not on radiolytic dissolution but on the conventional dissolution of the spent fuel. SKB has developed three alternative hydrogeological models for the one of the two analysed sites for which the site data is most mature. Alternative descriptions of the buffer erosion process and the migration process are also considered. BfS/GRS-B/Colenco both considers instant or delayed brine saturation, and influence of gas.

NUMO and JAEA note that generally, available literature and site specific database could be quite limited at the early stage of site investigation, in particular, the largest uncertainties may be associated with the geological environment. Qualitative arguments in the safety case may be more meaningful than quantitative PA calculations at this stage, to scope uncertainties and identify data requirements for the Preliminary Investigation (PI) programme and to provide strategy and guidance for the development of the repository concept and safety case at later stages. At the PI stage, in which field investigations are initiated, alternative geological and hydrogeological models might be narrowed by site-specific data, based on several boreholes and geophysical investigations, although availability of geological information will still be limited and significant uncertainties may remain. An emphasis may still be placed on EBS performance in cases with limited geological information or complex and heterogeneous geology. The development of alternative models at this stage also provides guidance for subsequent, more detailed investigations (including that in underground characterisation facilities at the DIAs) to reduce any identified uncertainties in the geological database. Also Nirex notes that this issue is not so relevant in a generic assessment such as the GPA, but in the Nirex 97 assessment of the Sellafield site, various conceptual models for groundwater flow were considered. Also, different conceptual models of the effect of organic complexants on near-field solubility and sorption were considered.

Generally, the identified alternatives are propagated through the safety assessment. However, while (e.g.) USDOE-YMP identified and tested alternate conceptual models, the more conservative one was folded into the system model. Similarly, BfS, GRS-B and Colenco noted that the need to develop alternative conceptual models was reduced by selecting the most pessimistic of several possible situations. Nagra notes that the computer codes used to implement different alternative models were, in general, the same as those used for the reference conceptualisation. Depending on the parameter values applied, pathways can represent the undisturbed host rock (the reference conceptualisation), or, in addition, pathways through the access tunnel system in an alternative conceptualisation where such pathways are assumed to be significant. However, in some cases alternative codes were applied (in particular, in the cases dealing with release of volatile nuclides via the gas pathway and with the effect of glacial loading/unloading on radionuclide release).

3.3.8 Stylised approach

Regulators generally accept stylised approaches for assessing aspects of scenario analysis, for assessing future human actions and for assessing the biosphere evolution. However, the extent of stylising is still a matter for interpretation. Stylised approaches may be sufficient for assessing future human actions and biosphere development.

Judging from responses there is not a clear definition of the meaning of the word “stylised”. They are generally applied for assessing future human actions and biosphere development. However, some respondents also consider stylised approaches for assessing the relevance of low probability events.

It is noted that stylised representations can be an appropriate way of dealing with some uncertainties, provided there is agreement on the adopted approach. The greater the strength of that agreement, for example when it is recommended by an authoritative, international body, the more acceptable it is likely to be.

Compilation of answers

Regulators generally accept stylised approaches for assessing aspects of scenario analysis, for assessing future human actions and for assessing the biosphere evolution. However, the extent of stylising is still a matter for interpretation. According to the CNSC, the NEA international FEPs lists can be used to develop initial generic scenarios in the absence of site-specific data, or as default FEPs for developing stylised scenarios. Application of stylised scenarios may be useful where site-specific information is lacking, or where the purpose of the assessment does not require detailed site-specific information. A stylised approach to defining the biosphere may meet the purpose of the assessment. SSI has issued guidelines concerning geological disposal of spent nuclear fuel and nuclear waste (SSI FS 2005:5) that foresees a qualitative handling on some components in a safety case, the assumptions used for the description of the biosphere, as such and exposure pathways in the biosphere taken into account in the analysis, and for climate evolutions. However, according to the UK/EA it is up to the implementer to develop and justify an approach. GRS-Cologne notes that in addition to human intrusion scenarios biosphere assessment is an area where stylised approaches are required and where regulatory guidance at a rather detailed level is foreseen. The exact approach for this is, however, still under development.

Judging from responses there is not a clear definition of the meaning of the word “stylised”. OPG has not yet decided its approach, however, the standard practice for receptors, such as reference human critical group and non-human biota groups, could be considered stylised. BfS/GRS-B/Colenco regards the biosphere model a stylised approach as well as how to assess the potential consequences of human intrusion scenarios. Similarly, SKB essentially applies a stylised approach for future human action scenarios. NUMO and JAEA widely use stylised approaches in the modelling of the human intrusion, biosphere and the treatment of the very long-term evolution of the geological environment for some types of natural events in the future safety analyses of the repository. Also Nagra uses a stylised approach for the treatment of uncertainties in some aspects of the evolution of the biosphere, and in the nature and timing of future human actions

According to Andra, the Altered Evolution Scenario (SEA) represents different situations in a "bounding" way, i.e. it provides a description that generally overestimates the different possible effects. In the example given, the SEA would imagine the total "disappearance" of the container after 200 years. In some cases, an altered evolution scenario may not represent any physically possible situation: in this case one speaks of a "what if" scenario.

RAWRA has decided to consider a stylised approach when assessing the relevance of low probability events (near field issues) and to assess the case if data from host structure are still missing. According to Posiva stylised approaches are deemed to suit in situations where there are uncertainties practically impossible to quantify and to reduce. USDOE-YMP has used expert elicitation to determine uncertainties for some parameters and probabilities for events unlikely to occur.

According to Nirex, stylised approach is essentially to take a specific uncertainty in a parameter outside the remit of a performance assessment. When this is done with the agreement of the regulators and/or other generally respected stakeholders this is a legitimate approach, e.g. concerning uncertain parameters connected with future human actions and concerning stylised biosphere scenarios. The greater the strength of that agreement, for example when it is recommended by an authoritative, international body, the more acceptable it is likely to be.

3.3.9 What-if

What-if cases are acknowledged by regulators as a means to assess disruptive events that cannot be integrated directly into the normal evolution scenario, as a means of illustrating the significance of individual barriers and barrier functions. Such cases might also be needed to address stakeholder concerns or to demonstrate the performance of the system. However, some caution is recommended in the presentation of results from "what-if" calculation cases, since they may convey a distorted picture of the risk contributing factors.

In fact, most assessments consider "what-if" cases. They usually concern assumed loss of barrier function(s). However, their rationale, as well as the view whether they lie outside the risk contribution slightly varies between respondents. For some such cases are not necessarily physically impossible, but lie outside the range of possibilities reasonably expected to occur according to the scientific understanding available to the safety assessors. For others they are tools for testing or demonstrating the resilience and integrity of the repository concept, and for demonstrating multiple safety arguments or concern issues discussed by the community or requested in review.

Compilation of answers

According to CNSC the decision about which natural disruptive events should be included is based on the probability of their occurrence within the timeframe of the assessment. Disruptive events usually cannot be integrated directly into the normal evolution scenario where barriers are assumed to remain intact for their entire design life. In the SKI guidance (SKI FS 2002:1), residual scenarios are discussed as a means of illustrating the significance of individual barriers and barrier functions. However, some caution is recommended in the presentation of results from "what-if" calculation cases, since they may convey a distorted picture of the risk contributing factors. According to the UK/EA analysis of such scenarios might be needed to address stakeholder concerns or to demonstrate the performance of the system. According to GRS-Cologne, there is no guidance on the issue. In fact, most assessment do consider "what-if" cases (Ondraf/Niras, OPG, Posiva, Andra, NUMO, JAEA, SKB, Nagra, USDOE-YMP). However, BfS, GRS-B and Colenco do not consider any explicit "what if" cases.

"What-if" cases usually concern assumed loss of barrier function(s). However, their rationale, as well as the view whether they lie outside the risk contribution slightly varies between respondents. For

Nagra such cases while not necessarily physically impossible, lie outside the range of possibilities reasonably expected to occur according to the scientific understanding available to the safety assessors. According to Ondraf and Niras, they are tools to decide on factors that can be left out the detailed assessments and tools to test the robustness of the system. OPG considers them important for testing or demonstrating the resilience and integrity of the repository concept, and for demonstrating multiple safety arguments. Andra altered evolution scenarios provides description that generally overestimates the different possible effects. An altered evolution scenario may not represent any physically possible situation: in this case one speaks of a "what if" scenario. As an example, a situation such as a whole series of defective containers resulting from a quality control error, which considers very early loss of the functionalities of the metal containers on a series of containers and for the entire inventory. This extremely "what-if" scenario finally covers all forms of uncertainty concerning the corrosion conditions. NUMO and JAEA will apply "what if?" analyses for the long-term evolution scenarios, which have extremely low probability but likely have high consequence in order to know the extent of the effect apart from the compliance with the regulation. For SKB, the rationale for their inclusion is to understand sensitivity to these phenomena and to understand robustness against misunderstanding of scientific and technical phenomena. USDOE-YMP have done one-off and other physically impossible analyses to gain insight. Posiva assessed issues discussed by the community or requested in review.

Nirex notes that as the GPA is a generic assessment, and we are not considering a specific site, so the range of possibilities that would exist at a hypothetical site are not yet known in sufficient detail to differentiate this, in general.

3.3.10 Time cut-off

Many countries do not have a pre-defined time cut-off, but rather require assessments to include the period of time during which the maximum impact is predicted to occur. Other countries have specified time periods, or contemplate including them, in their regulations, but the periods and associated stipulated means of assessment within these periods vary. However, usually these regulations suggest applications of less strict criteria for the very long time frames. Guidance in some countries points out that both the time when the estimated peak dose appears and uncertainties in predictability of system behaviour at that time should be considered. It may be helpful to differentiate between the period for which numerical assessment results are presented (i.e. the safety assessment) and the overall safety case, which may present more qualitative safety arguments for a longer period.

Compilation of answers

Many countries do not have a pre-defined time cut-off, but rather require assessments to include the period of time during which the maximum impact is predicted to occur. In Canada, the CNSC expects assessments of the future impact that may arise from the radioactive waste to include the period of time during which the maximum impact is predicted to occur. OPG will, of course, follow this policy but for very long times alternative indicators will be considered. In the Czech Republic, the regulator at present postulates that evidence for the dose maximum should be made – no "cut-off" of the calculation times exist. In Switzerland, dose and/or risk associated with any releases from the repository must, according to regulations, be evaluated at least until the time of their maxima. Nagra notes that this implies that the more effective the disposal system is in this regard, the longer into the future the calculations have to extend in order to satisfy the regulations. In the United Kingdom, the relevant regulatory guidance does not specify any cut off time. According to Ondraf/Niras, this issue will require additional work within the Belgian programme. GRS-Cologne notes that the radiation protection objectives remain valid unlimited in time. There is, however, a limitation of timeframes for which reliable prognoses can be made. Prognoses or even calculations beyond these timeframes are seen as beyond the limits of practical rationality. Site selection and design should ensure that scientific prognoses are possible for at least one million years. This is also the timeframe for which quantitative criteria are applicable which does, however, not necessarily imply that protection objectives are no longer met at later times.

In Japan, the safety regulation is under discussion, but it is noted in the NSC report that safety analysis should be carried out until the time when the peak dose appears. No cut-off time has been considered. It is also mentioned that uncertainty associated with the assessment results will increase with time and this should be taken into consideration in judging safety of the disposal system. A more recent NSC report on common key issues for radioactive waste disposal suggests the need for discussion on the timescales for the post-closure safety of a repository, focusing on time period, e.g. the first few thousands years after disposal, for which more reliable assessment could be conducted to ensure system performance as far as possible and thereby to enhance robustness for the longer term. It is also suggested to use supplementary safety indicators, e.g. comparison with concentration of naturally occurring radionuclides, as safety criteria in the very long term. NISA discussion to establish the regulatory basis of radioactive waste disposal points out that both the time when the estimated peak dose appears and uncertainties in predictability of system behaviour at that time should be considered.

According to Nirex it is helpful to differentiate between the period for which numerical assessment results are presented (i.e. the safety assessment) and the overall safety case, which may present more qualitative safety arguments for a longer period. The period for which numerical assessment calculations are performed will be determined by the relevant regulatory guidance; concerns and expectations of stakeholders; the characteristics (half-life) of the wastes and the practicality and confidence placed in long-term modelling. In the Nirex Generic Performance Assessment (GPA) an assessment period of one million years is considered based on general guidance from the NRPB and IAEA and an analysis of the GPA Reference case, which indicated no significant increase in calculated peak risk beyond 1 million years. The UK regulations state that: "At times longer than those for which the conditions of the engineered and geological barriers can be modelled or reasonably assumed, scoping calculations or qualitative arguments may be used to indicate the continuing level of safety."

Other countries have specified time periods on their regulations, but the periods and associated stipulated means of assessment within these periods vary. The Finnish regulatory Guide YVL 8.4 issued by STUK (2001) defines the time frames to be assessed. Dose should be calculated up to several thousand years, whereas activity release constraints comprise from ten thousands of years after the closure of the repository up to one million years. Judgement of safety beyond one million years can mainly be based on the complementary considerations such as e.g. bounding analyses by simplified methods. Andra carried out the assessment for a million years, but notes that the uncertainties are not of the same kind depending on the time periods, components or parts of the repository and its environment. These phenomena determine the timescales and physical extent data used to support the safety analysis. In that respect, when discussing the evolution of the repository, Andra adopted a segmentation of the repository in time and space (called APSS/PARS). The methodological approach to define the timescales relied upon spatial fractioning according to the main repository components and segmentation into "situations" corresponding to the phenomenological state of part of the repository or of its environment during a given period of time. The BfS geological scenario analysis of BfS, GRS-Bs and Colenco covers a timescale of 150 000 years and gives only general statements for longer times. This is due to the strong increase of uncertainty for times after the next glaciation and – even more – after several glaciations. The "cut-off" time for dose calculations has been selected to be 1 million years. In Sweden, SSI criterion for individual risk is expressed as a design target and is not associated with an upper time limit. However, SSI guidance (SSI, 2005) on cut-off times and presentation of the risk analysis reflects the fact that the value of quantitative risk calculations for compliance demonstration will decrease as uncertainties increase with time. A different level of ambition is required the first 1 000 years, the time including a full glacial cycle (i.e. about up to 100 000 years) and times up to 1 million years. Following the guidance SKB applies an assessment time of one million years, and dose/risk calculations are also carried out in that time perspective, but the risk criterion is strictly applied in a one hundred thousand year time scale. In the USA revised standards are underway. For the 10 000-year standard, USDOE-YMP performed 20 000-year calculations. For the proposed million-year standard, million-year calculations will be performed.

3.3.11 Handling diverse sources of opinion

From a regulatory perspective uncertainty discussions should extend to contradictory expert opinion. Generally it would be up to the implementer to justify an approach. Expert panel elicitation could be a valuable tool to achieve an overall view on a situation with a disparity of views among experts.

Several examples of handling diverse opinions are applied, including:

- Established documentation procedures for experts to take into account all relevant available sources of information, drawing conclusions regarding uncertainties and, based on these conclusions, prescribe a defendable way of handling the process in question in the safety assessment.
- Safety assessment team separate from experts providing the scientific documentation.
- Establishing that authors are responsible for the use of information and in this they should follow the normal scientific method and practice.
- Probability distribution functions to represent diverse sources of information on parameter values.
- What-if cases to consider alternative models or assumptions.
- Expert panels and meetings
- Review by outside experts.
- Development of the safety case through multiple iterations, so that contradictory opinions can be recognised early and therefore provide time for obtaining relevant information for resolution.
- Comparing with assessments and FEPs from other countries.

Compilation of answers

According to CNSC rejection of inconsistent data, information and interpretations should be justified, and uncertainty discussions should extend to contradictory expert opinion. According to UK/EA it would be up to the implementer to justify an approach. GRS-Cologne notes that it is expected that the regulatory guideline about assessing post-closure safety will require formal procedures about the guidance, use and documentation of subjective decisions especially in the development of scenarios. The extent to which these requirements should be prescriptive is still being debated.

Several examples of handling diverse opinions are applied, including:

- Established documentation procedures for experts to take into account all relevant available sources of information, drawing conclusions regarding uncertainties and, based on these conclusions, prescribe a defendable way of handling the process in question in the safety assessment. Andra incorporates all scientific information in various levels of documentation. SKB has designed a procedure to force the expert responsible for the process documentation to take into account all relevant available sources of information, drawing conclusions regarding uncertainties and, based on these conclusions, prescribe a defendable way of handling the process in question in the safety assessment. Experts within the science and technology group of Nagra (or used by that group) were asked to take account of the views of the scientific and technical community as a whole, and not simply to present their own personal opinions; and to interact with others in their own field and in other relevant fields. USDOE-YMP applies a formal process and procedure to govern the documentation of differing expert opinion and the decision made in the face of that opinion difference. Nirex notes that it is important to ensure that all data and model inputs are traceable and that this will mean being clear on the extent and role of expert judgement, for example recording all expert input in an appropriate database that can be easily linked to the models generated, thus creating an audit trail for the impact of such judgements.

- Safety assessment team separate from experts providing the scientific documentation: The Andra safety analysis was conducted by Andra engineers who were not involved in writing the scientific documents. In this way, the safety analysis is given a certain degree of independence, since the people in charge of analysing the uncertainties and the possible altered situations (the safety engineers) are not the same as those who established the phenomenological plan for normal evolution. In the SKB data report, there is a clear separation between expert input and judgements made by the SR-Can project team.
- Establishing that authors are responsible for the use of information and in this they should follow the normal scientific method and practice (Posiva). According to NUMO and JAEA, all of diverse sources information and opinion should be taken into account in safety assessment and in the safety case if such sources are supported or not completely eliminated by scientifically reasonable evidences and arguments. The possibility of occurrence on FEPs relevant to such sources should however also be argued and taken into account in the discussion of the confidence in the safety case.
- Probability distribution functions to represent diverse sources of information on parameter values (OPG).
- What-if cases to consider alternative models or assumptions (OPG). Nirex notes that where there is more than one expert view, it may be best to conduct two parallel sets of calculations to determine the relative impacts of the conflicting views.
- Expert panels and meetings. OPG early developed expert panels and applies different techniques to draw out areas of consensus. Information and opinion of the responsible contractors were periodically and frequently presented and discussed in meetings, attended by representatives of contractors responsible for different, related topics and chaired by BfS. According to Nirex, differences should ideally be resolved by discussion between the experts, or with an independent third party if necessary.
- Review by outside experts (listed by Ondraf/Niras, OPG and ANDRA, Nirex; but certainly applied by more).
- Development of the safety case through multiple iterations, so that contradictory opinions can be recognised early and therefore provide time for obtaining relevant information for resolution (OPG).
- Comparing with assessments and FEPs from other countries. Andra has backed-up the qualitative safety analysis by comparing the results with analyses conducted internationally. Andra relied on the FEP databases available internationally, in particular the FEP 2000 database of the OECD/NEA and FEPCAT. In addition to an aim of completeness, the comparison facilitated dialogue between engineers contributing to the safety analysis and engineers contributing to the development of scientific documents.

4. THE ASSESSMENT BASIS

According to the NEA Safety Case brochure the assessment basis is the collection of information and analysis tools for safety assessment and includes: the *system concept*, which is the description of the disposal system, its components and their safety functions and, depending on the stage of planning and development, the construction, operation, monitoring and control procedures in as far as they impact on the feasibility of implementation and post-closure safety, as well as quality management procedures to assure that the specification of the engineered features are met; the scientific and technical data and understanding relevant to the assessment of safety; and the assessment methods, models, computer codes and databases for analysing system performance.

The quality and reliability of a safety assessment is contingent on the quality and reliability of the assessment basis. A discussion of the assessment basis and the presentation of evidence and arguments to support the quality and reliability of its components is thus a key component of the presentation of a safety case.

4.1 The system concept

Judging from responses there is a wide agreement that the description of the system concept is a key part of the safety case. However, some respondents appear to focus on the radionuclide retention aspects of the safety functions. Others put most of the emphasis on the containment (isolating) functions and derive safety functions related to the ability of the system to provide containment. There is a general agreement that the biosphere should not fulfil any safety functions. However, its properties influence how groundwater contamination is distributed in the human environment and this needs to be assessed. More detailed lessons are provided from assessing the individual answers.

4.1.1 Role of barriers

Generally, regulators require that the Safety Case should describe the design and characteristics of each barrier. The disposal system should be described in sufficient detail to provide a clear understanding of how safety and environmental protection will be achieved, and how the different components of the system will interact with each other and with the environment in the long term.

Repository design follows a conventional approach, which consists of identifying the functions to be fulfilled by the installation and matching them to technical solutions. Most respondents note that the multiple-barrier principle is the concept guiding the approach to selecting barriers and consequently assess and describe the safety functions associated to the barriers. Generally, the barriers, and thus applicable the safety functions, are site and concept specific. Selection of barriers is an iterative process meeting the protection objectives, technical feasibility, robustness of system and robustness of safety demonstration. It is generally noted that safety does not necessarily simply involve placing successive physical barriers between humans and radioactivity and it is rather a need for multiple safety functions that needs to be maintained through proper selection of repository components. Functions may be redundant, i.e. have the same effect and be able to replace each other, but most of them are complementary and contribute jointly to achieving the safety objectives. The loss of a function then leads to deterioration in the safety level, but this loss can be acceptable if the other functions are maintained.

Containment (or isolation) of the waste is a key safety function in many safety cases. Long-term containment within the canisters in turn depends primarily on: on the proven technical quality of the engineered barrier system (EBS) and on favourable near-field conditions for the canisters that promote their longevity. Favourable and long-term predictability of, at least parts of, the geosphere is another key part of the safety functions.

Assessment of barrier/safety functions is a key part of most safety cases. However, some respondents appear to focus on the radionuclide retention aspects of the safety functions. Others put most of the emphasis on the containment (isolating) functions and derive safety functions related to the ability of the system to provide containment.

Compilation of answers

Generally, regulators require that the Safety Case should describe the design and characteristics of each barrier. According to CNSC, the disposal system should be described in sufficient detail to provide a clear understanding of how safety and environmental protection will be achieved, and how the different components of the system will interact with each other and with the environment in the long term. The UK/EA notes that an understanding of the role, relevance and function of each barrier is an important part of the safety case and that regulatory guidance specifies that there should be a multiple factor safety case. SSI and SKI require that the regulatory requirements connected to the need for several barriers as well as the use of "best available technique" are considered. GRS-Cologne notes that the draft safety requirements demand a system of multiple safety functions with emphasis on the geological barrier – according to AKEnd: a "repository concept based on a favourable overall geological setting" for which "the geological barriers and the shaft barrier shall form the main barrier" while "the [other] technical barriers have a supplementary function" is considered the preferred option.

Andra notes that the repository's design follows a conventional approach, which consists of identifying the functions to be fulfilled by the installation and matching them to technical solutions. Two problems are entirely specific to the design of a repository in a deep geological formation. They are, on the one hand, the requirement for the disposal procedures to be reversible. Furthermore, the designer must consider the long-term evolution of the repository, which must remain safe without human intervention, beyond a necessarily limited systematic surveillance period.

Nirex notes that documentation of the safety function of each component of the disposal system is one of the most important aspects of the safety case. In Nirex next assessment, the focus will be on describing the safety functions and the timescales over which they are most important.

Most respondents (e.g. RAWRA, Posiva, Andra, NUMO, JAEA, SKB, Nagra, Nirex, USDOE-YMP), note that the multiple-barrier principle is the concept guiding the approach to selecting barriers and consequently assess and describe the safety functions associated to the barriers. Generally, the barriers, and thus the applicable safety functions, are site and concept specific. Ondraf/Niras notes that selection of main safety functions is largely based on a priori knowledge from previous assessments (see below) and on robustness considerations (aim at a simple system). BfS/GRS-Bs/Colenco points out that selection of barriers is an iterative process "meeting the protection objectives", "technical feasibility", "robustness of system", "robustness of safety demonstration". However, safety does not necessarily simply involve placing successive physical barriers between humans and radioactivity. It is rather the various safety functions associated to the system of the barrier that are important. Nirex notes that the multi-barrier principle is fundamental to the choice of design concept. In fact, it is a regulatory requirement to demonstrate that the overall safety case does not depend unduly on any single component of the case and also applies to the cautionary principle. This leads to a strategy to develop a concept based on the use of well-characterised materials and using established engineering techniques wherever possible.

Andra has implemented a system of controlling the safety of the repository by assigning safety functions as a method that complements the so-called “multi-barrier” approach. The notion of multiple safety functions constitutes a generalisation of the notion of multiple barriers. It consists of meeting the safety objectives by implementing different types of action that all contribute to the safety of the repository. These actions are accomplished by the repository’s components, the operators or the organisational provisions implemented. Functions may be redundant, i.e. have the same effect and be able to replace each other, but most of them are complementary and contribute jointly to achieving the safety objectives. The loss of a function then leads to deterioration in the safety level, but this loss can be acceptable if the other functions are maintained.

Containment (or isolation) of the waste is a key safety function in many safety cases. As pointed out by e.g. Posiva, SKB and Nagra, long-term containment within the canisters in turn depends primarily on: the proven technical quality of the engineered barrier system (EBS) and on favourable near-field conditions for the canisters that promote their longevity. The technical quality of the EBS is favoured by the use of components with well-characterised material properties and by the development of appropriate acceptance specifications and design criteria.

Favourable and long-term predictability of the geosphere is another key part of the safety functions. For OPG, the safety case is based on the intrinsic quality of the geosphere at the site. Favourable and predictable bedrock and groundwater conditions are a requirement for selecting a waste disposal site (Posiva, SKB). Nagra notes that the long-term stability is one of the key principles related to siting; i.e. that the selected site has to provide a stable and protected environment for the repository.

Assessment of barrier/safety functions is a key part of most safety cases. Ondraf/Niras use safety functions to describe in a qualitative manner the contribution of each component of the system to the overall performance of the system. BfS, GRS-Bs and Colenco first describe processes and relevant barriers in a qualitative and systematic way for the reference scenario, including interactions and combined effects. Based on this, deviations from the reference case were described and resulting changes of the safety functions identified. SKB devotes an entire chapter of the safety report to the identification of safety functions, safety function indicators and safety function indicator criteria (see further Chapter 7) of SKB TR-06-09. Nagra separates between the “System concept” – the description of the key features of the system and its evolution and the “safety concept” – the understanding why the disposal system is safe (which is based on the system concept). Nirex will include a range of arguments to build confidence in their understanding of the function and evolution of the safety functions, including direct references to research and comparisons with natural and anthropogenic analogues. These arguments will be supported by quantitative performance indicators for each of the main safety barriers. There is no specific “prioritisation” of the safety barriers, rather it is recognised that the barriers play different and complementary roles and that their relative significance will vary over different timescales and for different radionuclides.

Some respondents focus on the radionuclide retention aspects of the safety functions. Ondraf/Niras assesses concentrations in and fluxes between repository components. USDOE-YMP apply sensitivity and importance analyses to identify the most important features and processes in each barrier, where barriers are defined as slowing radionuclide migration or water movement. Others, notably SKB, put most of the emphasis on the containment (isolating) functions and derive safety functions related to the ability of the system to provide containment. Similarly, Nagra ocuses attention in the development and analysis of assessment cases on phenomena that have the potential to perturb the pillars of safety.

4.1.2 Biosphere – contributing safety functions?

Generally, regulators require biosphere modelling, since the biosphere is the receiving environment for potential releases, but do not consider the biosphere to have any safety functions. The "disperse and dilute" strategy is not accepted in radiation protection. To varying degrees a stylised representation is allowed.

Generally, the respondents state that the biosphere should not fulfil any safety functions. However, its properties influence how groundwater contamination is distributed in the human environment and this needs to be assessed.

The degree of complexity in the biosphere assessment varies. Some provide an extensive assessment of the present site biosphere and its development. There are also examples of very stylised approaches, usually stipulated in regulations.

Apart from human actions and climatic changes the biosphere per se is not likely to be considered as a source of relevant disruptions.

Compilation of answers

Generally, regulators require biosphere modelling being the receiving environment for potential releases, but do not consider the biosphere to have any safety functions. To varying degrees a stylised representation is allowed. According to the CNSC, the applicant should model the biosphere, which will be the receiving environment for the contaminants, based as much as possible on the site specific information in the system description. A stylised assessment may be acceptable. SSI and SKI state that the "disperse and dilute" strategy is not accepted in radiation protection and BAT require efforts to isolate and contain the waste through a barrier system. According to the UK/EA it is up to the implementer to justify the terminology and approach. GRS-Cologne notes that no safety functions are allocated to the biosphere since no scientific prognoses can be made about it for the timescales of concern. It cannot contribute to isolation and containment, which are considered the primary safety functions. The only role of the biosphere is to help assessing the indicators for isolation and containment (e.g. concentrations or fluxes in accessible media).

Generally, most respondents state that the biosphere should not fulfil any safety functions. However, its properties influence how groundwater contamination is distributed in the human environment and this needs to be assessed (Similar answers provided by Ondraf, Niras, OPG, RAWRA, Posiva, Andra, BfS, GRS-Bs, Colenco, NUMO, JAEA, SKB, Nagra, Nirex, USDOE-YMP). However, the degree of complexity in the biosphere assessment varies.

Some provide an extensive assessment of the present site biosphere and its development. Posiva plans an extensive biosphere assessment formulated into a biosphere portfolio supporting the Biosphere (Summary) Report in the overall Safety Case Portfolio. A similar approach is already developed by SKB. It is also noted that this biosphere assessment takes the responsibility of the geosphere-biosphere interface issues, in co-operation with the rest of the Safety Case team.

There are also examples of more stylised approaches. Posiva notes that the activity inflow criteria to be applied after a few thousands of years do not require consideration of the biosphere over longer times. Andra notes that the concept of "standard biospheres" (i.e. stylised) was introduced in Basic Safety Rule RFS III.2.f. These are defined on the basis of lifestyles as they are known today, without attempting to anticipate their evolution, as this cannot currently be reliably predicted. The major determinants of climate change and surface geodynamic evolution, to the extent that they can be predicted by models, are however taken into consideration when defining the model. For BfS, GRS-Bs and Colenco, a standardised model with specific exposure pathways and parameters is defined by general administrative regulations and its application is mandatory. NUMO and JAEA make no attempt to model the evolution of the surface environment and the lifestyles of future generations, due to uncertainties that are largely irreducible. Sets of assumptions are made about these aspects of biosphere modelling, giving rise to stylised representations of the biosphere ("Reference Biospheres"). These are used to convert radionuclide fluxes to doses, and thus provide a means to evaluate the radiological consequences of geological disposal under the assumptions of the Reference Biospheres. At Nirex, the biosphere model for the GPA was developed to represent terrestrial releases under temperate climate conditions. The risks were evaluated to representative individual members of a potentially exposed group (PEG). The PEG adopted for the groundwater pathway in the GPA was a farming community making maximum use of local resources. All members of the PEG were assumed to live in the area where there is the highest concentration of radionuclides discharging to the biosphere from the repository via the groundwater pathway.

Apart from human actions and climatic changes the biosphere per se is not likely to be considered as a source of relevant disruptions. This is directly noted by e.g. OPG, BfS, GRS-Bs, Colenco, SKB, whereas Ondraf, Niras and Posiva listed climatic changes and human actions as examples of changes that need to be considered.

4.2 Scientific and technical information

According to the Safety Case Brochure the presentation of scientific data and understanding in a safety case should highlight evidence that the information base is consistent, well founded and adequate for the purposes of safety assessment. Any relevant uncertainties should, where possible, be quantified or bounded, including how uncertainties vary over time. Expected features, events and processes (FEPs) that are potentially important for the safety of a system, as well as those that are unexpected but still plausible should be considered. As will be seen by the compilation of individual answers, all respondents generally support this ambition level and there are several examples of specific actions for meeting these ambitions.

4.2.1 Arguments given for the adequacy of scientific understanding

The general regulator perspective is that the applicant should demonstrate a thorough understanding of the underlying science and engineering principles that are controlling the assessment results. Such demonstration may include adequate quality assurance, publications in well known scientific journals, scientific peer review, independent safety evaluation, sufficient documentation of expert judgements, possible use of expert panel elicitation or by showing that even limiting cases are associated with small consequences.

The responses from the implementing organisations are in line with these requirements and makes special provision for documenting their scientific understanding, e.g. in special process and data reports. The answers from the implementing organisations also provide several examples on how the scientific understanding is demonstrated, including:

- Demonstrated systematic evaluation of uncertainties.
- Assessment is based on relatively few and well known processes, basic site characteristics, and their interaction.
- Understanding is based on sound science and that the system has complementary and redundant features.
- Key features of the disposal system are supported by wide ranging information, including that from laboratory and field experiments and from observations of natural systems.

- Investigation data, if such exist, showing that conditions at repository depth have been unchanged for very long times (i.e. demonstrating stability and predictability).
- Multiple lines of reasoning and multiple lines of evidence.
- "What-if" cases.
- Support by natural analogues.
- Support by simulation with detailed mechanistic models.
- Support by expert opinion.
- Comparison of results from two independent groups.
- Comparison with relevant international programmes

However, it should be noted that the supporting arguments are seldom based on a single piece of evidence. It is the chain of arguments rather than individual arguments that is important. A primary interest is in "reasonable" predictability of the geological system. It is recognised that most geological systems evolve with time. All details of this are not needed for demonstrating safety, but there is a need to find well-reasoned bounds for the future evolution.

Compilation of answers

The general regulator perspective is, as stated by the CNSC, that the applicant should demonstrate a thorough understanding of the underlying science and engineering principles that are controlling the assessment results. The UK/EA notes this is an important part of the safety case. SSI and SKI specify that such demonstration may include adequate quality assurance, publications in well known scientific journals, scientific peer review, independent safety evaluation, sufficient documentation of expert judgements, possible use of expert panel elicitation or by showing that even limiting cases are associated with small consequences. GRS-Cologne notes that the proposed safety criteria require to document evidence about scientific basis of the safety case including the use of multiple lines of arguments but are not prescriptive about the way to provide this evidence.

The responses from the implementing organisations are in line with these requirements and makes special provision for documenting their scientific understanding. According to Ondraf/Niras the scientific understanding should be up to the level of the general scientific understanding of the studied characteristics and processes and remaining scientific uncertainties should not significantly affect performance. Posiva presents its scientific understanding presented in "the safety case portfolio" composed of ten main reports (Site report, Characteristics of spent fuel, Canister design, and Repository design, Process report, Evolution of site). Andra notes that building confidence in the adequacy of scientific understanding of key features of the disposal system has involved a stepwise process that has been embodied in several technical reports: The reference knowledge documents of the 2005 file's architecture collects the pertinent input data regarding the site, the radionuclides, the radioactive waste package release models, the radioactive waste inventory model, and the repository materials. The Phenomenological Analysis of Repository Situations (PARS) then provides a space-time description of the various phenomena affecting the repository's components and its environment. Finally, the conceptual models are described in about forty specific notes, based on the geological and engineered components and the major processes identified in the PARS. SKB documents their systematic evaluation of uncertainties in the process and data reports being part of the safety assessment. Nirex notes that a performance assessment in support of a safety case will include a range of quantitative performance indicators, together with alternative lines of reasoning and qualitative considerations, such as the intrinsic quality of the repository design, to build understanding in the overall repository performance and hence determine whether it satisfies the relevant safety requirements. The "Analysis and Model Reports (AMRs), produced by USDOE-YMP contain the full scientific basis.

The answers from the implementing organisations also provide several examples on how the scientific understanding is demonstrated, including:

- The assessment is based on relatively few and well known processes, basic site characteristics, and their interaction (BfS, GRS-Bs and Colenco).
- The understanding of the performance of the components of the multi-barrier system is based on sound science and that the system has complementary and redundant features (Posiva, NUMO and JAEA).
- Key features of the disposal system are supported by wide ranging information, including that from laboratory and field experiments and from observations of natural systems (NUMO, JAEA, Nagra). Calibration against observations and measurements at the site (OPG).
- Investigations are expected to show that conditions at repository depth have been unchanged for at least the past 100 000 years, and therefore have been largely unaffected by the presence of glaciation and similar natural phenomena (OPG). According to Nirex, the most important argument is to present a clear understanding of past geological evolution at the particular site, consistent with the global understanding of geological evolution. Efforts should be made to achieve a broad consensus on this from many independent experts.
- Multiple lines of reasoning and multiple lines of evidence (Ondraf, Niras, OPG, Posiva, Nagra, NUMO, JAEA, Nirex).
- Support by natural analogues (NUMO, JAEA).
- Support by simulation with detailed mechanistic models (NUMO, JAEA).
- Support by expert opinion (NUMO, JAEA).
- "What-if" cases (OPG, Posiva).
- Comparison of two independent groups (BfS).
- Comparison with relevant international programmes (RAWRA) Nirex considers sharing experiences between different programs is crucial in assessing strengths and weaknesses in "own" arguments.

However, Nirex notes that the supporting arguments are seldom based on a single piece of evidence. It is the chain of arguments rather than individual arguments that is important. A primary interest is in "reasonable" predictability of the geological system. It is recognised that most geological systems evolve with time. All details of this are not needed for demonstrating safety, but there is a need to find well-reasoned bounds for the future evolution.

4.2.2 Ensure that all relevant scientific information is taken into account

From a regulatory perspective it is essential to ensure that all relevant scientific information is taken into account in describing the system; its evolution and its performance; and that no significant features, events and processes (FEPs), interactions and associated uncertainties have been overlooked. A systematic, transparent and traceable approach is essential for this. Furthermore, peer reviews, independent of the assessment teams are essential.

Examples for demonstrating that all relevant scientific information is taken into account include:

- Iterative approach in which the model and conclusions are progressively refined further as new knowledge arises and also based on information from prior iterations on what is important, and taking account of review and input from all disciplines.
- Systematic development of a project FEP database.
- Systematic assessment and documentation of FEP interactions and to identify model requirements.

- Auditing the completeness of the FEPs against the NEA FEPs or other widely accepted databases.
- Systematic assessment of all processes provided through the safety case reporting structure.
- Systematic completeness checks, as well as interactions with other agencies and auditing the completeness of the safety case against published safety cases in other countries.
- Selection of knowledgeable and experienced contractors and allocation of responsibilities to the different groups of personnel contributing to the safety case.
- Systematic reviews by experts not directly involved in the assessment.
- Use of specialist and interdisciplinary workshops.

Compilation of answers

From a regulatory perspective it is essential to ensure that all relevant scientific information is taken into account in describing the system; its evolution and its performance; and that no significant features, events and processes (FEPs), interactions and associated uncertainties have been overlooked. A systematic, transparent and traceable approach is essential for this. According to CNSC, a safety assessment should justify the techniques and criteria applied to develop the scenarios that are analysed. Scenarios should be developed in a systematic, transparent and traceable manner through a structured analysis. SSI and SKI state that an important measure will be that primary safety review as well as independent safety review are carried out (as required by SKI regulations SKI FS 2004:1). A systematic comparison with the international NEA FEP database has been suggested to be the main method for checking completeness of FEPs. According to the UK/EA, the developer would be expected to demonstrate a reasonably comprehensive approach.

Examples for demonstrating that all relevant scientific information is taken into account include:[1]

- Iterative approach in which the model and conclusions are progressively refined further as both new knowledge arises and also based on information from prior iterations on what is important, and taking account of review and input from all disciplines (OPG). USDOE-YMP applies a formal process iterates scenario and FEP development through the process level (with several AMRs devoted to describing and cataloguing FEPs for larger building blocks of the repository up to the system level, and back again as any changes are made in the scientific basis at the AMR or higher levels.
- Systematic development of a project FEP data base: For example, Andra notes that establishing a link between each FEP and each part of the analysis requires going into detail of the qualitative safety analysis arguments, but did prove possible in practice, and useful for verifying and clarifying the safety analysis. SKB has developed a FEP data base, based on results of earlier assessments in a structure that enforces an appropriate handling of each FEP. BfS (as well as the others) try to make a systematic scenario analysis. OPG performs a specialist FEPs analysis, e.g. specific to host rock characteristics. For H12, a comprehensive list of relevant FEPs was developed by review (JAEA). Nirex aimed to be comprehensive in its identification of all relevant FEPs. This was achieved by eliciting FEPs in a structured way using a wide range of appropriate experts. The FEPs were structured on a Master Directed Diagram (MDD) that has the performance indicator, radiological risk, as the top-level FEP. The development of the next level requires identification of those FEPs required to determine the top FEP, i.e. radiological dose and radiotoxicology, which are linked to the top FEP by an "AND" logic gate. Each of these second level FEPs was developed in the

1. Organisations providing these examples in their answers are indicated. However, most likely some of the approaches are taken also by the organisations not directly listing this in their answer.

same fashion, and so on to increasingly lower levels of details as the FEPs become more and more specific. The lowest level FEPs on the MDD reflect an appropriate level of detail to form the basis of model development.

- Systematic assessment and documentation of FEP interactions. NUMO and JAEA note that in H12 the implications of the individual FEPs, the relationships with other FEPs, their uncertainties and the possible impact to the safety assessment are clarified based on scientific principles, state-of-the-art scientific knowledge, technical information from laboratory experiments, field investigation and expert opinion. Nirex used a matrix diagram to examine the interactions between FEPs and to identify model requirements (listed by Nirex, but applied by many more). Nirex considered all potential interactions in a systematic manner and the matrix diagram has been used to define modelling requirements for new software modules and to assist in packaging assessment work by identifying potential impacts of specific FEPs.
- Auditing the completeness of their FEPs against the NEA FEPs data base list (Ondraf, Niras, Andra, NUMO, JAEA, SKB, Nagra, Nirex). For example, Andra notes that the comparison between the FEPs databases and Andra own analyses proved to be very useful to safety engineers in ensuring that no fundamental characteristic of the components and no phenomenological process likely to have an influence on the repository had been forgotten.
- Systematic assessment of all processes provided through the reporting structure, e.g. by the Safety Case portfolio approach covering site, characteristics of spent fuel, canister design, repository design, processes, evolution of site and repository, biosphere assessment, radionuclide transport, complementary evaluations, summary used by Posiva, or through SKB development of a number of Process reports. Nirex associated all non-screened FEPs with one or more conceptual models. NUMO and JAEA note that in H12 a set of FEPs to be considered in the safety assessment is identified and recorded together with the reasons underlying the decisions. Scenarios for the safety assessment are then developed using the remaining FEPs along with the systematic methodology. Transparency and traceability in scenario development process are ensured by comprehensively recording the process and the judgements. It is important that above processes should be done iteratively and reviewed by experts to enhance the reliability and the completeness.
- Systematic completeness checks (Nagra), as well as interactions with other agencies and auditing the completeness of the safety case against published safety cases in other countries (Ondraf, Niras, OPG, Posiva; NUMO, JAEA, Nirex). In constructing the MDD Nirex did no exclude FEPs on the basis that they were insignificant. All FEPs were included, although some were later screened from inclusion in assessment models where there was good and agreed justification to do so. Furthermore, the software platform on which the MDD was developed allows “influence audits” to be created from any FEP, allowing the construction of “spider diagrams” in which all FEPs can eventually be traced to a conceptual model. This is one tool that facilitates the demonstration that all relevant FEPs have been addressed in the safety case.
- Selection of knowledgeable and experienced contractors and allocation of responsibilities to the different groups of personnel contributing to the safety case (OPG, Posiva, Nagra).
- Systematic reviews by experts not directly involved in the assessment (listed by Ondraf, Niras, OPG, SKB, Nirex but most likely also made by other organisations). The Nirex MDD, matrix diagram and the model development strategy utilising them, were all reviewed by an international expert team; and Nirex has an on-going commitment to peer preview and review of all aspects of its safety case development.
- Use of specialist and interdisciplinary workshops (OPG).

4.3 Methods, models, computer codes and databases

According to the NEA Safety Case Brochure the assessment methods, models, computer codes and databases must also be clearly and logically presented. As will be seen by the compilation of individual answers, all respondents generally support this ambition level and there are several examples of specific actions for meeting these ambitions. There are also actions not discussed or highlighted in the brochure. The most important examples being preparation of a geosynthesis, (i.e. collecting geoscience information from a variety of perspectives such as structural geology, hydrogeology, and geochemistry and synthesising this data into an integrated geosphere model that is consistent with the knowledge and history of the site), and the increased account of the construction and operational period. Some respondents systematically address the thermal, mechanical, hydraulic and chemical processes/alterations for this stage, using the same methodology as for subsequent, post-closure stages, whereas other still develop their approach – or even question whether it is important for post closure safety.

4.3.1 Process to obtain the accurate models and databases?

From a regulatory perspective, simplifications and assumptions and any resulting restrictions or limitations in the model should be identified and discussed. Data and information inconsistent with the conceptual model of the site and the waste management system should also be identified. It is necessary that models are tested and evaluated to a sufficient extent (model verification and model validation). In the management of databases, sufficient data checking and quality assurance procedures are needed.

Generally, respondents acknowledge the need for sound conceptual models based on the existing scientific understanding. However, generally assessment models should not be described as "accurate" – in that they do not provide accurate "predictions"; rather, they are "suited to purpose".

As with approaches for demonstrating that all relevant scientific information is taken into account, there are numerous examples listed on how respondents assess adequacy of models and data bases – in fact there is substantial overlap between this and the previous issue. Listed examples for checking adequacy of assessment models include:

- Systematic assessment governed by the safety case reporting structure, e.g. in special process and model reports.
- Making the people working on the assessment basis (system understanding) responsible for developing the conceptual models that are needed to understand the evolution of the system.
- Model testing and calibration by utilising observations from well-defined field and laboratory conditions.
- Evaluation of alternative conceptual models or application of independent assessment codes.
- Process understanding and process models provide the starting point for the development of often more simplified assessment models and insight models for specific scenarios, conceptualisations and assessment cases.
- Development of a single simulation platform allowing integration of different computer codes.
- Using simplified analytical solutions to develop understanding of the broad features of system evolution and performance for different combinations of initial and boundary conditions.
- Participation in international projects.
- Code verification and inter-comparison.

Examples listed for checking adequacy of the databases include:

- Documenting and assessing the database is documented in a special report.
- Collecting geoscience information from a variety of perspectives (e.g. structural geology, hydrogeology, and geochemistry) and synthesising this data into an integrated geosphere model that is consistent with the knowledge and history of the site.
- Review by internal and external experts
- Open of the databases via e.g. Internet to allow various users to obtain any indications.
- Develop procedures to control the impacts of changes in understanding/data and to control the processing of data and maintain databases.

Compilation of answers

According to CNSC simplifications and assumptions, and any resulting restrictions or limitations in the model, should be identified and discussed. Data and information inconsistent with the conceptual model of the site and the waste management system should also be identified: SSI and SKI point out it is necessary that models are tested and evaluated to a sufficient extent (model verification and model validation). In the management of databases, sufficient data checking and quality assurance procedures are needed. The UK/EA notes that some process should be used to justify the models that are used in the assessment. According to GRS-Cologne the guidelines under development require that the implementer provides evidence about the scientific basis of the assessment but are not prescriptive about the way this has to be done. The applicability of models has to be substantiated e.g. by means of lab and *in-situ* tests and natural analogues. If the available information allows for several interpretations, alternative models have to be discussed and, if necessary, to be used. The issue of upscaling has to be addressed.

Generally, respondents acknowledge the need for sound conceptual models based on the existing scientific understanding is recognised (as pointed out by Posiva). Nagra notes that generally assessment models should not be described as “accurate” – in that they do not provide accurate “predictions”; rather, they are “suited to purpose”. This comment is likely valid for the other respondents as well.

As with approaches for demonstrating that all relevant scientific information is taken into account, there are numerous examples listed on how respondents assess adequacy of models and data bases – in fact there is substantial overlap between this and the previous issue. Listed examples for checking adequacy of assessment models include:

- Systematic assessment governed by the safety case reporting structure, e.g. SKB describes the handling of each process in specific Process reports. Motives for using key models presented in a Model summary report.
- The people working on the assessment basis (system understanding) are responsible for developing the conceptual models that are needed to understand the evolution of the system (Ondraf and Niras). By including personnel and contractors having either experience in salt mining or in safety assessment for nuclear repositories, the joint team was qualified to simplify the conceptual system model for the assessment (BfS, GRS-Bs and Colenco).
- Model testing and calibration by utilising observations from well-defined field and laboratory conditions (Posiva, NUMO and JAEA).
- Andra, together with CEA and later joined by EDF, has developed a simulation platform, “Alliance” offering all the means required to model the repository and conduct safety calculations. It enables the user to integrate computer codes from various origins and couple the various phases of calculation within a single environment.

- Evaluation of alternative conceptual models (Posiva). Two independent assessment codes have been made available (BfS, GRS-Bs and Colenco).
- Process understanding and process models provide the starting point for the development of often more simplified assessment models and insight models for specific scenarios, conceptualisations and assessment cases (Nagra).
- Using simplified analytical solutions are to develop understanding of the broad features of system evolution and performance for different combinations of initial and boundary conditions (Posiva).
- Participation in international projects, such as the NEA EBS project (RAWRA, Posiva).
- Code verification and inter-comparison. Posiva notes that following the development of a new code or the modification of an existing code, testing must be carried out to ensure that the code is free from errors… state-of-the-art tools that are widely used in nuclear waste management studies and in other fields of science are preferred over codes developed in-house. NUMO and JAEA check the appropriateness of mathematical and numerical codes by comparison with analytical steady-state solutions, inter-comparison with other numerical codes and compared with experimental results.
- Quality measures in developing the models and databases including external audits for some crucial elements (Ondraf and Niras).

Even if Nagra regards development of scientific understanding, process models and databases to proceed concurrently, and not as separate activities, there are anyway also some listed examples for checking adequacy of the databases:

- The database is documented in a special report that also includes the origin of the data (BfS). Data assessed in specified format – presented in a data report (SKB). Standardising data acquisition and application of QA (NUMO and JAEA).
- Review by internal and external experts (NUMO, JAEA and many others).
- Open of the databases via e.g. Internet to allow various users to obtain any indications (NUMO and JAEA).
- Collecting geoscience information from a variety of perspectives (e.g. structural geology, hydrogeology, and geochemistry) and synthesising this data into an integrated geosphere model that is consistent with the knowledge and history of the site (listed by OPG but certainly also a key part of safety cases prepared by Posiva, SKB and Nagra). Collecting state-of-the-art knowledge and inter-comparison of relevant data (NUMO and JAEA).
- "Procedures are in place to control the impacts of changes in understanding/data and to control the processing of data and maintain databases (USDOE-YMP).

4.3.2 What types of evidence support the applicability of models and databases

Generally, there is a large overlap between the responses to the question on the process to support the applicability of models and associated databases (see previous section) and the responses to the question on the type of evidence presented to support this applicability. Listed examples include:

- Structured documentation and assessment of input data and their technical basis.
- Systematic and transparent approach to model development.
- Laboratory and field experiments and tests.
- Site characterisation data obtained by a suite of methods including seismic surveys, borehole measurements, and laboratory sample analysis.

- Scientific and technical literature.
- Internationally approved databases (e.g. TDB).
- Natural analogues and palaeohydrogeological models to evaluate uncertainties arising from the temporal scales of concern – can be used to develop and test detailed process model.
- Expert judgement and critical internal and external review.

Compilation of answers

Generally, there is a large overlap between the responses to the question on the process to support the applicability of models and associated databases (see previous section) and the responses to the question on the type of evidence presented to support this applicability. Listed examples include:

- Input data and the fruit of the analyses conducted structured into a documentary architecture organised according to the safety approach (Andra).
- Systematic and transparent approach to model development (Andra, SKB, Nagra).
- Laboratory and field experiments and tests (Ondraf and Niras, RAWRA, Posiva, BfS, GRS-BsF, Colenco, NUMO and JAEA, SKB, Nagra, USDOE-YMP).
- Site characterisation data obtained by a suite of methods including seismic surveys, borehole measurements, and laboratory sample analysis (OPG, Posiva, Andra, BfS, GRS-Bs, Colenco, SKB, Nagra, USDOE-YMP).
- Scientific and technical literature (Ondraf and Niras, OPG).
- Internationally approved databases (e.g. TDB) (Ondraf and Niras).
- Natural analogues and palaeohydrogeological models to evaluate uncertainties arising from the temporal scales of concern – can be used to develop and test detailed process model (CNSC, RAWRA, Posiva, NUMO and JAEA, SKB, Nagra, USDOE-YMP).
- Expert judgement and critical internal and external review (Posiva, NUMO and JAEA, SKB, Nagra, USDOE-YMP).

It may also be noted that CNSC recognises that models of individual processes or phenomena can sometimes be validated by experiments and blind predictions, whereas the long-term predictions cannot be confirmed.

4.3.3 Utilise data, results, technical guidance from international sources

International sources are utilised in the assessment bases and safety cases, but generally more for inspiration and audits, than fully replacing the needs for project specific information.

- The NEA FEPs database is used by many, but mainly for completeness checks. Most respondents use the NEA thermodynamic database, but additional data and assessments needed.
- The IAEA biomass project is used mainly as inspiration.
- Other international projects mentioned include the migration studies in the EBS and FUNMIG projects and the IAEA ISAM methodology.
- Also, principles elaborated by international organisations (IAEA, OCDE/NEA, ICRP) are generally considered. For example, beyond the questions simply related to impact, recent developments in international reflective thinking insist on the notion of “safety case” in addition to “safety assessment” alone.

Assessment methodologies published by other national programs, or internationally in the NEA IPAG reports, as well as international peer reviews, are also important input to the assessment basis, although mainly for inspiration. At least in Germany international sources, especially NEA and IAEA guides, extensive reviews of recent safety reports and bilateral exchanges with regulators have been a basis for the criteria revision and guideline development.

Compilation of answers

International sources are utilised in the assessment bases and safety cases, but generally more for inspiration and audits, than fully replacing the needs for project specific information. The NEA FEP data base is used by many, but mainly for completeness checks, as noted by OPG, RAWRA, Posiva, Andra, NUMO, JAEA, SKB, Nagra and USDOE-YMP. In addition, the Ondraf/Niras FEPs structure is based on the NEA FEP data base organisation.

Most respondents, e.g. Ondraf and Niras, RAWRA, Posiva, SKB, Nagra and USDOE-YMP, use the NEA thermodynamic database. But additional data and assessments are needed since the TDB does not cover all elements. JAEA developed its in-house thermodynamic database and sorption database taking account of the NEA Thermodynamic databases.

The IAEA biomass project is used mainly as inspiration (Ondraf, Niras, Posiva, SKB, Nagra, USDOE-YMP). RAWRA (among others) follow and learn from the migration studies in the EBS and FUNMIG projects. NUMO/JAEA note that the H12 biosphere assessment was conducted based on Reference Biospheres Methodology developed in BIOMASS. Overall, the safety assessment of OPG will follow the IAEA ISAM methodology.

Andra (but certaily other organisations as well, took into account a number of principles elaborated by the organisations (IAEA, OCDE/NEA, ICRP). The texts related to safety issued by international organisations (IAEA "requirements", OECD leaflets, ICRP recommendations) were considered as a reference for the creation of the present dossier. These texts determine the principles which allow dialoguing with the international community by establishing references common to all. In particular and without prejudice to the application of other texts, Andra referred to ICRP 81 for questions related to the radiological protection of the public within the framework of the management of long-lived waste. The main question raised is that of real or potential long-term exposures. Beyond the questions simply related to impact, recent developments in international reflective thinking (IAEA "safety requirement" project no. DS 154, "Post-closure safety case for geological repositories" of OECD/NEA) insist on the notion of "safety case" in addition to "safety assessment" alone. NUMO and JAEA fefer to elements of safety case, examples of methods for assessments, etc. in the NEA Safety Case Brochure/IAEA WS-R-4 and consider the ICRP Pub. 81 in their approach to scenario treatment (e.g. classification), approaches to show whether constrains are satisfied (aggregated or disaggregated approach).

Assessment methodologies published by other national programs, as well as international peer reviews, are also important input to the assessment basis, although mainly for inspiration. Ondraf and Niras base to a large extent their current work on the methodology of SFC 1 on reviews of the most recent work conducted in the leading disposal programmes. Posiva and SKB have an extensive collaboration. Posiva follows developments of the assessment methodologies of other national programs. According to BfS, GRS-Bs and Colenco the safety assessment is performed by experts which are familiar with the international state of the art in this field and which work in accordance with the general basic principles stipulated by the international community. In the Project Opalinus Clay safety case the methodology employed by Nagra draws on the results of interactions with other waste management organisations and on insights from participating in committees of international organisations. NUMO and JAEA refer to the NEA IPAG reports concerning contents of safety report, measures to increase confidence, etc.

According to GRS-Cologne, the German criteria revision and guideline development is based on IAEA and NEA documents and the IAEA safety requirements guide, an extensive review of recent safety reports, bilateral exchanges with regulators, GRS assessment experiences and the guideline on long-term safety assessment suggests the use of the NEA FEP database.

4.3.4 Account of construction and operational period

From a regulatory perspective long-term impacts of events and processes occurring before closure needs to be assessed. It is important that any significant impacts that arise as a result of processes or events that occur prior to closure are analysed in the post-closure safety case.

Most respondents consider the constructions and operational period, but the level of detail varies, possibly, but not only, related to the type of repository and host rock envisaged. Some systematically address the thermal, mechanical, hydraulic and chemical processes/alterations for this stage, using the same methodology as for subsequent, post-closure stages, whereas other still develop their approach. Feedback to the design and construction planning is also considered, e.g. in dimensioning the characteristics of certain components and how to plan construction and repository operation activities in such a way as to limit the disturbance of the host rock.

Examples of issues considered include:

- Effects of shaft construction methods on repository sealing.
- Mechanical impact of excavation including the excavation damaged zone.
- Modelling of hydro-mechanical evolution in the vicinity of the emplacement tunnels.
- Chemical disturbances of the host rock due to the presence of oxygen in the open repository are studied, also from the perspective of host rock disturbances.
- Drying of the surface layers of the host rock by pre-closure ventilation.
- Oxygenation of the host formation.
- Resaturation time.
- Thermal impacts.
- Sealing of monitoring wells.
- Consequences of an abandonment of the repository without proper closure.

In contrast some do not directly include the duration of construction and pre-closure in the assessment and even suggest that the durations of the construction and operational periods has little impact on post closure safety.

Compilation of answers

From a regulatory perspective long-term impacts of events and processes occurring before closure needs to be assessed. The UK/EA states that it is important that any significant impacts that arise as a result of processes or events that occur prior to closure are analysed in the post-closure safety case. The CNSC states that the approach taken to determine respective periods of time used in the assessment should take into account the duration of the operational period (before the facility reaches its end state). Furthermore, SSI and SKI state that regulationrequire that an account should be given of measures undertaken for radiation protection of workers that may have a negative impact on the protective capability of the repository. In contrast, GRS-Cologne notes that this issue is not addressed in the proposal for the revised German safety criteria and guidelines.

Most respondents consider the constructions and operational period, but the level of detail varies, possibly, but not only, related to the type of repository and host rock envisaged. For OPG, the detailed safety case including analysis of FEPs, is under development. Aspects of construction and operation which may be of interest for post-closure analysis include effects of shaft construction methods on repository sealing, excavation damaged zone, drying of the surface layers of the host rock by pre-closure ventilation, effects on gas generation, resaturation time, which may be very long due to the very low permeability of the host rock and sealing of monitoring wells. Posiva assesses this phase in specific chapter in the report on the evolution of the site and repository, being part of the Safety Case portfolio. Andra studies the possible link between time frames in the post closure phase and events occurring during the operational and reversibility phase. No pre-defined duration is fixed as regards the operational phase, and Andra takes into account the fact it could last for several centuries, depending on the demands of society, associated with reversibility. Also several long-term phenomena, including thermal phase, resaturation, mechanical evolution and canister corrosion may have already started at that time in the repository depending on the works progress history. Because of the uncertainty and variability regarding these phenomena and their starting point, pessimistic assumptions have been made. For BfS/GRS-Bs/Colenco implications of (mine) construction and the duration of the (mine) operation is a fundamental boundary condition to the safety assessment. SKB systematically addresses thermal, mechanical, hydraulic and chemical processes/alterations for this stage, using the same methodology as for subsequent, post-closure stages. An analysis of the potential effects of the pre-closure phase on long-term safety has been conducted (Chapter 7 in Nagra 2002c).

Nirex notes that several processes and conditions during the operation phase, may have long-term implications. In Nirex 97, repository resaturation was modelled explicitly as part of the investigation aimed at understanding the evolution of the groundwater pathway – this is appropriate for a site-specific investigation. However, given the generic nature of the GPA, it was not considered that modelling resaturation in detail was necessary. As part of the assessment of the gas pathway in the GPA, the evolution of the oxygen content of the repository is modelled explicitly – once the oxygen is consumed and anaerobic conditions are established, for example hydrogen gas generation from steel corrosion will commence. The software used in both the GPA and Nirex 97 models the evolution of the repository inventory but cannot explicitly model the time evolution of the properties of the engineered system as it cannot handle time-dependent parameters. Instead, where appropriate, conservative assumptions are applied, and "probability density functions" (PDFs) are used that take account of some of the variations of the properties with time (particularly for radionuclide solubility and sorption). The evolution of the repository and surrounding rock, in terms of its response to stress changes, is not explicitly considered in performance assessment models. However, its potential consequences on the evolution of, for example, the groundwater pathway, could be scoped at an appropriate level of detail as part of a concurrent research programme. In future assessments, more explicit account will be taken of the duration and nature of the construction, operational and pre-closure open periods in the safety case as these periods will be described and assessed and included in the resulting Environmental Safety Case (ESC) together with the post-closure timeframes. The proposed integration of the operational safety assessments with the post-closure assessment in the ESC should ensure a complete and comprehensive safety case.

Examples of issues considered include:

- Effects of shaft construction methods on repository sealing (OPG, BfS/GRS-Bs/Colenco).
- Mechanical impact of excavation including the excavation damaged zone (listed by OPG, Andra, NUMO/JAEA and Nagra, certainly also considered by Posiva and SKB).
- Modelling of the hydro-mechanical evolution in the vicinity of the emplacement tunnels (SKB, Nagra).
- Chemical disturbances of the host rock due to the presence of oxygen in the open repository are studied, also from the perspective of host rock disturbances (listed by Ondraf, Niras, NUMO and JAEA, but certainly studied by others as well).

- Drying of the surface layers of the host rock by pre-closure ventilation (OPG).
- Desaturation and resaturation time as well as influences of long opening of tunnels (if required). (OPG, Andra, BfS/GRS-Bs/Colenco, Posiva, NUMO, JAEA and SKB).
- Oxygenation of the host formation (Andra). Presence of plugs and seals and drainage during the operational period (NUMO and JAEA).
- Thermal impacts (listed by Andra, NUMO, JAEA and SKB but certainly addressed by many others as well).
- Influences of any monitoring systems – if included (NUMO(JAEA). Sealing of monitoring wells (OPG).
- Consequences of an abandonment of the repository without proper closure (Nagra).

Furthermore, according to Ondraf andNiras all construction and repository operation activities have to be planned and conducted in such a way as to limit the disturbance of the host rock as a radionuclide transport barrier (the safety function fulfilled by the host rock being a crucial contributor to safety). Andra notes that the long operational period has to be taken into account when considering the dimensioning the characteristics of certain components (for example, canister dimensions take into account a possible exposure to oxidising conditions, and so do the studies on the EDZ). NUMO and JAEA conclude that the possible changes/perturbations in the pre-closure period affect the timeframes in which some processes, like resaturation, elevated temperatures or chemical degradation of cementitious materials are modelled, but would not change timeframes for the EBS functions.

In contrast, RAWRA do not directly include the duration of construction and pre-closure in the assessment. The USDOE-YMP post closure safety begins as the repository is closed and sealed and the durations of these construction and operational periods has little impact on post closure safety.

4.3.5 Roles of detailed mechanistic models

Generally, the regulatory perspective is that detailed mechanistic models would be important in a demonstrating understanding of the results of laboratory or field investigations and to justify simplified models and parameter values. With few exceptions detailed mechanistic models are not directly used in consequence analyses, but underpins the safety case since they are used to assess specific safety functions or for derivation of parameter values to assessment models.

Compilation of answers

Generally, the regulatory perspective is that detailed mechanistic models would be important in a demonstrating understanding of the results of laboratory or field investigations and to justify simplified models and parameter values. According to the CNSC, sophisticated detailed models of processes can be used to determine if those processes are sufficiently influential to include them in the long-term assessment model, or if they can be ignored with no detriment to the reliability of the predictions. SSI and SKI note they are needed to support assumptions and parameter values used in the compliance evaluation. The general expectation of the UK/EA is that detailed mechanistic models would be important in a number of roles e.g. to demonstrate a detailed understanding of the results of laboratory or field investigations, to justify simplified models and parameter values. GRS-Cologne notes that this is not explicitly addressed in the proposal for the revised safety criteria and guidelines, but in principle such models could contribution to, and demonstration of, understanding of key phenomena including coupled THMC phenomena, derivation of averaged or upscaled parameters for integrated modelling and justification of model simplifications in the integrated PA model.

Detailed mechanistic process models are, indeed, primarily used for justification of simplifying assumptions and for derivation of parameter values to assessment models. Ondraf/Niras note such models are needed to support assumptions and parameter values used in the compliance evaluation. System understanding or performance assessment calculations/modelling will be used to justify model simplification and abstraction and to identify (and to the extent possible quantify) safety reserves. For Posiva, detailed mechanistic models of specific processes are limitedly applied for specific purposes like the evaluation of parameters (e.g. sorption coefficients) for simplified models. It is regarded that mechanistic modelling needs to undergo substantial developments before it can serve as a principal performance assessment tool. For Nagra, the development such models is an intrinsic part of the development of a scientific understanding of system evolution, and, as such, underpins the entire safety case, even if they are not incorporated directly in the near-field/geosphere/biosphere assessment model chain. BfS, GRS-Bs and Colenco note that detailed mechanistic models are fundamental in the safety case. In a more or less direct way and with more or less simplifications mechanistic models are used to quantify all relevant processes. NUMO and JAEA use detailed mechanistic models to support scientific understanding of relevant FEPs, to justify simplifications into assessment models, to derive parameter values, to design repository, and to provide input for site characterisation. Nirex has developed a range of computer software that enables representation of repository system components at different levels of detail. These models form a hierarchy, which has as its basis a wide variety of data, acquired from research and investigations carried out by Nirex, other repository programmes and within other scientific fields. The USDOE-YMP safety case has a safety assessment that is system-level, but calls several process models as well as abstracted models. The burden is to show that abstracted models properly mimic the process models, and that, in turn, the process models are appropriate for their use.

For example, OPG performs detailed modelling of the geochemistry with PHREEQC to assess the importance of evolutionary processes (dissolution of limestone). SKB applies detailed mechanistic models for assessing the THM behaviour of the canister-buffer-backfill system, the THM responses of the rock and the canister failure criteria for rock shear movements. Chemical models are used to derive K_d-values for the buffer.

4.3.6 Source for estimating waste inventory – uncertainties?

Waste amounts and activity estimates are generally based on information on waste production by the waste producers and inventories are calculated or assessed using information on burn-up and by tracking existing tracking inventories.

Depending on waste type the inventories of some nuclides are judged more uncertain, but these uncertainties are generally not judged to be of any major importance for the safety case. Generally, the life-time of the reactors and the extent of their operation during the life-time are uncertain. This is taken into consideration by considering the safety and design implications of uncertainty in the waste amounts. Assessment of various production scenarios, e.g. in terms of reprocessing cycles or burn-up allow examination on how the repository architecture can take into account various inventories and possible management modes downstream from the nuclear fuel cycle.

Compilation of answers

Waste amounts and activity estimates are generally based on information on waste production and burn-up from waste producers and by tracking existing tracking inventories. The waste producers provide Ondraf and Niras with radionuclide activity values and estimated waste volumes. OPG primarily extract the inventories from an Integrated Waste Tracking System used to track the waste placed into interim storage. These data include both directly measured quantities as well as inventory estimated by various scaling factors. For RAWRA the principal waste source is the spent fuel from

Czech NPPs and this information is continuously reviewed and compared with the previous records. Posiva base their estimates from burn-ups of fuel from each power reactor, cooling times, material specifications of the fuel assemblies, including relevant impurities and carries out inventory calculations with ORIGEN2.1. In order to conduct the study of repository possibilities, Andra created an inventory model (MID or modèle d'inventaire de dimensionnement) aiming to consolidate the data and assumptions on the HLLL wastes taking into account the wastes already produced and presently stored on their production sites, as well as the future wastes based on the assumption of an average operating period of forty years for the existing electronuclear reactors. For BfS/GRS-Bs/Colenco the waste producers have to declare the radiological and non-radiological components of the waste packages. The inventory of the radioactive waste is acquired and controlled by measurements and calculations based on these measurements. NUMO and JAEA note that the vitrified waste from JNFL reprocessing plant at Rokkasyo, and vitrified wastes from COGEMA and BNFL reprocessing plants as well as the vitrified waste from JAEA Tokai Vitrification Plant is considered. The inventory of these vitrified wastes is estimated based on the prediction of future electricity demand and overseas reprocessing. The radionuclide inventory in a vitrified waste is estimated by calculation (e.g. using ORIGEN code) and information of chemical analysis of high-level liquid waste at reprocessing plant. SKB makes yearly evaluations of the current inventory and from the forecasted production during the estimated life-time of existing reactors. The UK/EA notes that the national inventory is compiled on information provided by waste producers.

Actions on how to deal with the uncertainties in the radionuclide inventories during waste acceptance has recently been launched within Ondraf and Niras. Information on some long-lived radionuclides and on the exact material composition of the waste is subject to some uncertainty (OPG). Andra selected various production scenarios (in terms of reprocessing and burn-up) in order to provide access to a wide range of waste types, even hypothetical, and thus allow dealing with the various problems for the study of their repository. These scenarios were created in relation with the waste producers. The objective of these scenarios is not to prefigure an overall industrial model, but to examine how a repository architecture can take into account various inventories and possible management modes downstream from the electronuclear cycle. For BfS, the highest uncertainty is to be seen in the inventory of the waste with negligible heat generation due to its chemical heterogeneity, but it is assumed that existing uncertainties are covered by the variation of parameters in the safety assessment. NUMO/JAEA note that an important uncertainty associated with inventory information is the iodine content in vitrified waste. According to SSI/SKI uncertainties in the inventory of spent fuel are more pronounced for a few minor nuclides, e.g. Cl-36, Se-79, Sn-126, Pd-107. SKB notes that the life-time of the reactors and the extent of their operation during the life-time are uncertain. This is taken into consideration by dimensioning the repository to be able to receive 6 000 canisters, whereas the best estimate of the extent of the reactor programme suggests that 4 500 canisters would be required to handle the spent nuclear fuel. Nagra applies a reference power plant lifetime of 60 years – assumed to be a cautious estimate and also assesses a variant inventory that corresponds to a 300 GWa (e) power production scenario in order to illustrate the impacts of a much larger inventory of waste. According to USDOE-YMP, uncertainty is neither great nor important, to the safety case and will be corrected over time.

5. EVIDENCE, ANALYSES AND ARGUMENTS

5.1 Evaluation of performance/safety indicators

According to the NEA safety case brochure, most national regulations give safety criteria in terms of dose and/or risk, and the evaluation of these indicators, using either mathematical analyses or more qualitative arguments, for a range of evolution scenarios for the disposal system, appears prominently in all safety cases that are intended for regulatory review. Robustness of the safety case is, however, strengthened by the use of multiple lines of evidence leading to complementary safety arguments that can compensate for shortcomings in any single argument. Complementary types of evidence and arguments in support of a case for safety include general evidence for the strength of geological disposal as a waste management option, evidence for the intrinsic quality of the site and design, safety indicators complementary to dose and risk, and arguments for the adequacy of the strategy to address and manage uncertainties and open questions.

Judging from the questionnaire responses several actions are, indeed, taken for checking reliability or plausibility of safety cases including validation against large scale experiments or field data, various QA procedures, the iterative approach in which the safety case is progressively refined and reviewed, comparison with "simplified analytic approaches, peer review and various international exercises. Some of the cited assessments show doses and/or risks at or above acceptance levels, in altered evolution scenarios or other cases of low likelihood – or at very late times. However, in light of the uncertainties, these cases are not seen to violate eventual compliance with regulation. Safety and performance indicators in addition to dose and risk are indeed used, mainly for illustrative purposes and the selection reflect the measures that have been discussed in various international fora.

5.1.1 Methodologies for checking reliability or plausibility

From a regulatory perspective the implementer is expected to carry out and document procedures for checking reliability or plausibility as part of their safety case. The implementer should demonstrate a thorough understanding of the underlying science and engineering principles that are controlling the assessment results and that the results of the assessment are analysed to show consistency with system performance expectations and with the complete set of assumptions and simplifications used in developing the models and scenarios. Furthermore, the regulator may carry out independent modelling activities to check reliability.

Several actions are taken for checking reliability or plausibility including:

- Validation against large scale experiments or field data.
- Qualitative arguments.
- QA procedures for checking appropriateness of conceptual models, of mathematical models (e.g. equations, initial and boundary conditions), of numerical solution techniques, of input data and of results and arguments (see also answers in Section 3.1.6).
- Iterative approach in which the safety case is progressively refined and reviewed.
- Comparison with "simplified analytic approaches" and "benchmarking".

- Transparency, traceability and openness.
- Peer review and internal expert reviews.
- International examples of similar safety assessments for plausibility checks.
- International exercises like HYDROCOIN, INTRACOIN, INTRAVAL, GEOTRAP, DECOVALEX, CHEMVAL.

It should also be noted that there are several actions listed already under previous questions.

Compilation of answers

From a regulatory perspective the implementer is expected to carry out and document procedures for checking reliability or plausibility as part of their safety case. The CNSC expects an applicant to demonstrate a thorough understanding of the underlying science and engineering principles that are controlling the assessment results and that the results of the assessment are analysed to show consistency with system performance expectations and with the complete set of assumptions and simplifications used in developing the models and scenarios. The UK/EA recognises that there are a range of possible approaches including QA measures, model verification and validation, using independent data from the specific site to test models, obtaining a key result by more than one at least partially independent model and demonstrating that the results and variation of the results as a function of input parameters is understood. Furthermore, according to SSI and SKI the regulator may carry out independent modelling activities to check reliability and plausibility as part of their review process.

Examples of actions taken for checking reliability or plausibility include:

- Validation against large scale experiments or field data. When possible Ondraf and Niras aim at validating essential processes by large scale experiments". Posiva (among others) carry out modelling exercises on the basis of the observations and field tests at natural analogue sites and the experiments in the TVO Research Tunnel at Olkiluoto and in the underground research laboratories at Stripa and Äspö in Sweden.
- Qualitative arguments. Although a large part of Dossier Andra 2005 is devoted to impact assessments Andra has tried to get as much information as possible out of these assessments beyond the calculation alone. The chapters treating the repository's design, the management of uncertainties or the teachings from safety analysis are also given equal importance.
- QA procedures for checking appropriateness of conceptual models, of mathematical models (e.g. equations, initial and boundary conditions), of numerical solution techniques, of input data and of results and arguments. (Nagra, OPG, NUMO, JAEA and Posiva note the importance of QA – but others apply QA, see answers in Section 3.1.6).
- Iterative approach in which the safety case is progressively refined (OPG). Also Ondraf and Niras point out that successive PA and SA calculations, spread over decades, provide a means to compare results obtained, often with widely varying models and data, and to interpret differences and to avoid unreliable results.
- Comparison with "simplified analytic approaches", "benchmarking": Ondraf and Niras performed calculations with different calculation tools to compare results and interpret differences. RAWRA performed parallel calculations of the same or a similar case in particular studies. Posiva carry out "Back-of-the-envelope" calculations and have decided to evaluate the feasibility of alternative assessment codes for supplementary or diversifying near-field and far-field calculations. BfS, GRS-Bs and Colenco have reproduced the interim results and the final results of the model calculations step by step by simplified analytic

approaches. Additionally, two independent calculations for the same closure concept and the same parameter set have been performed by independent teams. As a complement to the numerical models for assessment calculations, SKB has developed a set of analytical models that use the same input as the numerical models and that have been demonstrated to produce essentially the same result in a number of benchmarking cases. In some cases Nagra have performed additional independent calculations (simplified or equally complex). USDOE-YMP has carried out a series of checking calculations to certify that key portions of the total system model are doing what they are intended to do. In the Nirex 95 and Nirex 97 assessments, a simple analytic model of the safety functions of the multiple barrier system was shown to give a good approximation to the results of the more complex modelling for the groundwater pathway. Confidence can be provided in the results of the complex numerical models by showing that similar results may be obtained on the basis of simple models whose basis may be more easily explained and that can be shown to capture the essential features of the system.

- Transparency, traceability and openness. Andra notes that the following qualities are expected from a "safety case": "transparency", that is, clarity and intelligibility, and a concern for its adaptability to the various targeted readers; "traceability", that is, ability to backtrack to the source of any assertion, data, assumption, by a clear presentation and the use of references; and "openness", that is, accounting and discussion of the uncertainties, open questions, or any element forcing reconsideration of the repository's safety.
- Peer review and internal expert reviews (OPG, Andra, USDOE-YMP, Nagra – among others).
- International examples of similar safety assessments (OPG). Nagra made plausibility checks through comparison with information from other performance assessment studies and for numerical results comparison with results from other analyses or other cases.
- International excercises like HYDROCOIN, INTRACOIN, INTRAVAL, GEOTRAP, DECOVALEX, CHEMVAL (Posiva).

(As for other questions, the fact that a certain organisation did not mention a certain procedure does not mean this procedure is not followed).

5.1.2 Doses and/or risks at or above acceptance limits?

Generally, the regulatory perspective on doses and/or risks at or above acceptance levels is that such results should be interpreted in light of the degree of uncertainty associated with the assessment. At least some regulators stress that it is always a good idea to evaluate realisations with high consequences separately (so-called "high-risk re-analysis") in order to clarify the causes for these high consequences (e.g. certain parameter combinations).

Some of the cited assessments show doses and/or risks at or above acceptance levels, in altered evolution scenarios or other cases of low likelihood – or at very late times. However, in light of the uncertainties, these cases are not seen to violate eventual compliance with regulation. However, at least some respondents note, that the results are used to reach a better understanding of key phenomena in the evolution of safety functions and to, possibly at later stages, suggest design modifications that would lead to lower consequences.

Compilation of answers

Generally, the regulatory perspective on doses and/or risks at or above acceptance limits is that such results should be interpreted in light of the degree of uncertainty associated with the assessment (CSNC). The UK/EA note that the expectation value of risk is the quantity for comparison with the risk target and it is likely that in particular realisations the conditional risk exceeds the regulatory target. According to GRS-Cologne draft safety requirements formulate targets for the probabilistic assessment of scenarios in a way that some realisations may exceed these targets (confidence limits for percentiles). GRS, however, believes that it is always a good idea to evaluate realisations with high consequences separately (so-called "high-risk re-analysis") in order to clarify the causes for these high consequences (e.g. certain parameter combinations).

Some of the cited assessments show doses and/or risks at or above acceptance limits, in altered evolution scenarios or other cases of low likelihood – or at very late times. However, in light of the uncertainties, these cases are not seen to violate eventual compliance with regulations. Ondraf/Niras evaluated such cases by also discussing their likelihood of occurrence and by explicating and discussing the pessimistic assumptions underlying the scenario and safety models. This is seen as an area requiring further discussions with the regulator. Posiva notes that the deterministic dose rates from a few purely hypothetical or very unlikely scenarios exceeded the dose rate limit. However, in this case the probabilities should also be considered, which means that the risk criterion was not violated. According to Andra, current dose constraints for operating situations are understood to be the levels not to be exceeded, the objective being to reduce in any case the exposures as much as reasonably possible. However, a complete radiological protection optimisation approach is not presented in Dossier Argile because it is premature at this stage. In addition, the constraints apply to a normal situation; for the accident studies, for the public as well as the workers, the impact is judged acceptable for each specific case according to the likelihood of the situation considered. NUMO and JAEA note that some "what if?" calculation cases (e.g. a new fault hits the repository) give rise to targeted dose. For such cases, the likelihood of scenarios is taken into consideration and risk-based arguments are made. The estimated risks were still less than the risk level equivalent to the targeted dose. According to USDOE-YMP, the doses from some very unlikely events, should they occur, would be unacceptable especially in the earlier parts of the postclosure phase, but their unlikely nature makes them represent a very low and acceptable risk.

In the BfS, GRS-Bs and Colenco case a few (< 1%) probabilistic realisations gave doses slightly above the acceptance limit, but detailed analysis of these cases shows that combinations of unfavourable parameter values result in an extreme system behaviour, which can in all cases be mitigated by activating reserve FEPs. SKB have calculated such high risk levels, but only for pessimistically derived scenarios in a (long) one million year perspective. These results are used to reach a better understanding of key phenomena in the evolution of safety functions and to, possibly at later stages, suggest design modifications that would lead to smaller releases.

5.1.3 Safety and performance indicators in addition to dose and risk

From a regulatory perspective safety and performance indicators in addition to dose and risk are seen as illustration and/or providing more robust measure for distant time periods. However, apart from the Finnish regulator STUK, regulators have not developed any quantitative criteria for assessing such safety indicators.

Safety and performance indicators in addition to dose and risk are indeed used, mainly for illustrative purposes and the selection reflects the measures that have been discussed in various international fora, i.e.:

- Radionuclide flux to and concentration in biosphere, compared with natural radioactivity in the local environment. These indicators, although not entirely independent of the assumptions of the assessment biosphere models, are at least independent of assumptions regarding exposure pathways.
- Activity releases from the repository compared to the release constraints issued by the Finnish regulator STUK.

- Radiotoxicity of the waste, radiotoxicity concentration and flux – compared with the radiotoxicity of various natural occurrences of radionuclides, such as the radiotoxicity of earth crust in a volume of the disposal area.
- Distribution of the radiotoxicity among the different parts of the disposal system as function of time and the integrated release of radiotoxicity from the different barriers or repository system compartments as function of time.
- Key factors describing the evolution of various safety function over time.

Compilation of answers

From a regulatory perspective safety and performance indicators in addition to dose and risk are seen as illustration and/or providing more robust measure for distant time periods. According to CNSC several other safety indicators, such as those that reflect containment barrier effectiveness or site-specific characteristics that can be directly related to contaminant release and transport phenomena, can be presented to illustrate the long-term performance of a waste management system. According to SSI and SKI compliance for distant time periods (i.e. beyond 100 000 years) may instead be based on more robust measures of repository performance, such as various measures of barrier performance and radionuclide fluxes in the geosphere, but SSI has not developed any quantitative criteria for assessing such safety indicators. According to the UK/EA, the developer may feel that additional performance indicators are helpful in demonstrating and communicating safety. GRS-Cologne states that consequence calculations should as far as possible rely on the modelling of repository components the evolution of which can be forecasted over the assessment timeframe, and on components the safety concept is based on (i.e. which should provide the basic safety function of isolation and confinement). GRS stresses the role of concentrations and fluxes as major indicators which allow, together with other lines of evidence, to judge about the confinement capability of a repository system. As far as possible, concentrations/fluxes occurring in nature should be used as yardsticks. This has, however, its limitations with regard to the assessment of potential releases of artificial radionuclides the assessment of which has to be based on radiological considerations using standardised models. Thus, assessment calculations serve as one of multiple lines of evidence substantiating that the safety function "confinement/isolation" is ensured. It can then be argued that, if the confinement of the waste is ensured, the protection objectives for humans and the environment are met. In turn, the confinement is ensured if the already existing system is perturbed as little as possible. A set of indicators – most of which are located at the boundary of the isolating rock zone – based on these ideas is presently being debated in Germany.

Safety and performance indicators in addition to dose and risk are indeed used, including:

- Radionuclide flux to and concentration in biosphere: A comparison is made with natural radioactivity in the local environment. (Ondraf/Niras, OPG, Andra, NUMO, JAEA, SKB). NUMO and JAEA note that these indicators, although not entirely independent of the assumptions of the assessment biosphere models, are at least independent of assumptions regarding exposure pathways, especially human habits. In the Nirex GPA, other indicators are given – for example, the radionuclide flux out of the engineered barriers and out of the geosphere; and radioactivity levels in the main system components at various times. Nirex has also investigated the use of alternative safety indicators (for example radionuclide concentrations in the environment) and the roles for more qualitative safety measures (for example comparisons with natural and anthropogenic analogues) in a safety case.
- Calculated releases from the repository are compared to release constraints issued by the Finnish regulator STUK (SKB and Posiva).

- Radiotoxicity of the waste, radiotoxicity concentration and flux – compared with the radiotoxicity of various natural occurrences of radionuclides (listed by OPG, BfS, GRS-Bs, Colenco, NUMO, JAEA and Nagra). For example, BfS, GRS-Bs and Colenco compared the radiotoxicity of the waste with the radiotoxicity of 1 km^3 earth crust (the volume of the disposal areas) or with the radiotoxicity of the backfill in the disposal caverns, the radiotoxicity concentration in the aquifer was compared to the typical natural concentration in drinking water and the radiotoxicity flux from the geosphere was compared to the natural flux in groundwater near the site. NUMO and JAEA note that even if direct comparisons with natural concentration can, of course, only be made for radionuclides that are naturally present in the environment. The regulatory concentration limits for routine releases from existing nuclear facilities, which are derived from annual limits for intake can, however, be used to derive a common scale for all radionuclides of concern, allowing indirect comparisons to be made.
- BfS/GRS-Bs/Colenco presented the distribution of the radiotoxicity among the different parts of the disposal system as function of time and the integrated release of radiotoxicity from the different barriers as function of time.
- The fraction of the released amount of substance, U and Th concentrations, the contribution of released radionuclides to power density in groundwater and the contribution to radiotoxicity flux in groundwater are the indicators proposed by GRS for the boundary of the isolating rock zone. In addition, nuclide concentrations in accessible groundwater and effective individual dose might be considered.
- Key factors describing the evolution of various safety function over time. For example, OPG consider the age of the groundwater and its salinity direct indicator of expected performance and also consider the required thickness of shielding as a performance indicator. Andra assessed different indicators associated with the "resisting water circulation" function including Péclet (Pe) number, advective and diffusive flow indicators and the distribution between the radionuclide mass transiting along and/or in the structures made up of drifts and shafts and the mass migrating by diffusion. Andra also deduced indicators for assessing the "limiting the release of radionuclides and immobilising them in the repository" function.

In the GPA and Nirex 97, it is fair to say that radiological risk was the main performance indicator reported. In Nirex plans for an Environmental Safety Case (ESC) these alternative safety arguments will take on a key role. The aim will be to demonstrate our understanding of the performance and evolution of the repository system and its various components by reference to facts and situations with which the audience may be familiar.

5.2 Strength of geological disposal option

According to the NEA brochure a safety case will generally focus on evidence, analyses and arguments that pertain to a particular site and design. A safety case may, however, also contain more general evidence for the strength of geological disposal as a waste management option and may argue that it is prudent to pursue that option on an appropriate time schedule. However, only one respondent directly addressed the general strength of geological disposal in the safety assessment document. As a general remark, arguments for the strength of the geological disposal option are an issue to be (or that have been) addressed at the national policy level; but of course, the analyses and safety case must support a conclusion on the safety of geological disposal.

5.2.1 Arguments for strength of geological disposal option

Generally, regulators tend to view arguments for strength of geological disposal option to be a question for the implementer (CNSC). However, it should be noted that final disposal of the nuclear waste is actually stipulated in some regulations.

Only one respondent directly addressed the general strength of geological disposal in the safety assessment document. Some respondents have, or plan to, make such statements in other parts of the safety case documentation, e.g. in EIA documents. It should also be noted that some focuses more on building confidence through the site-specific aspects, even if the international consensus on geological disposal as the preferred waste management option for heat producing long-lived wastes is cited.

As a general remark, arguments for the strength of the geological disposal option are an issue to be (or that have been) addressed at the national policy level; but of course, the analyses and safety case must support a conclusion on the safety and feasibility of geological disposal.

Compilation of answers

Generally, regulators tend to view arguments for strength of geological disposal option to be a question for the implementer (CNSC). However, it should be noted that final disposal of the nuclear waste is actually stipulated in some regulations. For example, Nagra points out that the Swiss Nuclear Energy Law stipulates that all radioactive waste has to be disposed of in geological repositories (KEG 2003). The UK/EA notes that the UK Government's Advisory Committee on Radioactive Waste Management[1] have considered the pros and cons of deep geological disposal. GRS-Cologne notes that there is no such requirement in the draft criteria, but the AKEnd report concludes that "the Committee sees no alternative to the long-term safe disposal of radioactive waste other than the disposal in deep geological formations".

Only Nagra addressed the general strength of geological disposal in the safety assessment document. In Project Opalinus Clay, a number of such arguments have been put forward, i.e. being the only waste management option that offers long-term passive safety, reduces possibility of irresponsible interference and offers feasibility of safe disposal. However, some respondents have, or plan to, make such statements in other parts of the safety case documentation, e.g. in EIA documents. Ondraf/Niras foresees a strategic environmental assessment of deep disposal of HLW and LL waste, conducted in the framework of Ondraf and Niras waste management plan is foreseen, as imposed by a recent federal law. Overall argumentation for geologic disposal as a waste management option was a central part Posiva's Environmental Impact Assessment carried out in 1997-1999. NUMO and JAEA note that the selection of geological disposal as a favourable option is specified in the Act. In addition to this fact, the arguments are used to support that geological disposal is only a feasible option in the light of internationally agreed basic principles for waste management and in comparison with other options such as long-term storage.

It should also be noted that according to OPG the safety case focuses more on building confidence through site-specific aspects of the proposed DGR. There is however clear reference to international practice or proposals with respect to deep geological disposal that is intended in part to establish this as a reasonable approach. Andra has adopted a safety approach in accordance with the Basic Safety Rule which set a series of objectives: (i) absence of seismic risks in the long term, (ii) absence of significant water circulation inside the repository, (iii) rock suitable to underground installations excavation, (iv) confinement properties for radioactive substances, (v) sufficient depth to keep the waste safe from

1. www.corwm.or.uk/content-1092.

potential aggressions, (vi) absence of nearby rare exploitable resources. With regards to these objectives, the geological medium was at the core of the repository system. It must ensure the very long-term confinement of radioactive substances to prevent their migration into the environment. Quite significant results have been achieved in all fields of research, yielding a precise view concerning the properties of all repository components. The feasibility of a repository in a clay formation has been established. According to SKB general argumentation is not within the scope of the assessment project, but evaluation of confidence for the analysed method does, of course, support geological disposal. The USDOE-YMP did not address this explicitly, but the international consensus on geological disposal as the preferred waste management option for heat producing long-lived wastes is cited.

5.3 Feasibility of implementation as planned

According to the Safety Case brochure, a safety case should, however, show that any uncertainties that do have potential to compromise safety, as well as open questions regarding, for example, design options, can be adequately dealt with in future project stages via an appropriate research programme and management strategy. Judging from responses there is general aim to demonstrate that the system can be implemented with existing technology and according to the responding implementers this has also generally been achieved. Defects are taken into account by a varying degree, largely dependent on the repository concept and on the importance of defects in the Safety Case. Generally, the strategy to deal with remaining uncertainties is to assess them and device plans for sufficient resolution in RD&D plans and by providing feedback to the on-going site investigation and repository design projects.

5.3.1 Demonstrating that system can be implemented with existing technology

There were few regulatory responses to this question. However, it may be a regulatory challenge to review technologies for which there is little available experience and expertise.

There is general aim to demonstrate that the system can be implemented with existing technology and according to the responding implementers this has also generally been achieved. However, this does not mean that all technical solutions are fixed. The technical options should usually not be regarded as optimised solutions, either in technical/economic terms or from the safety standpoint. Examples listed of remaining issues include:

- Definition and setting of requirements on the basis of which the success of demonstration tests can be judged.
- Sealing aspects.
- Define the component requirements in detail and show that they can be implemented as required in a fully quality assured production system.
- Components, like low-pH cement and sealing methods for boreholes need to be further developed.

Furthermore, enhanced safety and efficiency may be possible by pursuing newer technologies over time.

Compilation of answers

There were few regulatory responses to this question. However, according to SSI and SKI, it will be a regulatory challenge to review technologies for which there is little available experience and expertise. GRS-Cologne notes that in the case of technical solutions, which are not yet state of technology, testing of such components will be required.

There is general aim to demonstrate that the system can be implemented with existing technology and according to the responding implementers this has also generally been achieved. For Ondraf and Niras, an important emphasis has been put in the current phase on demonstrating the technical feasibility of disposal in this phase of the programme. OPG believes that conventional mining and conventional radioactive waste handling aspects will be sufficient. Andra has selected a potential repository architecture that meets expectations and is industrially realistic. The repository design is based on available knowledge and technology. According to BfS, GRS-Bs and Colenco, the concept for backfilling and closure utilises only well-known materials and techniques and the feasibility of sealing tunnels and shafts has been demonstrated. According to Posiva, the KBS-3 concept can be implemented with existing technology. NUMO and JAEA note that in the H12 project, it is shown that construction of disposal system, emplacement of the waste forms and backfilling of the tunnels can be realised using currently available technologies or technological advances which are expected near future. In the development manufacturing methods of engineered barriers, such as metal overpack containers and consolidated large bentonite blocks were demonstrated in full scales. SKB state that all key components (canister, buffer and backfill) have been demonstrated on a prototype level. According to Nagra construction of the repository and the emplacement of the EBS and the sealing system has been shown to be feasible with existing technology. Existing technologies are seen as sufficient by USDOE-YMP.

At the current, generic, stage of the Nirex programme, the arguments that demonstrate that the system can be implemented with existing technology are presented in the "Viability report" – which is a statement about why Nirex believes its concept is viable, see Nirex, The viability of a phased geological repository concept for the long-term management of the United Kingdom's radioactive waste, Nirex Report 122, November 2005.

However, this does not mean that all technical solutions are fixed. Andra points out that the architecture studied does not in any way freeze the definition of a potential repository. The technical options should not be regarded as optimised solutions, either in technical/economic terms or from the safety standpoint. They may be developed further after 2006 USDOE-YMP point out that enhanced safety and efficiency may be possible by pursuing newer technologies over time.

Examples listed of remaining issues include:

- Definition and setting of requirements on the basis of which the success of demonstration tests can be judged (Ondraf and Niras).
- Sealing aspects (OPG).
- Define the component requirements in detail and show that they can be implemented as required (Posiva). Define the component requirements in detail for KBS-3 with a fully quality assured production system. Similarly NUMO and JAEA state that the practicality of construction of their EBS under strict quality assurance controls in an operational repository environment, considering underground conditions of restricted space, humidity, emplacement rate, remote handling, operational safety, robustness to perturbations, etc. require further development.
- Components, like low-pH cement and sealing methods for boreholes need to be further developed (SKB).

5.3.2 Defects: how assessed and treated in safety assessment

From a regulatory perspective the implementer should also take into account the failure modes of the containment and isolation systems. It is also suggested that there is a difference between failures, defects and mishaps which become obvious during implementation (e.g. accidents during transportation which damage repository installation and thereby influence long-term performance) and those which are not detected during operation (e.g. material failures in engineered barriers). While the latter are conceptually equal to other scenarios (e.g. not detected fault) and have to be handled similarly in assessments, the former can also be dealt with by measures during the operation period. Since the post-closure safety assessment has to be based on the state of the system at the time of closure, it is possible that the analysis of the pre-closure phase leads to more than one possible system state at the time of closure, e.g. states caused by possible mishaps during the operational phase.

Defects are taken into account by a varying degree, largely dependent on the repository concept and on the importance of defects in the Safety Case. Defects are generally more important in concepts building on a durable waste container. Several cases of container defect cases are assessed. Also other parts of the system, e.g. regarding buffer and repository sealing are evaluated. Repositories for LLW/ILW tend to be less dependent on engineering defects.

Compilation of answers

From a regulatory perspective the applicant should also take into account the failure modes of the containment and isolation systems (CNSC). According to SSI and SKI, there is a need for establishing procedures for detailed review of the design basis for the canister (and) to plan the future review and inspection of each individual canister during operations. GRS-Cologne notes that the implementer has to address these possibilities. GRS also makes a difference between failures, defects and mishaps which become obvious during implementation (e.g. accidents during transportation which damage repository installation and thereby influence long-term performance) and those which are not detected during operation (e.g. material failures in engineered barriers). While the latter are conceptually equal to other scenarios (e.g. not detected fault) and have to be handled similarly in assessments, the former can also be dealt with by measures during the operation period. Since the post-closure safety assessment has to be based on the state of the system at the time of closure, it is possible that the analysis of the pre-closure phase leads to more than one possible system state at the time of closure, e.g. states caused by possible mishaps during the operational phase.

Defects are taken into account by a varying degree, largely dependent on the repository concept on the importance of defects in the safety case.

Defects are generally more important in concepts building on a durable waste container. Posiva considered the possibility of defects through the choice of scenarios and sensitivity cases. In TILA-99 an assumption was made that one per mille of canisters could be defective from the outset. However, the basis of this assumption is being re-evaluated. SKB now treat (canister weld) defects quantitatively through statistics of the minimum copper thickness in the weld. In addition, “what if” cases are formulated to test the sensitivity to more severe flaws than predicted from the test statistics. The possibility of defects in waste and container fabrication, repository construction, operation and closure and other aspects of implementation were assessed as part of the comprehensive description of the disposal system and its evolution within the Nagra Project Opalinus Clay safety case. The USDOE-YMP evaluated the likelihood of unexpected but not impossible waste package failures at the time of emplacement using an industrial analogue, and is part of the safety assessment.

Also other parts of the system, e.g. regarding buffer and repository sealing are evaluated. Work is in progress within Ondraf and Niras. BfS, GRS-Bs and Colenco considered seal failures considered by the bandwidth for the initial permeability of the seals. NUMO and JAEA have not yet discussed the assessment of the defects in all repository components relevant to safety in detail. In the H12 safety analysis, however, initial defects such as incomplete sealing of the overpack, insufficient backfilling and/or plug/grout have been taken into account in calculation cases for perturbation scenarios. The rate of defects is defined based on the engineering experience in relevant industries. SKB studies “what if” cases with postulated (buffer) densities outside the (reference) interval. Nagra assessed the possibility of the repository being abandoned in the observational period without proper backfilling/sealing. USDOE-YMP factor operational decisions regarding materials and quantities and storage density/heat loading, having important effects on long-term repository behaviour/safety, into the safety assessment.

Repositories for LLW/ILW tend to be less dependent on engineering defects. According to OPG, the safety case does not rely on the waste form or container for any significant retention, so the possibility of these defects is not explicitly considered. BfS, GRS-Bs and Colenco, assessing a LLW repository in salt, did not take any credit of technical barriers (others than the seals). In Nirex assessments of the PGRC for ILW and LLW, it is assumed that the repository vaults are all resaturated and the waste packages fully degraded from the start of the post-closure period, so that the radionuclides are all in contact with the repository porewater. This is a conservative approach, which does not take any credit for any radionuclide containment by the waste containers or containment of radionuclides within the wasteform itself. Therefore, it is not necessary to consider defects to packages arising from pre-closure operations. Work is underway to develop more realistic models, which do take some account of the physical containment afforded by the waste packages. The possibility of defects in waste packages and container fabrication is something that is of relevance, however, in the assessment of operational safety.

5.3.3 Management of uncertainties and open issues in future project stages

While regulators may accept that early in the licensing lifecycle, it may be necessary to rely on design specifications, waste acceptance criteria, generic or default data, and assumptions to describe the waste management system in sufficient detail that its performance can be predicted. Follow up programmes would be needed to confirm assumptions and input data used in the assessment and to verify predictions.

Uncertainties and open issues for future project stages are generally identified and prioritised using review, results of safety assessments, site characterisation and R&D programme planning. The specific examples given of such uncertainty are clearly varying and stage of programme dependent. Furthermore, since there is substantial overlap between this questions and other questions related to uncertainties (see e.g. Section 3.3.1), the answers provided here are by no means complete.

Generally, the strategy to deal with remaining uncertainties is to assess them and device plans for sufficient resolution in RD&D plans and by providing feedback to the ongoing site investigation and repository design projects. It is also noted that the long-term science programme and a formal performance confirmation programme will continue during construction and operations until final closure.

Compilation of answers

CNSC notes that early in the licensing lifecycle, it may be necessary to rely on design specifications, waste acceptance criteria, generic or default data, and assumptions to describe the waste management system in sufficient detail that its performance can be predicted. However, the environmental assessments under the Canadian Environmental Assessment Act include provisions for follow up programs to confirm assumptions and input data used in the assessment and to verify predictions. SSI and SKI refer to their answer under II.2. GRS-Cologne notes that a list of the most crucial conceptual questions exists, but the evaluation of these questions, however, lead to the conclusion that they are sufficiently explored at a generic level. Some, however, require further regulatory guidance, which the criteria development attempts to give while others would need to be assessed at a site-specific level. In addition, the question arises to what extent alternative sites and concepts need to be studied and by which means they can be evaluated against each other. Presently, there are several initiatives in Germany underway which attempt to compile the current stage of knowledge and to draw conclusions for further work.

Uncertainties and open issues for future project stages are generally identified and prioritised using review, results of Safety Assessments, Site Characterisation and R&D programme planning (Ondraf, Niras, OPG, Posiva, Andra, SKB and Nagra). For example, Andra stressed that the representation of the processes and their inclusion in the safety assessment of Dossier 2005 involves simplified, conservative models in certain cases and that it would be important in a later phase to represent them in a more precise manner in order to increase the confidence that can be placed in the assessments. Nagra notes that future work should give priority to phenomena directly connected to the pillars of safety, since a further enhancement of understanding in these areas will strengthen future safety cases. NUMO and JAEA note that in H12 safety case based on generic feasibility study, the strategy for R&D after the year 2000 and general issues to be addressed in the upcoming site-specific stages are identified, but not has been specified on site-specific basis and not prioritised.

The specific examples given of such uncertainty are clearly varying and stage of programme dependent. OPG expects to find sufficient information to provide confidence on the impacts for the EIA, but thinks that the assessment process will identify aspects and uncertainties to be considered as part of further detailed work for the subsequent construction and operating licence process. Issues for potential further study noted by Andra include a finer climate sequencing, characterisation of the transport properties of the excavation damaged zone, enhanced modelling of coupled phenomena and assessment of corrosion and formation of corrosion gas. Andra also notes that it has been possible to draw up an initial list of processes, the implementation of which during the operating phase could restrict the duration of this phase from the point of view of long-term safety. Reversibility appears possible over a few centuries (typically two or three hundred years) or potentially longer periods. For SKB, buffer erosion mechanisms, rock spalling, as well as the need for verifiable acceptance criteria for deposition holes are current key issues to assess. Nagra states that remaining uncertainties and open questions do not put safety in question, but indicates a number of topics for further study in order to further reduce uncertainties and enhance process understanding. Furthermore, since there is substantial overlap between this questions and other questions related to uncertainties (Section 3.3.1), the answers provided here are by no means complete.

Generally, the strategy to deal with remaining uncertainties is to assess them and to present plans for how to sufficiently resolve them in RD&D plans and by providing feedback to the on-going site investigation and repository design projects (Posiva, OPG, Andra, NUMO, JAEA, SKB, Nagra,). The USDOE-YMP notes that the long-term science programme and a formal Performance Confirmation programme will continue during construction and operations until final closure.

5.4 Complementary evidence, lines of argument

According to the Safety Brochure, a safety case will include all the different lines of evidence, arguments and analyses that are available to support the quality and performance of the disposal system at a given stage of repository planning and development, as described in the previous sections. Any lines of evidence that are not supportive of the safety case should also be discussed and analysed. Such evidence is also presented in the safety cases being part of the INTESC. However, it may be noted that there is generally little distinction between arguments related to safety and complimentary arguments, and this division is probably not really helpful. The types of arguments listed in the brochure are used. However, few respondents use the term “reserve FEP”, even if the generally conservative approach in safety assessment is indeed brought forward. The benefit of a systematic and documented identification of safety functions and criteria for the safety functions is also mentioned.

5.4.1 What complementary arguments – if any

Arguments given regarding the "*strength of geological disposal as a waste management option*" are still site specific. Arguments based on observations of natural systems (including palaeohydrogeology and natural analogues) are used to support that safety over geological timescales is achievable at the studied site.

Only few listed arguments on "*adherence to disposal principles*", such as the existence of multiple passive safety barriers. However, as seen from responses to other questions, such principles are indeed followed by all safety cases.

Arguments on feasibility of design are given. They essentially state that the repository can be built and operated safely using proven technologies, see also the answers compiled in Section 5.3.

Many arguments concern the "*quality of underlying scientific understanding*". Specific arguments include that confidence in the site-descriptive model and confidence in the understanding of the site is obtained by a systematic and quality assured programme for site investigations and site modelling and that confidence in the scientific understanding of the repository evolution is essentially built on decades of documented R&D efforts. In addition, many organisations have submitted a comprehensive number of papers to academic journals or other quality assured proceedings, etc is used to support critical argument of key issues.

Other main arguments concern the "*quality and findings of safety assessment*". Arguments range from the small dose estimates, use of independent project teams, applied QA of conceptualisation, models and databases as well as the systematic and documented identification of safety functions and criteria for the safety functions.

Only few have listed "*reserve FEPs*" i.e. identifying FEPs with positive impacts on performance that could, if needed, be considered during future stages of the programme.

Generally, respondents give similar answers to the question on "complementary evidence and lines of argument" to the answers given in support of safety in the first place. There is a substantial overlap with the questions assessed in Sections 4.2.1 and 5.2.1.

Compilation of answers

Arguments given regarding the "Strength of geological disposal as a waste management option" are still site specific. Nagra uses arguments based on observations of natural systems (including palaeohydrogeology and natural analogues) that safety over geological timescales is achievable (Nagra). OPG makes several site specific arguments such as "rock is very old and stable", "deep groundwaters very old", "the wastes are dominated by relatively short-lived radionuclides" or that earthquakes, glaciation or other natural events will not disrupt the repository. Nirex describes the passive safety features of the repository and demonstrates that the design uses best practice scientific and engineering principles and also notes that the safety case may include more general arguments related to radioactive waste management, and information to put the results of performance and safety assessments into perspective.

Only one respondent listed arguments on adherence to disposal principles. For Nagra the adherence to the explicitly listed disposal principles (e.g. multiple passive safety barriers with a range of favourable properties, siting and design that favour low likelihood and consequences of human intrusion, etc.) constituted qualitative argument for safety and robustness.

Arguments on feasibility of design are given. According to OPG the repository can be built and operated safely using proven technologies. In a similar fashion, SKB states that the engineered parts of the repository system are based on, to various extents, demonstrated technology and established quality assurance procedures to achieve the initial state of the system.

Many arguments concern the quality of underlying scientific understanding. OPG has a good understanding of the site and the geology and hydrology are predictable at repository depth. For SKB confidence in the site-descriptive model and confidence in the understanding of the site is obtained by a systematic and quality assured programme for site investigations and site modelling. Confidence in the scientific understanding of the repository evolution is essentially built on decades of documented R&D efforts. Where possible Nagra supported their scientific understanding of key system features and properties (including their longevity) by multiple lines of evidence including, for example, evidence from natural systems, engineering experience, and laboratory and field experiments. For the USDOE-YMP, largely analogue arguments were available. Nirex makes comparisons with natural analogues, i.e. occurrences of materials or processes which resemble those expected in a proposed geological waste repository, shows consistency with independent site-specific evidence, such as observations in nature or palaeohydrogeological information and provides evidence for the intrinsic robustness of the repository system, for example demonstrating that relevant features and processes are well understood, often supported by evidence from underground research laboratories. NUMO and JAEA note that the additional complimentary evidence and lines of argument listed in earlier answers have been used, although the degree to apply is not at the same level for each example. In addition, comprehensive list of papers submitted to academic journals or other quality assured proceedings, etc is used to support critical argument of key issues. The procedure and result of independent peer review is also cited. Furthermore, a record of the iterative documentation process to provide a safety case, in which a draft is open to the public to ask comments from a range of interested people or groups, is used as a complementary evidence to support the final conclusions and recommendations of the safety case.

Other main arguments concern the quality and findings of safety assessment. The OPG postclosure dose estimates for transport via groundwater are very small. BfS point out that independent project teams set up the safety assessment. OPG applied documented QA of conceptualisation, models and databases. SKB understanding of safety is built on a systematic identification of safety functions and criteria for the safety functions, documented in a dedicated chapter the main report. The repository evolution is analysed in the main report with a structured approach in several time frames.

Regarding reserves of safety, Nagra used simplifying pessimistic or conservative assumptions in modelling, and reserve FEPS were identified that could, if needed, be considered during future stages of the programme.

Regarding monitoring, OPG notes that the site will be monitored to confirm its behaviour.

5.4.2 Natural analogues – observations from natural systems

Observations from site or directly relevant for the site and host formation are indeed used. Apart from the key role played by the integrated geosynthesis in supporting all site specific data in the safety assessment there are also examples of observations in support of the geosphere stability. Such examples include, isotope profiles, formation-distinct hydrogeochemical signatures suggesting an absence of cross formational groundwater flow such as high porewater concentrations and age of the porewaters. Assessment of past disturbances, e.g. thermal and stress, in relation to expected disturbances caused by the repository is also judged valuable.

More general natural analogues, i.e. studies of natural systems outside the host formation, are also used, but more for supporting process understanding, and there is a varying interest among respondents. Generally, data from analogues will support the safety case as they sometimes provide useful information for the understanding of specific processes, but they are not used directly as a basis for the assessment calculations. However, in some cases, when applicable, analogues are used to assess probabilities and the nature of unexpected events.

Compilation of answers

Observations from site or directly relevant for the site and host formation are indeed used. Ondraf and Niras tend to focus the work on natural observations that are directly relevant for the site and host formation under investigation (e.g. isotope profiles, etc.). OPG studies formation-distinct hydro-geochemical signatures suggesting an absence of cross formational groundwater flow such as high porewater concentrations. Andra illustrates the diffusion phenomenon inside the Callovo-Oxfordian formation with natural tracers (profile of oxygen isotopic composition in porewater). For Nagra the concentration profiles of natural isotopes measured in the deep borehole at Benken in the Zürcher Weinland and at the Mont Terri rock laboratory are among the multiple lines of evidence for slow, diffusion-dominated transport in the Opalinus Clay. According to BfS, the high age of the porewaters in the lower region of the cap-rock and of the overburden give evidence for very slow groundwater movement and low subrosion rates. Nagra also notes that the expected maximum temperature in the repository is in the same order as that which has occurred already in the past. GRS-Cologne notes that for the Konrad Safety Case, the use of groundwater velocities, groundwater ages and salinity measurements was especially useful and supporting arguments, especially the age of the formation, for a possible safety case for Gorleben were compiled.

Natural analogues, outside the studied host formation, are also used, but more for supporting process understanding, and there is a varying interest among respondents. Data from analogies will support the RAWRA safety case for reasoning and minimisation of uncertainties, but will not be used in calculations. Andra notes that a few natural analogues studies support the phenomenological evolution of some repository components, although in some cases they can help in illustrating their characteristics. SKB notes that natural analogues sometimes provide useful information for the understanding of specific processes, but there is no integrated account of how natural analogues support the safety argumentation in SR-Can. According to Nagra natural analogues are an important part of the Safety Case since they generally demonstrate that waste management concepts actually work in nature and for testing detailed process models etc. (immobilisation, corrosion rates…). Nirex notes that evidence from natural and anthropogenic analogues gives an indication of the extent and importance of processes over the timescales that are of relevance to long-term safety of radioactive waste management and that would be impossible to investigate over laboratory experimental timescales. The USDOE-YMP uses analogues to assess probabilities and the nature of unexpected events. According to NUMO and JAEA, the information from natural analogues and other observations can be used not only for process understanding to support applicability of models and databases, but also to contribute in increasing confidence by supporting conservatism in the assumptions of assessment models and data values, completeness of FEP list and longevity of the barriers and their expected safety functions.

Cited examples (from Andra, Nagra and Nirex) of using natural analogues in the above context include:

- Nirex notes that the most obvious natural analogues are the studies of ancient high-grade uranium ore bodies as analogues of spent fuel (uranium).
- Concerning the chemical interaction between iron (metal) and clay media in the broadest sense, Andra has taken advantage of the work carried out into natural diagenetic chloritisation processes (Andra).

- Andra has used studies of natural analogues of nuclear glasses (basaltic glasses) to check proposed approaches for characterising the dissolution processes of borosilicated nuclear glasses.
- Andra has supported its understanding of alkaline disturbance of the clays by cement-based fluids by the study of natural analogues, particularly at the Maqarin and Khushaym Matruck, Jordan, sites and model exercises. Also Nagra considers Hyperalkaline systems, such as Maqarin, to be useful analogues providing evidence for geochemical immobilisation in the ILW disposal system.
- Andra extrapolation of the corrosion process in both time and space is based on the study of a number of archaeological analogues which, though often representative of different conditions from those within a repository (essentially oxidising conditions), confirm the role of protective layers. Natural and anthropogenic analogues provide supporting evidence to Nagra for the assumed low corrosion rates of potential canister materials (carbon steel, copper).
- Nagra notes that observations of bentonite deposits indicate no detrimental effects from elevated temperatures in the expected range.
- Nirex notes that an example of an anthropogenic analogue would be the extension of laboratory measurements of steel corrosion rates for comparison with corrosion rates measured in buried industrial pipelines or archaeological artefacts.

6. SYNTHESIS

In general, a safety case will conclude that there is adequate confidence in the possibility of achieving a safe repository to justify a positive decision to proceed to the next stage of planning or implementation. This is a statement of confidence on the part of the author of the safety case – typically the developer – based on the analyses and arguments developed and the evidence gathered. The audience of the safety case must decide whether it believes the reasoning that is presented is adequate, and whether it shares the confidence of the safety case author. To this end, a synthesis of the available evidence, arguments and analyses is made. According to the NEA (2004), this should highlight the grounds on which the author of the safety case has come to a judgement that the planning and development of the disposal system should continue. Judging from the responses some assessments already include such statements, whereas other assessment intend to – when the safety case will be presented as part of an application. Furthermore, all assessments contain preliminary conclusions regarding safety.

6.1 Clear statement why sufficient confidence that the proposed system is safe

Some assessments include a clear statement why there is sufficient confidence that the proposed system is safe. Generally, these assessments have been part of a license application, or another important programmatic step. Other assessments do not yet include such statements, but intend to – when the safety case will be presented as part of an application. Furthermore, several assessments contain preliminary conclusions regarding safety.

Only few of the respondents listed the actual arguments given. They are anyway already covered by the answers given to previous questions.

Compilation of answers

Some assessments include a clear statement why there is sufficient confidence that the proposed system is safe. For example, Posiva notes that such statements are made on p. 217 of TILA-99 for the conclusion on safety and on p. 218 for implications on further programme steps. In Chapter 8 of the safety evaluation volume of the dossier 2005 Argile that is dedicated to the lessons of the safety analysis, Andra notes that "the feasibility of the repository seems to have been determined with a reasonable degree of confidence. In particular, the safety assessment shows that the radiological protection objectives assigned to the repository are complied with". .Such statements are provided in Chapter 6 of the Safety Case presented by BfS, GRS-Bs and Colenco. In Nagra safety report for Project Opalinus Clay, it is stated that the project "... provides a platform for discussion and a foundation for decision making on how to proceed with the Swiss HLW programme and to assess the role of the Opalinus Clay of the Zürcher Weinland in this programme" (p. 345 in Nagra, 2002a) and the report goes on to give the points as justification for this statement. NUMO/JAEA note that such statements are made in H12 (executive summary) covering technically feasibility and the research effort described demonstrates the robustness of the concept with more reliability and confidence than before. H3. It is concluded that these studies will provide a technical and scientific basis for the site selection process and for developing a regulatory framework. They also allow key requirements for future R&D to be specified, providing guidelines for an integrated R&D programme which optimises use of the available infrastructure in Japan together with complementary international collaborative studies.

At the current, generic, stage of the Nirex programme, Nirex feels this statement is best presented in the "Viability report" – which is a statement about why Nirex believes its concept is viable. However, this report covers more aspects than post-closure performance.

Others do not yet include such statements, but intend to. According to Ondraf/Niras this is work in progress. OPG notes that safety case documentation is under development. A complete safety case is not yet available (RAWRA). SKB notes that such a distinct statement is not made in SR-Can since the assessment is a preparatory step for the SR-Site assessment on which decisions will be based. The final chapter of SR-Can does, however, contain preliminary conclusions regarding safety. According to USDOE-YMP such statements have been made external to the documents, but the intent is to be explicit in the next (licensing related) safety case document. GRS-Cologne notes that a synthesis as described is required in the draft safety requirements.

Only few of the respondents listed the actual arguments given. They are anyway already covered by the answers given to previous questions.

7. PRESENTING THE SAFETY CASE

7.1 Concerns and requirements of the intended audience

The emphasis placed on particular lines of argument and analyses and other aspects of the style of presentation must take account of the interests, concerns and level of technical knowledge of the intended audience and the stage where the safety case is according to the step by step decision-making process. The audience may include the regulator, political decision makers or the public, as well as technical specialists within or outside the implementing organisation itself. Multiple levels of documentation may thus be required, but these products must remain consistent amongst one another. According to the NEA (2004), there is only one safety case, but it may be cast in different "language" at different levels of detail for various audiences. Furthermore, consideration must be given to factors including transparency, traceability and openness.

Judging from responses the safety case is mainly documented for a technical audience, primarily for review by the regulator. For these audiences the safety case is generally presented in a main safety report supported by several main references and a number of lower level reports. However, in applicable cases a summary of the Safety Case is, or will be, presented in the Environmental Impact Assessment, as well as shorter summaries and brochures are prepared for wider audiences. Only some respondents appear to give an important role to other types of media in addition to printed documents in presenting the safety case to different audiences (e.g. computer graphics, videos). Transparency and traceabilty are both identified as priorities, but few respondents addressed how to handle conflicts between transparency and traceability. Finally it may also be noted that most regulators have, or plan to, issue documents on how it will review a safety case.

7.1.1 Different levels of documentation – transparency and traceability?

Transparency as well as traceabilty are of key importance from a regulatory perspective. A well structured, transparent, and traceable methodology documentation, with clear and complete record of the decisions made and the assumptions adopted is needed. Documentation must be amenable to regulatory review, with ability to trace a justification and argument and with careful referencing between documents. A simplified version of the safety assessment may also be needed since there is a broad range of interest groups and stakeholders.

The safety case is mainly documented for a technical audience, primarily for review by the regulator. For these audiences the safety case is generally presented in a main safety report supported by several main references and a number of lower level reports. Other sources of information may also be important, such as:

- Records, calculation logs, computer files, databases, which are archived, or maintained, for audit purposes.
- Documents produced by other organisations, including on-line documentation (FAQs, meeting protocols etc.).

Few respondents addressed how to handle conflicts between transparency and traceability. Suggested means include:

- Trying to keeping the main documents fairly short and readable.
- Dividing the safety report for into two parts, were the first report aims at pulling together all arguments as transparently as possible, without giving all the details and the second report provides a traceable route.

In applicable cases a summary of the Safety Case is, or will be, presented in the Environmental Impact Assessment. Other documents prepared for a wider audience include summaries and brochures.

Compilation of answers

Regulators especially emphasised requirements for documentation. CNSC expects a well structured, transparent, and traceable methodology description and documentation that provides a clear and complete record of the decisions made and the assumptions adopted in developing the model of the waste management system. The terms of reference should present the purpose and rationale for the assessment, answering why is the assessment being conducted, who is/are the intended audience(s) for the assessment and what decision is the assessment supporting. In a similar fashion UK/EA require that documentation must be amenable to regulatory review, with ability to trace a justification and argument and with careful referencing between documents. SSI/SKI note that a simplified version of the safety assessment is also needed since there is a broad range of interest groups and stakeholders. According to GRS-Cologne the presentation and communication of the results of safety assessments is an essential issue in the context of informing the regulatory authority, stakeholder involvement, public acceptance and transparency. The Draft Criteria prescribe the required elements of the Safety Case but give no further guidance on its presentation. It is up to the implementer to present and communicate the findings in an adequate form to the corresponding audience.

The safety case is mainly documented for a technical audience, primarily for review by the regulator. For example, Posiva notes that the main safety case report TILA-99 and its supporting documents were primarily made for the regulator and their experts and the expert community in general. NUMO/JAEA note that the primary audience of the safety case in H12 project was the Atomic Energy Commission of Japan, but it was also intended to cover a relatively wide audience of individuals and groups who are technically interested in the geological disposal. For the technical audiences the safety case is generally presented in a main safety report supported by several main references and a number of lower level reports.

OPG will produce a Supporting Safety Case Document, which may be contained within a Preliminary Safety Report and reference reports for the safety case. According to RAWRA the structure of document is provided by SONS. The general structure of Andra Dossier 2005 Argile is based on four levels of documentations: The technical documents which include PARS, QSA, intermediate summary, and reports; The Reference documents (i) the site reference document, (ii) the source terms, (iii) the Material reference documents, (iv) the Inventory Model, and (v) the radionuclides reference documents; The three “Volumes”: TAG, Architecture and management of a geological repository; TEP, Phenomenological evolution of a geological repository; and TES, safety evaluation of a geological repository; and Summary documents which include a synthesis report and a “general public document”. The main SKB safety report (about 700 pages) is supported by several main references and a number of lower level reports, in a traditional report hierarchy. NUMO/JAEA note that the H12 documentation is made in a hierarchical structure of four technical reports: the project overview report and three supporting technical documents. The target audience of the overview report is general technical experts, while the supporting reports are provided for specific technical experts who are involved directly in the geological disposal programme. A supplementary volume was also written for the general Japanese public to introduce the internationally accepted concept of geological disposal of radioactive wastes.

According to Nirex the level of technical detail that is required by a regulatory audience may be quite different to that required by other stakeholders. For the Nirex 97 assessment at Sellafield, a high-level summary document was produced with some of these other audiences in mind. The level of detail for the GPA is slightly less technical than for the Nirex 97 and Nirex 95 assessments of the Sellafield site, to represent the fact that the audience at the generic stage might have a greater number of less-technically minded stakeholders. The concept overview report and the viability report are two documents that provide a higher-level summary of the current generic concept.

Other sources of information may also be important, e.g.

- Records, calculation logs, computer files, databases, which are archived, or maintained, for audit purposes (OPG).
- A range of documents produced by other organisations, including on-line documentation (FAQs, meeting protocols etc.) compiled by the "Technical Forum" (TF 2005), a body installed by the Federal Office of Energy for the purpose of addressing technical and scientific questions related to Project Opalinus Clay asked by the public, by politics and by communities, cantons, etc. (Nagra).

Few respondents addressed how to handle conflicts between transparency and traceability. However, according to Posiva transparency has been one objective in the documentation and this has been achieve, inter alia, by keeping the main documents fairly short and readable. Nagra tried to handle this by dividing the safety report for Project Opalinus Clay into two parts: (i) a report addressing long-term safety (Nagra, 2002a), and (ii) a report on models, codes and data (Nagra, 2002b). The first report (Nagra, 2002a) aims at pulling together all arguments as transparently as possible, without giving all the details. The second report (Nagra, 2002b) provides a traceable route.

In applicable cases a summary of the Safety Case is, or will be, presented in the Environmental Impact Assessment. In the Environmental Impact Assessment Report produced by Posiva, a shorter presentation is made for broader audiences. A summary of the safety case will be made within the EA Study Report to be produced by OPG.

Other documents prepared for a wider audience include:

- Summaries, e.g. BfS/GRS-Bs/Colenco prepared an abridged version of the main document to allow the interested public to judge about their involvement into the project. A simplified, around 100 pages summary in Swedish will be produced by SKB shortly after the publication of the expert documents. NUMO/JAEA note that a supplementary volume to H12 was also written for the general Japanese public to introduce the internationally accepted concept of geological disposal of radioactive wastes. The system of technical, management and public policy controls is described that will assure selection of a safe, long-term solution to the disposition of hazardous radioactive wastes in Japan.
- Brochures etc. A summary public communication brochure on the DGR project is prepared by OPG. Posiva has prepared brochures and videos for even easier understanding. USDOE-YMP have plain language descriptive and illustrative materials made to allow the public and the media to understand what we did to show the repository is likely to be safe.
- In the framework of the mission entrusted upon Andra by the Law of 30 December 1991, the Agency presented to the Ministers for Research and Industry the first version of a report on the feasibility of a repository for high-level and long-lived radioactive waste in a deep geological formation. A new version has been given to the government on 20 December 2005.

7.1.2 Role of other types of media

Only some respondents appear to give an important role to other types of media in addition to printed documents in presenting the safety case to different audiences (e.g. computer graphics, videos). However, answers may not be complete and may not reflect the views of their organisations.

Examples of other types of media include the Internet, where most organisations post a wide range of material for easy downloading, "virtual repository system" providing provides both general background information and a visual/audio/contact experience to help the public understand all aspects of the safety case, meetings with the public, exhibits, videos, and 3-D virtual reality for presenting and examining the geological information and its geosynthesis.

Compilation of answers

Only some respondents appear to give an important role to other types of media in addition to printed documents in presenting the safety case to different audiences (e.g. computer graphics, videos). However, answers may not be complete and may not reflect the views of their organisations.

Examples of other types of media include:

- The Internet. Nagra notes that the internet also plays an important role (e.g. www.nagra.ch, www.bfe.admin.ch, www.hsk.ch, etc.). USDOE-YMP notes that internet-accessible media and text files, videos, computer graphics, all will be used in the campaign to explain the license application and its content to non-regulator audiences, USDOE-YMP. As regards wider diffusion, a series of videos, publications and media's paper, as well as the main dossier itself, are available on the website of Andra and can easily be downloaded. According to Nirex, some material (such as diagrams of FEPs and the relationships between them) may lend itself to a web-based presentation. NUMO/JAEA not that for H12 a publicly available database system specific to the safety case has been developed and relevant information to the individual arguments can be accessed through the WWW in a format that is systematically designed to allow an interested observer to "mine" the information and reports supporting the safety case. (It should also be noted, although not mentioned in the responses, that many other organisation, e.g. Posiva, SKB, make all their printed reporting available as downloadable pdf-files on their websites).
- Videos, computer graphics (OPG, Posiva, Andra, NUMO/JAEA, Nirex).
- A "virtual repository system" was developed called GEOFUTURE 21. It is a tactile "ride-like" display that is part of the public outreach activities at JAEA community museum in Tokai-mura, Japan. It provides both general background information but a clear visual/audio/contact experience to help the public understand all aspects of the safety case.
- "Exhibits" (OPG).
- 3-D virtual reality for presenting and examining the geological information and its geosynthesis for technical audiences (OPG).
- Meetings with the public. A number of events were organised by different stakeholders including Nagra and the Federal Office of Energy to present the safety case for Project Opalinus Clay to the public. (Most likely the case for other organisations as well).

7.1.3 Documentation on how (regulator) will review a safety case

Most regulators have, or plan to, issue documents on how they will review a safety case. In same cases more detailed review plans are also (being) prepared. Generally all aspects of the safety case will be reviewed. Typically reviews will address assessment methodologies, structures, and approaches, scenario selection and analysis, handling of uncertainties, type of arguments included in the implementer's safety case application of optimisation and best available technique (if applicable) and quality assurance. In some cases the review plan has been prepared in consultation with the involved municipalities and other stakeholders.

Compilation of answers

Most regulators have, or plan to, issue documents on how it will review a safety case. In same cases more detailed review plans are also (being) prepared.

The CNSC Guide G-320 addresses the assessment of long-term safety to support licence applications, and includes discussion of assessment methodologies, structures, and approaches. STUK Guide YVL 8.4.specifies the general content of a safety case report and includes some advise for the scenario analysis, consideration of uncertainties etc. SSI and SKI regulations and guidance contain general requirements on what type of arguments that should be included in the implementer's safety case, e.g. concerning risk analysis, selection of scenarios, handling of uncertainties, application of optimisation and best available technique and quality assurance. Furthermore, SKI and SSI are currently developing more detailed review plans for the up-coming reviews of the license application. Much of this work is done in consultation with the involved municipalities and other stakeholders. Nagra notes that the main document regarding regulatory review of the safety case is HSK R-21 (HSK & KSA, 1993). In addition, HSK has produced a document on the concept of evaluation of Nagra siting feasibility study as part of Project Opalinus Clay (HSK, 1999). USDOE-YMP notes that the regulator has published the Yucca Mountain Review Plan (available at www.nrc.gov/reading.).

UKEA has not yet developed specific plans, but specific plans were produced for (Drigg) review. However, Nirex does have a formal arrangement with the Regulator whereby safety-related aspects of Nirex work are scrutinised and feedback given. A semi-formal procedure involving "Issue Resolution Forms" is used to record the feedback from this Regulatory scrutiny and Nirex response to it. The GPA has recently undergone such scrutiny and Nirex is awaiting the Regulator's report. The document, "Disposal Facilities on Land for Low- and Intermediate-Level Radioactive Wastes: Guidance on Requirements for Authorisation" (1997) produced by the regulators sets out the general principles that will be used in reviewing authorisations for future disposal facilities. However, it should be noted that the regulators are currently reviewing and updating this guidance document.

Andra took into account the recommendations of the Basic Safety Rule (RFS III.2.f), which defines a certain number of trends in terms of design. The BSR is not a regulatory text, but it makes up a basis for common discussion and understanding between the safety authority and the repository's designer. The BSR does not fix any requirements about format of the safety case but defines a certain number of principles related to safety in the post-closure phase, indicates the generic role of the main components and sets objectives in terms of radiological protection. It should be noted that the BSR applies only in a strict sense to the post-closure phase.

In contrast, BfS notes that no documentation exists on how the regulator plans to review the safety case. However, the current practice shows that all assessment reports as well as the complete documentation of information and basic data will be reviewed, all aspects of the safety case will be reviewed, the review is done by independent experts and questions resulting from the reviews are summarised according to topic by the regulator. GRS-Cologne notes that presently no such requirements exist.

7.2 *Purpose and context*

According to the Safety Case brochure, NEA (2004) in any description of the safety case, a clear statement of purpose and context is required. The description of the purpose and context of the safety case should include: the stage in the process currently reached; how the required attributes of the geological setting of the repository will be tested or confirmed; how the feasibility of the manufacture or construction of the engineered barrier system will be achieved; how the repository will be constructed, operated and closed; and how these procedures will be controlled, as well as programmatic and practical factors that constrain the way this process proceeds. It also may be advisable to describe the key decisions that have already been taken or must be taken in future, and actions that will follow from positive decisions, and the responsibilities of different organisations within the decision-making process.

Judging from the answers, this type of information and constraints are also addressed up front in the Safety Case reports. In case lessons learned from previous assessments exist, and are relevant to the assessed repository concept they are frequently referenced. When applicable, the documentation of the safety case makes reference to the contents of other national or international safety cases or peer reviews. Such references include NEA suggested safety case format.

7.2.1 How are the context and purpose of the safety case described in the safety reports?

How context and purpose of the safety case are described in the safety reports are, at least by some regulators, seen as being very important. Documentation should demonstrate understanding of regulatory requirements and include a description of the approach used to demonstrate safety. Generally, this type of information and constraints are also addressed up front in the safety case reports.

Compilation of answers

There appear to be varying view between regulators on how context and purpose of the safety case are described in the safety reports. According to CNSC, the safety report should present the purpose and rationale for the assessment, should demonstrate understanding of the federal and provincial regulatory requirements, as well as any international obligations that apply to the project and also include a description of the approach used to demonstrate safety over the long term and gain confidence in the results. UK/EA notes that context and purpose are very important. In contrast, SSI/SKI respond this is an implementer issue. GRS-Cologne finds this issue not applicable in the context of criteria/guideline development.

Generally, the context and purpose are described upfront in the Safety Case report. According to OPG, the description of the context and purpose, at the current stage, includes a simple description of the stage of the DGR programme and of the scope of the current iteration of the Safety Case. The context also includes a description of the acceptance criteria. RAWRA will document the licensing framework requiring a safety case, the strategy to investigate one or more host-rock options, the strategy to examine more than one design option (at present, alternative repository geometry: vertical/horizontal), data acquisition references and data availability and performance-assessment tools and computer codes description and verification. The context and purpose of the safety case are described in the first chapter of the safety report of Andra dossier 2005 Argile. This chapter presents the basic approach adopted to assess feasibility from a safety viewpoint within the context of a clay site based on the characteristics of the Meuse/Haute-Marne (MHM) laboratory site. NUMO/JAEA note that the H12 reports state that the studies are aimed to demonstrate technical feasibility and reliability of the deep underground geological disposal of HLW in Japan in stable host rock on a generic basis, considering a wide range of geological environments throughout Japan, and to provide a technical and scientific basis for implementation and the associated regulatory framework, following the AEC guidelines. Constraints explicitly mentioned by SKB include the requirement of a safety report in support of the application of a licence to build the final repository and the availability of site-specific data. Other constraints will be discussed in other parts of the documentation in support of a licence application for the final repository planned for 2009. Nagra safety report (Nagra, 2002a) describes the purpose and context of the safety case in the introductory chapter. USDOE-YMP discusses constraints as part of the text explaining the scientific work underlying the process models that are abstracted to be included in the system-level model. Nirex notes that the "Assessment Context" is the first main element of the safety case. It explains the current stage in the decision-making process and hence defines the basis for preparing the safety case. The assessment context includes a description of the facility concept, explaining how it will be constructed, operated and closed and how the required attributes of the facility will be tested or confirmed, with reference to the relevant Regulatory Guidance. The assessment context is described early in the safety reports as it is important for establishing the appropriate expectations for the safety case. For example, a different level of detail will be required for a generic safety case conducted at an early, concept development stage of the decision-making process, in comparison with a detailed safety case submitted as part of a repository authorisation.

7.2.2 Lessons learned from previous assessments

In case lessons learned from previous assessments exist, and are relevant to the assessed repository concept they are frequently referenced.

Compilation of answers

In case lessons learned from previous assessments exist and are relevant to the assessed repository concept they are frequently referenced. According to Posiva there has been a continuous development from TVO-92 to TILA-99 and the present work in the safety case is based on these assessments. Andra notes that the repository architectures proposed within the framework of the Dossier 2005 are the result of previous reviews and exchanges and take particularly into account what was learned from the previous safety assessments (especially the Dossier 2001). NUMO/JAEA note that H12 built on the findings and review of the earlier H3 performance assessment released in 1992. Following H3, the Japan Nuclear Cycle Development Institute (JNC, now JAEA) pursued R&D to provide more reliable data on geological conditions at two study sites, and completed the second progress report (referred to as H12). H12 follows the AEC guidelines issued in 1997, which specifies purpose (see VI.4) and boundary conditions for H12. This evolution of the programme has been described in background section of the H12 report. SKB makes frequent references to previous assessment and (e.g.) the FEP catalogue uses material in the SR 97 assessment as an important basis. Earlier assessments were acknowledged by Nagra as providing a starting point for developing the safety assessment methodology used in Project Opalinus Clay. The Nirex safety report refers to previous safety assessments and explains their role as part of the iterative process of developing a safety case. It is proposed that in the ESC documentation a section is devoted to recording the review process and any actions taken as a response to feedback form the regulator or indeed other stakeholders. According to USDOE-YMP, such lessons are captured in the discussion of key topical issues identified by regulatory (and other external) reviews.

7.2.3 Reference to the contents of other national or international safety cases or peer reviews

When applicable, the documentation of the safety case makes reference to the contents of other national or international safety cases or peer reviews. Such references include NEA suggested safety case format, reference to operating facilities for waste disposal in different countries and reference to assessment methodology and differences and similarities in the treatment of safety functions and the role of different barriers.

Compilation of answers

When applicable, the documentation of the safety case makes reference to the contents of other national or international safety cases or peer reviews. CNSC notes that claims of long-term safety submitted to support a licence application may be evaluated by the CNSC with reference to nationally and internationally accepted best practices. OPG safety case is informed by the international knowledge, for example it follows the NEA suggested safety case format and references international planned or operating facilities for waste disposal for context. Andra made comparison with other international programmes as well as with the NEA and IAEA guidance in order to provide additional line of arguments (in particular those related to FEPs). The H12 document referred to the safety reports in other national programmes as well as NEA IPAG in order to support the state-of-the-art knowledge, place results in perspective, and check if key elements of a safety case are incorporated (NUMO/JAEA). SKB makes such references e.g. regarding assessment methodology and differences and similarities in the treatment of safety functions and the role of different barriers. USDOE-YMP notes that peer reviews of previous versions of the safety assessment are definitely mentioned, but it remains to be seen what international safety assessments and cases are referenced in the safety case for licensing.

In contrasts, Nagra makes no specific comparison of the approach to making the safety case or the results of assessment calculations with the approaches/results of other safety cases made either in Switzerland or internationally. However, in a number of reference reports, such comparisons are explicitly made. In the Nirex GPA, the only reference made to other national or international safety cases are a mention of the Drigg assessment for LLW, and to the treatment of chemo-toxic materials in the assessment. In Nirex 97, the international context was provided in the overview report. Brief reference is also made to other international programmes in the section on biosphere modelling.

8. REFERENCES

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Nuclear Energy Agency (1999), *Confidence in the Long-term Safety of Deep Geological Repositories: Its Communication and Development*, OECD, Paris, France.

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Nuclear Energy Agency (2005), *Geological Repositories: Political and Technical Progress*, Workshop proceedings, Stockholm, Sweden 7-10 December 2003, OECD, Paris, France.

Note*:* References to safety cases and other documents used by respondents providing answers are given in Table 2.2 *Main references used on response* (p. 108).