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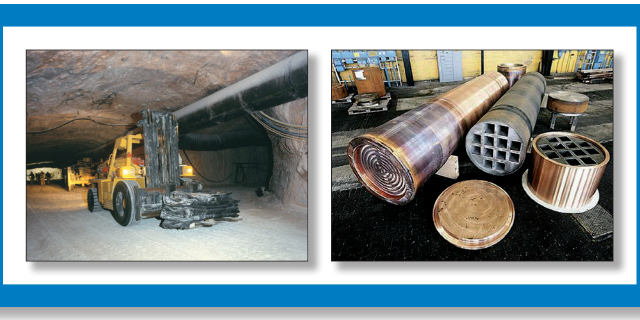
Methods for Safety Assessment of Geological Disposal Facilities for Radioactive Waste

Outcomes of the NEA MeSA Initiative



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NEA No. 6923

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Cover photos: Typical view of a geological disposal facility (Menkhaus, BfS); copper canisters for high-level waste disposal, Sweden (SKB).

Foreword

Disposal of radioactive waste in engineered geological repositories is the reference solution in many countries worldwide, and decision making and societal acceptance of geological disposal hinges upon the level of confidence achieved in the safety assessment of such repositories. Safety assessment is an interdisciplinary approach that focuses on the scientific understanding and performance assessment of safety functions as well as the hazards associated with a geological disposal facility. It provides crucial technical and scientific information to guide site investigation, research and development at various stages of repository development. Safety assessment is an essential component of the disposal safety case, providing inter alia the technical evidence to achieve confidence in the decision-making process.

The OECD Nuclear Energy Agency (NEA) conducted a comprehensive review of the different safety assessment methods used in various national radioactive waste management programmes. With the emergence of the safety case concept over the past decades, the NEA Integration Group for the Safety Case (IGSC) initiated a state-of-the-art review of safety assessment approaches in 2008. The goals of the project on "Methods for Safety Assessment for Geological Disposal Facilities for Radioactive Waste" (MeSA) were to examine and document methods used in safety assessment for radioactive waste disposal facilities, to generate collective views based on the methods' similarities and differences, and to identify future work. To finalise the project, a workshop was organised in 2010 to examine specific assessment strategy issues. Seven issue papers summarising the latest knowledge were produced on the following topics:

- Safety assessment in the context of the safety case.
- Safety assessment and safety case flowcharts.
- System description and scenarios.
- Modelling strategy.
- Indicators for safety assessment.
- Treatment of uncertainties.
- Regulatory issues.

This report summarises the key findings of the issue papers.

Acknowledgements

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Klaus-Jürgen Röhlig	Project Chair, Clausthal University of Technology (TUC), Germany
Abraham Van Luik	Department of Energy (DOE), Carlsbad Field Office, United States, Issue Paper No. 1
Jürg Schneider	*Nationale Genossenschaft für die Lagerung radioaktiver Abfälle* (Nagra), Switzerland, Issue Paper No. 2
Lise Griffault	*Agence nationale pour la gestion des déchets radioactifs* (Andra), France, Issue Paper No. 3
Paul Gierszewski	Nuclear Waste Management Organization (NWMO), Canada, Issue Paper No. 4
Ulrich Noseck	*Gesellschaft für Anlagen- und Reaktorsicherheit (GRS) mbH*, Germany, Issue Paper No. 5
Jörg Mönig	*Gesellschaft für Anlagen- und Reaktorsicherheit (GRS) mbH*, Germany, Issue Paper No. 6
Martin Navarro	*Gesellschaft für Anlagen- und Reaktorsicherheit (GRS) mbH*, Germany, Issue Paper No. 7

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Executive summary

In light of the substantial developments over the past 20 years, the NEA Integration Group for the Safety Case (IGSC) organised a project examining and documenting Methods for Safety Assessment for Geological Disposal Facilities for Radioactive Waste (MeSA).

Using the definition adopted in the project, a *safety assessment* is a systematic analysis of the hazards associated with a geological disposal facility, and the ability of the site and design to provide the safety functions and meet technical requirements. Safety assessment is an essential component of the safety case. From a regulatory perspective, providing the evidence to support the claims made in the safety assessment is just as important as the safety assessment calculations themselves.

Safety assessment in the context of the safety case

Its essential role in the safety case means that aspects of safety assessment relate to numerous elements of the safety case and the dividing line between safety assessment and safety case is not sharply drawn and need not be. What is important is that, firstly, safety assessment forms a central part of the safety case; and secondly, that the results of such assessments must be placed in context and augmented by additional information (i.e. in a safety case) to support decision-making.

Safety assessment also provides key information to focus research and site characterisation programmes, as well as engineering designs and testing. Conversely, these other aspects of repository development produce the data (and interpretations of that data) that support a high quality assessment. Given these links, an important aspect of repository planning is to ensure clear and effective information flow among the various groups and stakeholders involved with repository development.

Safety assessment and safety case flowcharts

Based on a review of approaches to safety assessment followed by various national and international organisations, a generic safety case and safety assessment flowchart was developed within MeSA. At a higher level, key assessment activities are "freezing of key data", comprehensiveness checking, a synthesis of evidence, arguments and analyses, and feedback to programme management. At a more detailed level, safety assessment generally starts with the development of an integrated description of the expected initial state of the disposal system and of its evolution. The safety concept is developed by describing the roles of the natural and engineered barriers and the safety functions that these are expected to provide in different time frames. This forms the basis for evaluation of the implication of uncertainties in the fulfilment of the safety functions over time, leading to the formulation of scenarios for the evolution of the repository over time and the derivation of related assessment cases. The results of the analyses of scenarios are complemented with arguments, for example, for the quality of the site and design (low impact of detrimental phenomena) and for the validity of model assumptions and boundary conditions from the assessment basis. They are also supplemented with any available independent supporting evidence for safety to place these results into context.

System description and scenarios

Scenarios represent specific descriptions of a potential evolution of the repository system from a given initial state. They describe the compilation and arrangement of safety relevant features, events and processes (FEPs) as a fundamental basis for the assessment of post-closure safety which includes assessing the potential consequences on humans and the environment. The development of scenarios for the safety case is of fundamental importance as it constitutes a key element of the management of uncertainties. In most regulatory environments, a qualitatively sufficient set of scenarios rather than a "complete" one meets regulatory expectations, as long as this set is comprehensive in the sense that it illustrates or bounds the credible evolutions of the repository system. Completeness in the context of all possible scenarios can easily become an idealistic and impractical goal. To assure a practicable safety assessment expectation, regulators may impose probability cut-offs or provide qualitative guidance on the types of scenarios that need to be considered and those that can be eliminated.

Typically, scenarios are divided into central scenarios aimed at representing the expected evolution(s) of the repository, plus plausible alternative scenarios representing less likely but still plausible repository evolutions, as well as extreme natural events that are very unlikely. A range of possible future human actions, which may significantly impair the performance of the disposal system, can be envisaged; these are often considered as a specific scenario category. Another category of scenarios, often called "what-if" scenarios, can also be considered in which implausible or physically impossible assumptions are adopted in order to help bound or conceptually test the repository robustness. Results from such unrealistic calculations need to be properly caveatted to prevent misinterpretation. They are not predictions of what will happen, they are not even predictions of what can happen, they are only hypothetical mathematical exercises that test robustness.

A prerequisite for assessing the future evolution of a repository is the establishment of a system description defining the initial state of the repository, including the waste form, the engineered systems and the site. The subsequent analysis of the evolution of the repository system is an indispensable task in developing a safety assessment. It requires a systematic identification and study of thermal (T), hydraulic (H), mechanical (M), chemical (C) and other processes that could occur in the repository system and affect the evolutions of the site and repository.

Scenarios are being derived based on the safety concept including the safety functions and taking into account safety-relevant phenomena and uncertainties. In some assessments, scenarios are derived using a bottom-up approach that begins by assessing a range of external events or conditions (e.g. climate change, human intrusion, initial container defect) that may trigger changes in the disposal system or affect its performance. Other programmes or organisations structure the scenario definition using a top-down approach, i.e. identifying first the crucial safety functions and then focussing on what combination of processes and conditions could jeopardise one or more safety functions. 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.

Databases of FEPs developed within specific projects, as well as the NEA FEP database have proved to be valuable tools, especially for disposal programmes that are in the early stages of repository planning. However, when a programme matures and THMC understanding increases, the knowledge to be managed and documented will go far beyond the capacity of simple FEP records. It will then become necessary to supplement FEP databases with other tools and means of documentation. For example, the understanding and knowledge of THMC processes may be compiled in "process reports", each one of which will have its own listing of FEPs specific to evaluating one or more processes. In this context, it is important to distinguish between concept-specific FEP catalogues or key safety-relevant phenomena derived from an integrated understanding of the system under consideration, which can have a central role in scenario development, and the more general NEA FEP database, which is increasingly used for completeness or comprehensiveness checking.

Modelling strategy

An assessment of the performance of a repository can be undertaken by simulation of the potential evolution of the repository system using mathematical or numerical models. Overall, there is wide consensus on the modelling strategies to support safety assessment, and no major areas of disagreement have been identified. In most safety analyses, deterministic and probabilistic calculations are now seen as complementary, and both approaches are applied. Greater differences exist between countries regarding the extent to which regulations allow simplified handling of the biosphere in the safety assessment.

Process-level models are developed in order to gain a solid understanding of certain aspects of the repository system and to form the basis for conceptual models incorporated into, and parameters used in, system-level models. Over the past 20 years, process-level models have become increasingly important and today such models are increasingly being applied to consider coupled THMC processes, although typically models at this point in time do not consider all of these processes simultaneously. However, there are instances where the processes determining the system's evolution result in little change to the system over time. Modelling such a system has been considered in some instances to be sufficiently straightforward to allow the direct coupling of process models to evaluate the total system.

The central part of the safety assessment is the integrated or system-level model, which is used to assess the performance of the disposal system as a whole, leading to a quantitative estimate of potential impact on humans and the environment over the assessment time frame. Simplifications are unavoidable; models, no matter how complex, are abstractions of nature. Simplifications have important consequences in terms of the level of conservatism and representativeness of the modelling results. However, as mentioned, there is a clear trend that models are becoming more capable (realistic) due to our improved understanding of the processes. The additional complexity introduced is ameanable to analysis due to the availability of more powerful computers. In general, the use of more complex models does not hurt our ability to understand the results.

Data gathering and management remains a prerequisite for modelling. Site characterisation, development of the engineered barrier system and associated experiments, and waste characterisation generate large amounts of data, and the traceability of data used in the safety assessment back to these data requires planning. Approaches currently used to help with this include data clearance procedures, site descriptive models, requirements management systems and reference datasets.

Due to the long temporal and large spatial scales involved in geological disposal, a complete comparison between safety assessment model results and experimental measurements cannot be made, but the modelling strategy should include elements of independent peer review of the theoretical bases, a software quality assurance process, verification that the computer codes accurately implement the mathematical models, and testing of the safety assessment model against experimental data, field data and/or detailed process models among other things. The assurance of data and information as well as of model and software development quality is a common theme across national regulatory requirements. In particular, the need for "traceable" and "transparent" links to the source data and references is seen as essential by regulators. It should also be noted that the difficulties associated with system model validation have contributed to the development of the safety case concept, with its emphasis on multiple lines of reasoning.

Indicators for safety assessment

The concept of using various types of indicators to complement dose and risk has developed considerably during the last 15 years in national and international projects, and has become internationally accepted. Experience has been gained in international fora such as SPIN, PAMINA, INTESC and various national projects. The early emphasis on using just dose and risk as safety indicators has been extended, and several types of complementary indicators are now used, most recently safety function indicators. The terminology used for indicators by different organisations is rather inhomogeneous and not consistent between national programmes; identical or very similar concepts are sometimes denoted differently, while in other cases the same term is used with different meanings.

The development of complementary indicators was driven by concern over the inherent uncertainty in estimating potential dose/risk to people in the far-future when climate and human behaviours may be radically different to today. To remove the uncertainty associated with the biosphere exposure pathway, safety assessors have considered other indicators such as the concentrations and fluxes of repository-derived radionuclides that would occur in the geosphere. These indicators may be compared to corresponding concentrations and fluxes of naturally-occurring radionuclides. More generally, complementary indicators usually fall into three categories, i.e. concentration related indicators, flux related indicators and indicators related to the state of barrier or component degradation, determining safety-function effectiveness.

Indicators may be distinguished according to their purpose into safety indicators, performance indicators and safety function indicators. Safety indicators give an indication of the safety of the repository and dose and risk are suitable for comparison with established regulatory criteria. Performance indicators provide information about how the system works in retaining radionuclides and how the level of safety is reached. Performance indicators are typically concentrations or fluxes of radionuclides in or between specific parts of the repository system, or other descriptive measures that demonstrate specific properties of the system. Safety function indicators are quantities that characterise the extent to which the safety function under consideration is fulfilled. For example, in some disposal concepts for spent fuel, the thickness of the copper container may be used as a safety function indicator for the role of the container. Many regulatory systems recognise the potential value of indicators additional to dose and risk.

Treatment of uncertainties

Uncertainties are, and always will be, associated with assessment results. In the safety case, the connection needs to be made between the key uncertainties that have been identified and the specific measures or actions that will be taken to address them, whether through an R&D programme, repository design studies or bounding safety assessment assumptions.

Internationally, there is now a consensus on the types and sources of uncertainties in safety assessments, although somewhat different terminology may be used. Typically, the uncertainties considered in safety assessment are classified into scenario uncertainties, model uncertainties, and data and parameter uncertainties. However, all three classes of uncertainties are related to each other, and particular uncertainties can be handled in different ways, such that they might be dealt with in one class or another. Furthermore, the improved and deeper understanding of the FEPs governing the evolution of a repository considered in recent models, has allowed a more realistic understanding of the repository as compared with earlier, more conservative representations.

Strategies for treating uncertainties within the safety assessment are well established. Generally, these fall into one or more of the following five strategies: (1) demonstrating that the uncertainty is irrelevant to safety, (2) addressing the uncertainty explicitly, (3) bounding the uncertainty, (4) ruling out the event or process adding to the uncertainty, and (5) using an agreed stylised approach to avoid addressing the uncertainty explicitly.

As integrated safety assessments develop, the assessments themselves are used to identify which areas of uncertainty most need to be reduced in order to increase confidence in the overall assessment results. Mathematical methods for assessing quantitatively the influence of uncertainties on the calculation end-points are available and are well established. Understanding of the advantages and drawbacks of specific methods has increased considerably in the last few years. A variety of methods (e.g. probabilistic, statistical) can be used to provide insight into the effect of uncertainty on system performance, insights that may be quantitative or qualitative. Use of a variety of methods is helpful for gaining more comprehensive understanding. The development of new methods is actively pursued. The choice between the various approaches is primarily driven by regulations. Many programmes consider that these approaches complement each other.

Regulators expect uncertainties to be identified, to the extent practicable quantitatively characterised or bounded, and their impact on safety clearly articulated in the safety case. Uncertainties which cannot be shown to be irrelevant should be avoided, mitigated or reduced as far as possible e.g. by means of site selection, site characterisation, repository design, and process-oriented research. Uncertainties connected to the assessment results can be placed into an understandable context for evaluation by using multiple lines of evidence.

In order to reduce uncertainties associated with the procedures used for data collection and assessments, regulators often require the application of auditable quality assurance measures to avoid inconsistencies or errors in the data or models, and the use of systematic approaches to prevent methodological mistakes. Following such quality-assurance procedures does not guarantee accurate data or analyses, but it documents that work has been done as described and that activities and results have been reviewed, witnessed or otherwise verified by an observer not directly involved in doing the specific tasks being verified.

Regulatory issues

Regulations and regulatory expectations have evolved considerably since the issuing of the NEA brochure on the methodology of safety assessment in 1991 and nowadays recognise more clearly the implications of the long assessment time frame for the demonstration of compliance on the assessment methodology that should be used. Regulators expect that the proponent not only assesses compliance with quantitative radiological criteria, but also demonstrates that the repository system is robust and that its possible evolution is well understood. Also, assurance of data and modelling tool quality, appropriate quality management and transparency and traceability of the assessment process are considered essential.

The regulators themselves have to provide qualitative and quantitative safety criteria and guidance on how to prepare adequate safety cases. It is generally considered beneficial to involve or inform regulators early in the process of developing a safety case in order to promote mutual understanding and to prevent unnecessary work being undertaken. Yet, the regulators still have to keep their independence which is an essential part of the national safety culture and of fundamental importance for the confidence of the stakeholders in the results of the safety case.

Part I

Background

1. Introduction

In 1991 the OECD/NEA compiled the state-of-the-art on safety assessment methods of disposal of radioactive waste of that time in a brochure called "Review of Safety Assessment Methods" (NEA 1991). It stated that safety assessment methods are available to evaluate adequately the potential long-term impacts of waste disposal systems but also concluded that assessment methods would be developed further as a result of ongoing work. While the overall conclusion of the 1991 brochure remains valid, substantial evolution since that time has taken place. This evolution is characterised by (see NEA 2007a):

- the development of the safety case concept, in which safety assessment is brought into a broader perspective;
- the submission of numerous safety cases on geological radioactive waste repositories, containing a variety of safety assessments with commonalities, differences, and new methodological developments;
- a considerable number of national and international activities devoted to the further development of several aspects of methodologies for safety assessments;
- a number of peer reviews of safety assessments and safety cases.

Since 1991, national and international regulations and regulatory expectations have also evolved to keep pace with the evolving safety assessment capabilities and the specific role of the safety assessment within the safety case. Several international initiatives and projects have developed recommendations, common views and opinions which have influenced the development of national and international regulations.

On the national level, several regulations and guidelines for safety assessments have been developed or revised in the NEA member countries during the last decade. On the international level, the ICRP has issued important recommendations with regard to the assessment of compliance with dose and risk constraints. Since 1991, the ICRP publications 77, 81, and 103 show a broadening view on the meaning of dose and risk constraints, and on the assessment of compliance for very long time frames. The IAEA safety fundamentals 111-F and SF-1 of 1995 and 2006, respectively, and the joint convention of 1997 have grounded the general requirement for safety assessments in the framework of radioactive waste disposal. Requirements regarding the methodology of safety assessment (which are not legally binding but represent good practices for national programmes to follow) have been defined in the IAEA 2006 document WS-R-4 which will be replaced by more general requirements (DS 354) in the future. More explicit guidance was given in 1999 by the IAEA safety guide WS-G-1.1 which is limited to near surface disposal facilities but will be superseded by a Safety Guide that will also cover deep geological disposal facilities (DS 355). The IAEA has also developed and applied a safety assessment methodology for near surface disposal facilities in the ISAM and ASAM projects, respectively. A common regulatory view on the treatment of uncertainties in safety assessments has been expressed recently by a group of European safety authorities and technical support organisations in the framework of the European Pilot Study (Bodenez *et al.* 2008, Vigfusson *et al.* 2007).

In light of this substantial development, the NEA Integration Group for the Safety Case (IGSC) organised a project examining and documenting Methods for Safety Assessment for long-term safety of geological repositories for disposal of radioactive waste (MeSA). Other international projects, notably the PAMINA project of the European Commission, have also devoted attention in some detail to certain aspects of safety assessment.

The goals of the MeSA project were to review and summarise developments since 1991 regarding safety assessment methods in order to:

- describe the state of the art;
- discuss the variety of methods and overall approaches;
- and confirm or establish a joint view about what are considered the necessary elements and agreed methods of modern safety assessments.

As noted above, the emergence and definition of the concept of a safety case has provided a new and different context in which to understand the role of safety assessment and to interpret the results. There are also other important aspects of the safety assessment methods that have evolved. The findings of MeSA are primarily documented in a series of related issue papers that address:

- Issue Paper No. 1: Safety assessment in the context of the safety case (Van Luik *et al.* 2011).
- Issue Paper No. 2: Safety assessment and safety case flowcharts (Schneider *et al.* 2011).
- Issue Paper No. 3: System description and scenarios (Röhlig *et al.* 2011).
- Issue Paper No. 4: Modelling strategy (Gierszewski *et al.* 2011).
- Issue Paper No. 5: Indicators for safety assessment (Noseck *et al.* 2011).
- Issue Paper No. 6: Treatment of uncertainties (Mönig *et al.* 2011).
- Issue Paper No. 7: Regulatory issues (Navarro *et al.* 2011).

The main findings of these papers are synthesised in the current document. The findings were also discussed at a workshop in May 2010. The structure of this synthesis does not follow the numerical topical sequence of the issue papers, it instead reorders them in an effort to “synthesise” the MeSA project outcome.

2. Overall regulatory perspective

Regulations and regulatory expectations have evolved considerably since the issuing of the NEA brochure on the methodology of safety assessment in 1991. The evolving safety case concept has led to a more sophisticated understanding of the role of safety assessment in the demonstration of repository safety and in the development and optimisation of a disposal system. Regulations nowadays recognise more precisely the implications of the enormous length of the assessment time frame for the demonstration of compliance and for the assessment methodology that should be used. In view of the inherent limitations of assessment methods, the outcomes of the safety assessment are now seen as lines of argument, which are accompanied by others in order to build confidence in repository safety.

Regulators expect that the proponent does not only assess compliance with quantitative radiological criteria but also demonstrates that the disposal system is robust and that its behaviour and evolution is well understood. The improvement of system understanding should be a main objective for all assessment methods. This ensures a sufficient level of realism overall even though conservative approaches are sometimes unavoidable in managing specific uncertainties.

Regulators expect the proponent to inspire confidence in the results of its safety assessment. Also, assurance of data and assessment tool quality, appropriate quality management, and transparency and traceability of the assessment process are considered as essential. Sometimes, this includes the call for complementary methods to determine the level of protection provided by the repository, e.g. by the use of indicators which are complementary to dose and risk.

The regulators themselves have to provide qualitative and quantitative safety criteria and guidance on how to build confidence in safety assessment results. The treatment of uncertainties and, in particular, of uncertainties which cannot be quantified, like e.g. those associated to human intrusion, or future biosphere evolution, is a useful area for the regulatory guidance. It is also important for the regulator to specify. Some regulators in that respect provide guidance on how to treat the biosphere in different time frames. When giving guidance, regulators usually consider how much freedom the proponent needs to optimise the system and to demonstrate that it is safe.

Regulators review the proponent's safety case and supporting safety assessments to ensure the repository will comply with legislation and regulations. They may also conduct their own assessments in order to gain confidence in the proponent's assessment results and to develop an independent understanding of the system.

In view of the fact that it is difficult to change the fundamentals of a safety case at late stages of a repository programme it is generally considered beneficial to involve or inform regulators as early as possible in the process. Yet, the regulators still have to keep their independence, which is an essential part of the national safety culture and of fundamental importance for the confidence of the stakeholders in the results of the safety case and its review by the regulator.

More specific regulatory aspects will be discussed for each of the safety assessment issues addressed in the following sections.

3. Safety assessment in the context of the safety case

3.1 Definitions

Over time, various definitions have been put forward for "safety assessment", "safety case" and related terms (see e.g. NEA 1997; NEA 1999; NEA 2004). The MeSA project focused on long-term safety; that is, safety in the period after disposal facility closure and beyond the time when active control of the facility can be relied on. In this context the MeSA project used the following basic definitions:

- Safety assessment is a systematic analysis of the hazards associated with geological disposal facility and the ability of the site and designs to provide the safety functions and meet technical requirements. The task involves developing an understanding of how, and under what circumstances, radionuclides might be released from a repository, how likely such releases are, and what would be the consequences of such releases to humans and the environment.
- The safety case is an integration of arguments and evidence that describe, quantify and substantiate the safety of the geological disposal facility and the associated level of confidence. In a safety case, the results of safety assessment – i.e. the calculated numerical results for safety indicators – are supplemented by a broader range of evidence that gives context to the conclusions or provides complementary safety arguments, either quantitative or qualitative. A safety case is the compilation of underlying evidence, models, designs and methods that give confidence in the quality of the scientific and institutional processes as well as the resulting information and analyses that support safety.

These definitions are based on those in the 2004 NEA brochure that documented the concept and elements of the safety case – which, in turn, closely match and elaborate on those incorporated in safety requirements published jointly by the International Atomic Energy Agency and the Nuclear Energy Agency (IAEA 2006).

There are some differences in terminology over time and across national programmes, so the definitions given above may not match precisely what is used in different countries. A term often used interchangeably with safety assessment is performance assessment. There are varying perceptions about the relationship between safety assessment and performance assessment. For instance, according to the IAEA Safety Glossary (IAEA 2007), safety assessment is the assessment of all aspects of a practice that are relevant to protection and safety (including siting, design and operation of the facility) whereas performance assessment is defined as the assessment of the performance of a system or subsystem and its implications for protection and safety. From that perspective performance assessment may be considered a component of safety assessment, but there is not universal agreement on this point. The term safety analysis is also used in some programmes. For the purpose of this project, the term "safety assessment" is used as defined above.

Similarly, a safety case may be referred to as a "safety case", "a post-closure safety case" or a "long-term safety case." In fact, not all programmes use the term "safety case" to describe the broader range of arguments and evidence of which safety assessment forms one part; they may alternatively call such products a "safety report", "safety dossier" or "license application", for example.

3.2 The safety case as context for safety assessment

A safety case is presented, most often by organisations responsible for implementing waste disposal solutions, at specific points in the process of repository development. 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 or in view of testing the methodology for developing a safety case. Furthermore, the iterative nature of preparation of a safety case and the potential subsequent modification of a repository design should be noted.

The NEA Safety Case Brochure (NEA 2004) described the essential elements of a safety case as follows:

- A clear statement of purpose provides context for the safety case.
- The safety strategy is the high-level approach adopted for achieving safe disposal, including an overall management strategy, a siting and design strategy and an assessment strategy. It incorporates good management and engineering practice, and provides sufficient flexibility to cope with new information and technical advances. Strategies favour robustness and minimise uncertainty by selecting a site with assessable features and by tailoring repository design to its geological setting.
- The assessment strategy ensures that events and processes relevant to safety are identified and guides how their consequences will be quantified. The assessment strategy involves the definition of conceptual models and mathematical approaches to be used to evaluate them, and is an integral part of 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 and its geological setting; 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 depends on the quality and reliability of the assessment basis. The definition of the assessment basis should be tailored to provide the necessary information supporting evidence, analyses and arguments for safety. The description of the process that leads from evidence to a safety evaluation is an important part of the safety case.
- Evidence, analyses and arguments for safety must be compiled into a safety case. Results of analyses are typically compared against safety criteria, often in terms of radiological dose and/or risk, but there may also be other performance measures applied either for regulatory compliance or as indicators of performance that provide insights into system behaviour. The evaluation of these performance measures or indicators, using mathematical analyses (i.e. safety assessment) is typically accompanied by more qualitative arguments that provide a context or support for the performance-calculation results. A series or range of appropriate evolution scenarios may be addressed for the disposal system. Evaluating system performance under various scenarios may provide an opportunity to optimise the system and to increases the robustness of the safety case. Robustness of the safety case may also be strengthened by the use of multiple lines of evidence, leading to complementary safety arguments, to compensate for any shortcomings in confidence in any single argument.
- The synthesis of available evidence, arguments and analyses, supported by the quality and reliability of the assessment basis, supports a safety case statement of confidence, typically made by the implementer. It should explicitly state that

sufficient confidence exists in the safety of the system to justify a positive decision to proceed to the next stage of planning or implementation or closing of a disposal system.

Its essential role in the safety case means that aspects of safety assessment relate to numerous elements of the safety case. Safety assessment provides an important platform for integrating information; for organising and testing conceptual understanding of a disposal system; for assessing the relevance and significance of uncertainties; and for quantifying performance and safety in a format that is readily comparable to established safety criteria. Safety assessment is only one of many components of a safety case. For example, the safety case is supported by components of repository development activities, including aspects of site characterisation and disposal system engineering design that are usually not considered part of a safety assessment even though specific measurements, features and processes relevant to the site and design are integral parts of the safety assessment.

Experience in the succeeding time since the NEA brochure of 2004 (NEA 2004) has shown, see e.g. the findings of the NEA INTESC initiative (NEA 2009), that the dividing line between safety assessment and safety case is not sharply drawn. There may be, for example, information that serves dual roles in safety assessment as well as supporting other, usually more qualitative, arguments for safety. In addition, national programmes have different interpretations and expressions of the elements of safety assessment, which overlap to various degrees with the definitions above.

While, it is difficult to draw a clear dividing line between safety assessment and the safety case, it is also recognised that is it is not necessarily useful to seek to make a sharp delineation, especially in view of the variety of definitions used internationally. What is important is that: firstly, safety assessment – a systematic and scientifically-supported analysis of repository performance – forms a central part of the safety case; and secondly, that the results of such assessments must be placed in context and augmented by additional information (i.e. in a safety case) to support decision-making.

3.3 Scope of safety assessment

The “scope” of safety assessment is largely established by its very definition – it considers the performance of the repository system in terms of radiological impact or some other global measure(s) of impact on safety. Still, within this framework, there can be variety concerning the time frame(s) considered relevant, the level of detail, the range of issues considered, and the degree of precision required for input data and in resulting calculations. The purpose of the safety case and the state of programme development often dictate the scope and degree of detail needed in safety assessment.

The time frames over which the safety indicators have to be evaluated vary considerably between national regulations and sometimes has to be determined and justified by the proponent. The selection of the time frames influences many aspects of safety assessment, including the range of scenarios that might occur and the level of uncertainty that must be accommodated. Furthermore, the time frame under consideration has a significant effect on how the results of safety assessment can be interpreted.

The assessment planner must also decide on what calculational endpoints to address. Where there is clear regulatory guidance it is to be followed, of course. However, where there is no guidance that covers all selected calculational time frames, the use of alternative performance or safety indicators may be appropriate as is further addressed in Section 7. Another significant aspect in designing a safety assessment is to define the range of scenarios and how they will be addressed, see further discussion in Section 5.

Ultimately, it is necessary to establish a boundary delineating events that lie outside the scope of safety assessment – in order to limit the complexity and uncertainty in safety assessment, as well to encourage attention on those aspects most relevant to safety. This may be done on the basis of probability cut-offs or other criteria, which raises the issue of uncertainties regarding the nature and probability of occurrence of key events and processes. There are several approaches available to do this type of uncertainty evaluation, usually employing a mix of probabilistic and deterministic approaches.

3.4 Importance of the assessment basis

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, i.e. its components (including the waste type(s) to be disposed and their quantities, engineered aspects including excavations, waste packages, buffers, etc., and the host rock and surrounding geological environment) and their safety functions.
- The scientific and technical data and understanding relevant to the assessment of safety.
- The assessment methods, models, computer codes and databases for analysing system performance.

Obviously, the quality of the safety assessment depends on the quality of the assessment basis. The information base should be consistent, well-founded, transparent and adequate for the purpose of the assessment and associated stage of repository development. From a regulatory perspective it should be noted 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.

3.5 Handling uncertainties

Uncertainties regarding a post-closure safety assessment are unavoidable due to the complexity of the phenomena of concern and the scales in time and space under consideration, and their management is central when developing a repository system and assessing its safety. These include uncertainty about whether all the relevant features, events and processes have been considered, uncertainty in their description and how they should be modelled, and uncertainty in the data that is needed in an analysis. The safety assessment methodology must account for uncertainties, and various approaches can be taken. Thus, safety assessment needs to be integrated within the uncertainty management strategy. Importantly, safety assessment itself is also a valuable tool to identify and evaluate uncertainties regarding system behaviour, and to judge their significance for safety.

Uncertainties relevant to safety should, where possible, be quantified and bounded in the conduct of safety assessment, see further the discussion in Section 8. However, the role of the safety case, however, goes beyond a pure quantification and assessment of uncertainties. A decision to move to a next step of a repository development is an expression of confidence in the proposed concept and in the findings of the safety assessment (and safety case) despite the existence of uncertainties, some of which will have to be addressed in the next step while others will inevitably remain. A safety case should propose a strategy to address uncertainties when moving to the next step.

3.6 Evolution of the safety assessment and the safety case over time

A given safety case exists in a specific context in terms of the decision being supported and of the site and design information, of the modelling tools and data that are available at that time. Updated safety cases may need to be prepared from the earliest stages of planning at time intervals up until (and sometimes even after) a repository is closed, spanning a period of several decades up to centuries. As investigations continue, data availability increases and the models used for safety assessments are re-evaluated in terms of appropriateness in the context of new information when necessary.

As programmes are implemented it is likely there will also be differences between what was assumed in earlier safety assessments and what has actually been built and placed in the repository. Deviations from original plans and assumptions need to be identified, evaluated, and in some cases justified. Furthermore, given the long time frames of repository development and, thus, safety assessment iterations, care must be exercised to preserve key data and the ancillary information that establishes the quality of those data.

3.7 Feedback and links with site characterisation, testing, engineering, design

There is significant interaction and iteration between safety assessment and other aspects of repository development, notably site characterisation and repository design. In some cases, preliminary safety assessment results are key inputs to guide these activities. In other cases, the results of these activities are key inputs to safety assessment.

One of the most prominent examples of feedback in repository development is the information flow between safety assessment and site characterisation. Preliminary system models are typically developed and used to some extent in the site selection process. Later characterisation of the site selected will then allow refinement of the preliminary modelling to reflect actual field conditions based on the information gained: after all, this is the purpose of site characterisation.

There is also closed-loop feedback between safety assessment and engineered design and barriers of a repository system. In early stages of development, safety assessment results can be utilised in selecting between various options or conceptual designs for disposal. Safety assessment also provides important input to establishing engineered system design requirements.

Safety assessment also provides a means to integrate information and to understand the interactions between various parts of the disposal system or between different sets of requirements. Furthermore, some requirements may compete with one another or imply opposing options. While post-closure safety is a main driver in repository design, operational safety and engineering feasibility are also essential: none can be disregarded in the design of the repository. Safety assessment provides assurance that a change made to solve one problem, such as avoiding the consequences of an uncertainty through a robust design, does not introduce other, potentially more serious problems or uncertainties. Thus, it is clear that safety assessment provides key information to drive research and site characterisation programmes and well as engineering designs and testing. Conversely, these aspects of repository development produce the data (and interpretations of that data) that support a high quality assessment upon which the quality of the safety assessment depends. Given these links and mutual dependencies, an important aspect of repository planning as well as a sound safety assessment is to ensure clear and effective information flow among the various components of repository development.

3.8 Safety assessment results and communication

The results of the safety assessment are compared against agreed-upon criteria for safety and performance indicators, which usually include radiation dose or risk and possibly other measures of the performance or possible consequences of releases from the disposal system. This provides one of the main lines of evidence in a safety case, supplemented by additional evidence and information, but ideally, a safety case should be summarised and synthesised in a concluding confidence statement. Uncertainties remaining in a given stage of repository development are addressed. In the safety case, the connection is made between key uncertainties that have been identified and the specific measures or actions that will be taken to address them, especially with regard to the design option, the scenarios and related R&D programme.

The uncertainties in safety assessment and the interpretation of results also complicate the communication of safety assessment results. The "measures of merit" deemed representative in terms of comparison with safety criteria are not necessarily those that are easiest to explain, especially to a non-technical audience. The presentation of a safety case to the public needs to emphasise issues that are likely to be of greatest public concern. It also needs to adopt a style that is accessible to an audience with a broad range of technical and non-technical backgrounds. However, there is one comprehensive safety case; that is, the evidence, arguments, reasoning and underlying basis are the same and what differs is simply the manner and degree of detail in the presentation.

3.9 Regulatory perspective

National regulations generally require the proponent to prepare a safety assessment as a prerequisite to licensing. However, even before reaching the licensing stage, safety assessments play a crucial role in the evolution of the disposal concept. At early stages of the project, safety assessments are used to compare alternative sites and or designs and also to identify data gaps including further site characterisation and for guiding research.

It is also commonly understood that safety assessments are analyses that cannot and do not constitute absolute proof of safety, but efforts are made to design and conduct these analyses such that there may be a sufficient degree of confidence in their results to make a case for moving to the next step in the repository programme. Other arguments such as those based on natural analogues, accelerated experiments, plans for performance confirmation, and plans for monitoring of both engineered and natural components may be put forward to enhance overall confidence. Together with the main safety assessment results, such additional arguments constitute the main components of a safety case.

As a generality, 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 (NEA 2009, p. 11). This suggests that regulators have always called for a safety assessment to be accompanied by the type of supportive and ancillary information that puts it into the context of a safety case.

Furthermore, from a regulatory perspective, it is expected that there will be a systematic and clear treatment of uncertainties in a safety assessment. In some cases, the treatment of uncertainties encompasses the treatment of contradictory expert opinions which may lead to a creation of alternative models, data sets, or to a formal decision process that is documented so as to allow a reviewer to see the basis for the resulting modelling or design decision.

It must be appreciated that the regulator is challenged with having to review first-of-a-kind methods and information (NEA 2009, p. 43). The safety assessment comprises one of these, but at the same time provides the means to assess other aspects, such as to understand to what extent it would be possible to modify an existing design choice or related programme decision.

From a regulatory perspective it is also important to keep in mind that safety assessment results are often reported in various documents or at several levels of technical sophistication. To be effective, the safety assessment needs to be reasonably transparent and regardless of the level of detail, the various presentations must be consistent; that is, they must rely on the same safety arguments and reach the same conclusions regarding safety.

4. Safety assessment and safety case flowcharts

4.1 Development of assessment strategy flowcharts

Assessment strategy flowcharts are presented in many safety cases, although not always referred to as such. An early example is the flowchart presented in the NEA Review of Safety Assessment Methods, published in 1991 (NEA 1991), where the main tasks identified in a safety assessments being:

- scenario analysis;
- model representation; and
- consequence analysis, including comparison with safety criteria.

It is also shown how these tasks are supported by extensive and systematic use of information from many scientific and technical areas. This information base roughly corresponds to what has more recently become known as the assessment basis (see e.g. NEA 2004).

In 1999, the NEA published the document *Confidence in the Long-term Safety of Deep Geological Repositories: Its Development and Communication* (NEA 1999). Among other things it emphasises that the development of the assessment basis benefits from the experience gained in previous development stages (including interaction with decision makers).

In 2004, the NEA published a Safety Case Brochure (NEA 2004). It emphasises the broad nature of the supporting argumentation, which extends beyond the modelling of scenarios and that a key element of the assessment strategy is the adequate treatment of uncertainty. However, the Safety Case Brochure gives little description of the process defined by the assessment strategy, including the carrying out of a safety assessment.

The IAEA has proposed a flowchart in the context of its ISAM methodology: “Improvement of Safety Assessment Methodologies for Near Surface Disposal Facilities” (IAEA 2000, 2004). The ISAM flowchart is more limited in its scope than the Safety Case Brochure flowchart, in the sense that it focuses on safety analyses and their results, rather than the broader range of evidence, analyses and arguments that are synthesised in a safety case. Consequently, the iteration loops shown are limited to the assessment, while the idea that assessment results can serve as a basis for system optimisation (i.e. improving system performance and/or robustness) is missing. Nonetheless, although they differ in scope, in their degree of detail and in the terminology adopted, many common elements and linkages may be identified between the NEA flowcharts, the ISAM flowchart and many other recent flowcharts.

In conclusion, flowcharts can be developed for the steps typically undertaken for different stages of a safety assessment and the development of a safety case. Such flowcharts can also illustrate linkages and feedback among components of safety assessment and to other parts of the safety case. The comparison – especially with the 1991 NEA Review of Safety Assessment Methods – shows that flowcharts have tended to become more comprehensive and broader in scope in the intervening years, often including elements of the safety case over and above the quantitative analysis of evolution scenarios. The importance of feedback from safety assessment via programme management to scientific and design studies is widely recognised, as is the iterative nature of safety case development, and these aspects appear explicitly in some of the more recent flowcharts.

There remain some differences in the terminology used in flowcharts. Furthermore, the scope and level of detail of flowcharts presented will always depend on the stage and purpose of the project that they support and the role of the flowchart within that project (which will, for example, influence whether feedback loops are important to show).

4.2 Generic assessment strategy flowchart

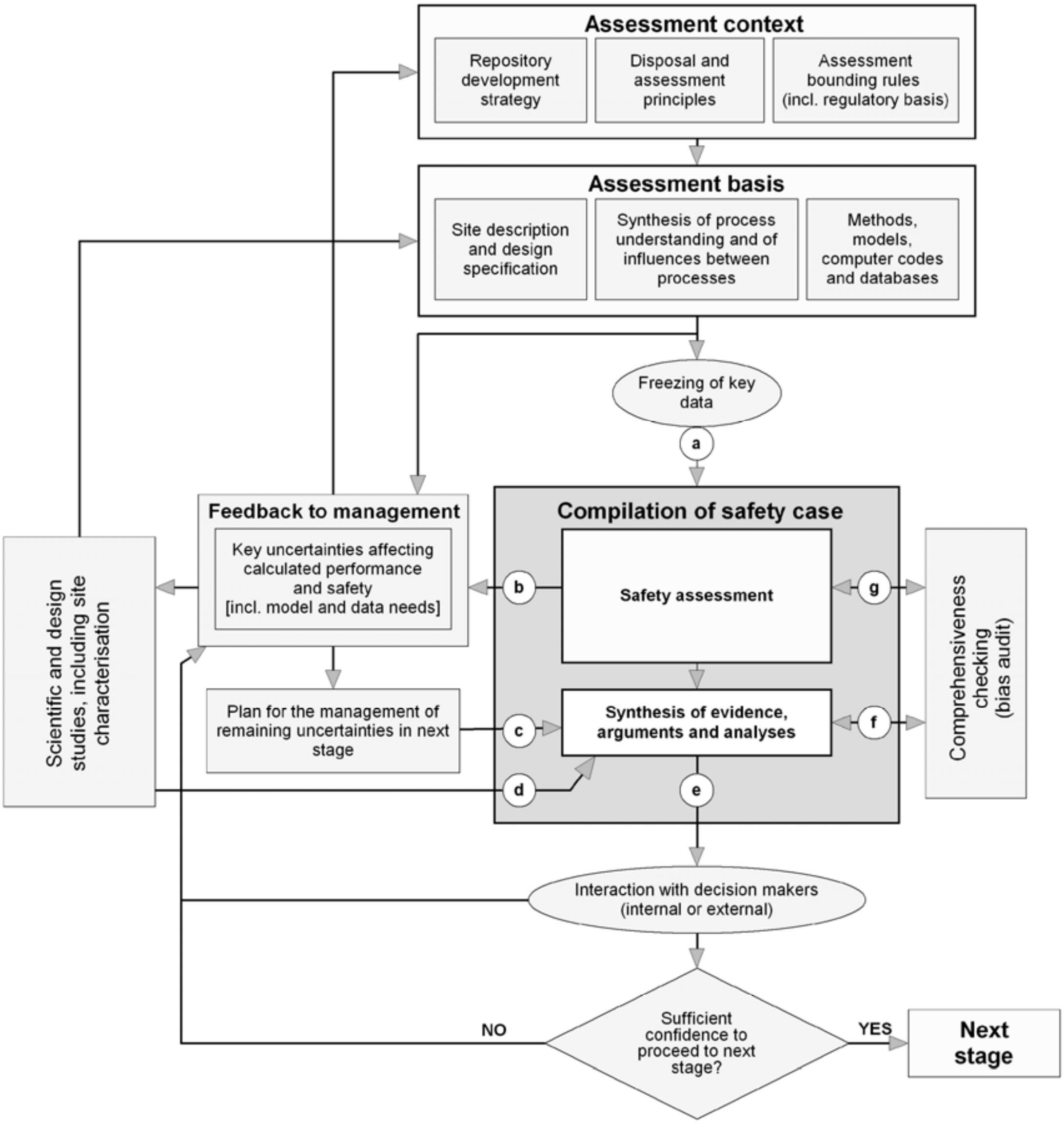
Based on a review of common elements and differences of flowcharts presented by a range of national and international organisation, as well as trends in such flowcharts that are apparent over time, a generic assessment strategy flowchart, divided into a higher and a detailed level one, has been developed within MeSA. In spite of some differences in terminology and presentation, the present generic assessment strategy flowchart is judged to be broadly consistent with flowcharts produced in recent safety assessments and with the NEA Safety Case Brochure of 2004.

The proposed higher-level generic safety case and safety assessment strategy flowchart shown in Figure 4.1, is an illustration of what the main common elements and linkages identified in recent assessment strategies could be. Elements of a safety assessment are shown in Figure 4.2, focussing on the steps involved in developing the safety case. Labelled arrows show the main flows of information during the course of developing a safety case.

The starting point of the generic flowcharts is the assessment context. Examples of the elements that may fall within the scope of the assessment context are as follows.

- The repository development strategy: The repository development strategy defines the iterative process of planning and implementing the repository, including the various milestones and decision points that are foreseen or bounded by national Acts.
- The disposal and assessment principles: The disposal principles are principles related to safety that are integrated within the safety strategy and guide the development of the disposal system and implementation procedures. Disposal principles include, for example, providing safety through well understood phenomena, and ensuring flexibility in implementation by keeping multiple options available. Some disposal principles may be given in regulation. The assessment principles are principles that are integrated within the assessment strategy and guide the carrying out of the safety assessment. Assessment principles include, for example, principles related to the treatment of uncertainty (use of conservatism, use of stylised approaches, etc.), the role and treatment of the biosphere and the treatment of future human actions.
- The assessment bounding rules: The assessment bounding rules define the assumptions on which the assessment is based (e.g. the wastes to be disposed of in the repository) and the regulatory context, which will typically determine the main assessment end points (e.g. safety indicators such as dose and risk) and may also provide guidance for carrying out the safety assessment such as defining certain phenomena or scenarios that must be analysed, and others that need not be analysed, and may also include the definition of the time frames over which assessment cases are evaluated.
- The synthesis of process understanding and influences between processes: This is a unified and consistent description of the various features, events and processes (and interactions between these) that may affect the evolution and performance of the repository, based on the multi-disciplinary information collected by science and technology. Approaches might include sophisticated tools and methods which address complex, often coupled THMC processes and their influence on safety functions.
- The assessment methods, models, computer codes and databases for analysing system performance.

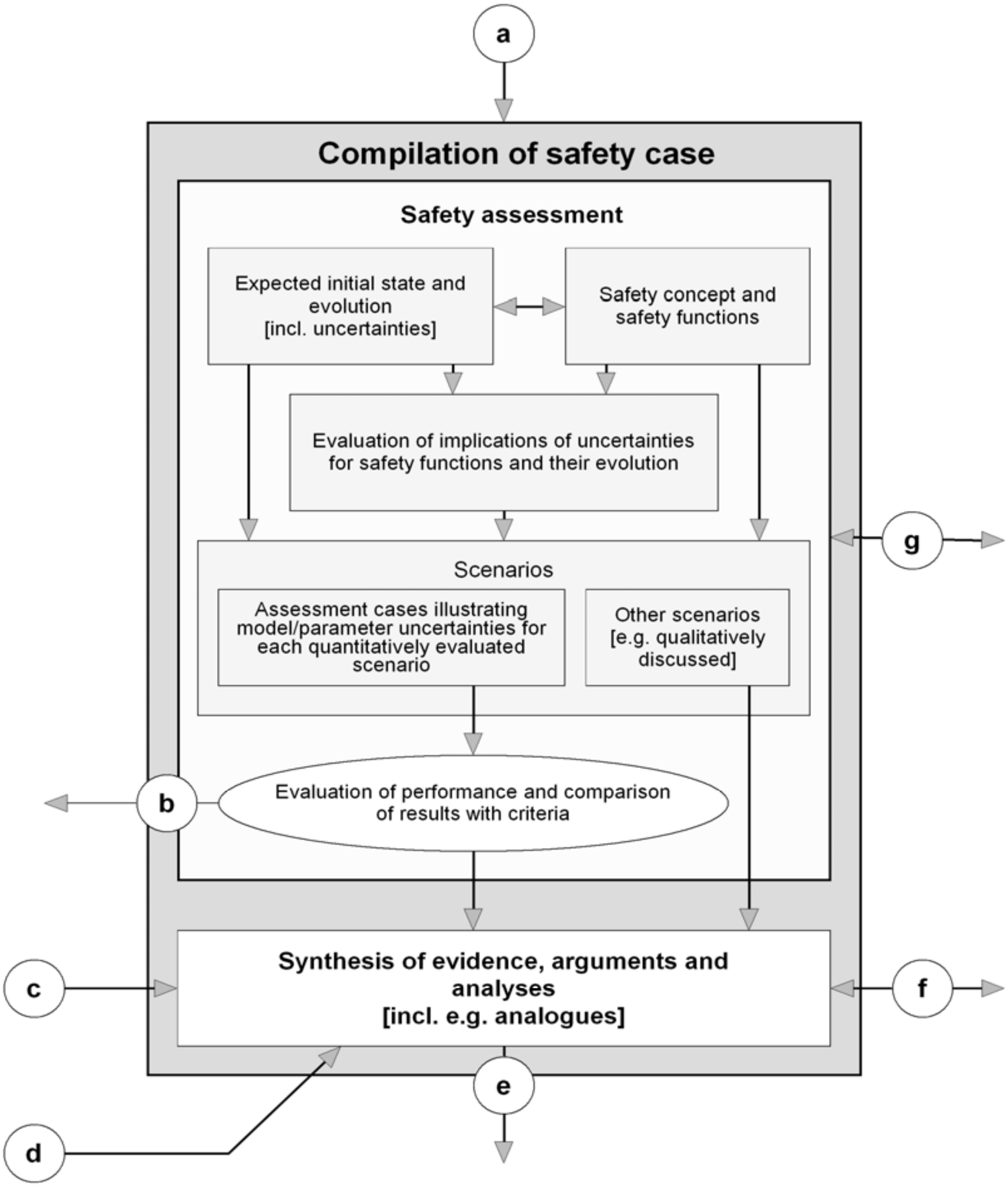
Figure 4.1: Example of a high-level generic safety case flowchart, showing the key elements and linkages



Note: The arrows labelled with a letter correspond to the arrows labelled with the same letter in Figure 4.2.

From the assessment basis, safety assessment generally starts with the development of an integrated description of the expected initial state of the disposal system and of its expected evolution, including uncertainties in both of these (see Figure 4.2). The description will include the processes and events expected to influence repository evolution and performance in the course of time. It will also indicate how various features, events and processes relate to the safety concept and safety functions of the repository. However, the position of expected evolution in the flowchart depends on how the boundary is defined between the activity of assessment basis development and the activity of safety assessment, and is an operational choice that varies between different programmes.

Figure 4.2: Detailed generic flowchart of the safety assessment component which is included in the compilation of a safety case of the upper level generic flowchart



Note: The labelled arrows correspond to the arrows labelled with the same letter in Figure 4.1.

The safety concept is the understanding of why the disposal system is safe, irrespective of identified uncertainties and detrimental phenomena; i.e. why it is expected to be robust. It includes a description of the roles of the natural and engineered barriers and the safety functions that these are expected to provide in different time frames, and why the disposal system is expected to be safe.

As part of the safety concept, broad safety functions, such as isolation by the geological environment from the surface environment and containment by engineered and/or geological components, will be defined before the details of the system description. However, more detailed safety functions, such as the function of a clay buffer in filtering colloids generated around the waste, require the specification of clay as a buffer material, which may be regarded as part of the system description. The system description and safety concept are therefore developed to some extent both iteratively and in parallel. Whatever definition of safety functions is adopted, safety assessment generally involves an evaluation of the implication of uncertainties for the safety functions and their evolution, leading to the formulation of scenarios for the assessment of post closure safety.

Scenarios are analysed by means of conceptual models, mathematical models, their abstraction into assessment models (and corresponding computer codes) and data. Uncertainties may lead to the definition of a range of calculation cases, also sometimes termed assessment cases. If, for example, considerations of alternative models are found to be consistent with current scientific understanding, then calculation cases may be defined that explore the effects of this model uncertainty. Conversely, model simplifications may mean that some calculation cases need not be evaluated (e.g. cases relating to uncertain phenomena that are conservatively omitted in models).

Assessment cases may be defined and evaluated with parameter values specified individually (deterministically). Alternatively, large numbers of calculations may be performed probabilistically using parameter values sampled at random from probability density functions (PDFs). Models, computer codes and data (individual parameter values or PDFs) are selected by the safety assessment team, based on the synthesis of scientific understanding in the assessment basis.

The results of the analyses of scenarios are complemented with arguments, for example, for the quality of the site and design (low impact of detrimental phenomena) and for the validity of model assumptions and boundary conditions from the assessment basis. They are also combined with any independent supporting evidence for safety (e.g. the existence of relevant natural analogues for the repository or some important processes) to construct the synthesis of evidence, analyses and arguments that quantify and substantiate the safety and constitute the safety case. Supporting evidence, such as that related to groundwater ages, can provide direct support for the quality of the system (in this case the geological barrier). This and other evidence can also support modelling assumptions made in carrying out a safety assessment.

Another important element in recent safety assessments and in recent and planned safety cases is the greater emphasis on quality assurance. A specific aspect of quality assurance is the use of compilations of features, events and processes (FEP databases) for checking the comprehensiveness of the phenomena analysed in the assessments and considered in safety cases, see further Section 5. Such checking can be seen as part of a wider “bias audit” carried out by some organisations. The intention with the latter is that comprehensiveness checking should be at least partly an independent process, separate from the main line of safety assessment activities. The targeted and judicious use of external expert peer reviews could play a role in this bias auditing process and will be discussed further in section 6 on how to achieve model quality assurance.

The process of carrying out a safety assessment can reveal issues and uncertainties that need to be addressed by further scientific and design studies. Furthermore, an element of the safety case will be arguments that an adequate programme of scientific and design studies is in place to resolve remaining safety-relevant issues. These issues will typically be identified and discussed in the safety case, see also Section 3.7. According to the Safety Case Brochure (NEA 2004): “A safety case should acknowledge uncertainties, show how they have been identified and taken into account, discuss their implications and explain how any that are critical to safety are to be further addressed or otherwise managed in future project stages.” These types of feedback to scientific and design studies are illustrated by the arrows leading to the “scientific and design studies” box in Figure 4.1.

4.3 Regulatory perspective

Despite differences in national regulatory frameworks, a common international understanding on the main elements and goals of a safety assessment has evolved (Bodenez *et al.* 2008). As mentioned before, the idea behind safety assessments is not only to demonstrate compliance with regulatory requirements by comparing aggregated assessment results with safety standards, but also to demonstrate that the system under consideration has been well understood and that it is sufficiently robust.

Safety assessments are performed throughout the process of site selection and repository development, e.g. for optimisation purposes, and regulators often expect to be kept informed early in this process even if regulations do not require this explicitly. Doing so will likely facilitate the process of repository development and licensing and may be regarded as a part of the assessment strategy. Quality management strategies and procedures which are used to deal with huge amounts of data and which ensure that the data and models used in the safety assessment are consistent and adequate and remain so during all updates may be understood as another part of the assessment strategy.

5. System description and scenarios

5.1 Scenarios in safety assessment

The place and purpose of scenarios in safety assessment and the safety case has been discussed in several international fora. Scenarios aim at defining

> "the broad range of possible futures to be considered in the subsequent modelling and consequence calculations"... "Scenario development is concerned with the identification, broad description, and selection of potential futures relevant to safety assessment of radioactive waste repositories." (NEA 1991)

Scenarios are needed because

> "… it is virtually impossible to predict exactly what will be the evolution of the disposal system through time. A scenario describes one possible future of the disposal system, corresponding to a combination of events and processes together with their characteristics and their chronological sequence." (PAMINA 2006-2009)

Scenario development is thus an essential part of the assessment strategy.

The term "scenario" represents (and is understood as) a description of a potential specific evolution of the repository system from a given initial state. Scenarios describe the compilation and arrangement of safety relevant features, events and processes (FEPs) as a fundamental basis for the assessment of post closure safety which includes assessing the potential consequences on humans and their environment.

The uncertainties considered for a geological repository such as those caused by the randomness or unpredictability of certain events, the natural variability of geological media and the biosphere, the lack of characterisation of processes and the limited possibility to forecast distant-future biospheres and human habits imply a broad range of the possible evolutions of the system over the very long timescales considered in safety assessment. However, the use of scenarios enables investigation of the impact of distinctly different sets of FEPs (e.g. to represent climate evolution, human intrusion, early canister failure or seal defects) to see if and how they might impact on repository safety. Through this type of analysis, performance assessment results can usually be condensed into a handful of typical and variant scenarios and robust arguments made in the safety case for safe repository evolution under all expected circumstances.

5.2 System description: initial state and evolution

The background required for the development of scenarios has been identified in the 1991 NEA brochure: "... Data must be gathered on the repository layout, the waste composition, the material used to construct the engineered barriers, and site characteristics...." These data and the system description based upon them provide the assessment basis and ensure that the assessment is consistent with the knowledge about the disposal system, in particular about the features and phenomena relevant for safety as well as the elements of the repository design. Over the last two decades, several organisations developed large acquisition programmes that allowed production of extensive lists and descriptions of data and phenomena concerning the characteristics of a proposed repository's constituent parts:

- the identification and characterisation of the waste to be disposed of;
- the characterisation of the site;
- the characterisation of the system design with its natural and engineered barriers and the related safety functions that these are expected to provide in different time frames.

Besides the inventory of radionuclides and chemotoxic components, the physico-chemical characteristics of the waste, as well as their long term evolution in disposal condition, are input data to design and determine the dimensions of the disposal system. Due to the potential variety of waste types and forms, some organisations have collected the main characteristics of the waste in specific documents which present the typology, radiological contents and radionuclide release processes from the waste. It should also be noted that waste characterisation is not a completely descriptive activity – on the contrary, it becomes prescriptive when formulating waste acceptance criteria. Safety assessment is one of several bases for the derivation of such criteria. It is also important to note that as a repository programme advances through its operational phase, the as-built repository and the as-emplaced waste inventory ought to be periodically evaluated to assure that the post-closure safety case is still within the performance envelope assured in the approved license application. This is the reason some regulators require periodic updates of the licensing basis during the operational phase.

The characterisation of the host rock and its surroundings concerns the collection and integration of the geoscientific information. The acquisition of knowledge is a progressive process which is strongly linked with the maturity of the project and the availability of a designated host formation. Its objectives are (i) obtaining a detailed understanding of the geological host medium and its surroundings, which includes characterising the geological configuration, its properties and evolution and (ii) characterising its long-term behaviour under the effect of the disturbances caused by the repository. Furthermore, most organisations today compile and assess the geoscientific information into a “geosynthesis” or “site descriptive model” in order to ensure interdisciplinary consistency and that these descriptions focus on the needs of the safety assessment.

The characterisation of the repository concept addresses the design and layout of the facility, the features and properties of the engineered components and the functions assigned to the engineered and geological components of the system. Based on material and engineering sciences, the features and processes relevant for safety and their interaction are identified and described and the data relevant for the assessment are compiled.

The analysis of the initial state and the evolution of the repository system is an indispensable task in order to get insight on how the entire system is characterised and will behave under certain circumstances and on what the relevant factors, effects, FEPs and uncertainties influencing the evolution of the disposal system and the safety functions are. It requires:

- a systematic identification and study of chemical (C), thermal (T), hydraulic (H), mechanical (M), gas formation (G), radiation (R), and biological (B) processes, effects and influences of other waste and repository induced phenomena, and their interactions (at present and in the future);
- the prediction/modelling of potential evolutions of the site and the disposal system including influences of any disturbances (natural or human induced).

Since 1991, several methods to analyse and integrate data and illustrate process understanding have emerged. Such approaches consider the identification of FEPs with their interactions, their analyses and their conceptualisation by fractioning the concept of the disposal system in time and space sequences or situations. Each space-time sequence corresponds to a space and time interval within which a few major phenomena dominate the evolution of the component, the initial state being start of the first of those sequences. These situations or key-time sequences represent the basis for identification of uncertainties and their analyses (qualitative and quantitative analyses), and the background for definition and assessment of scenarios (reference or altered evolution scenarios).

The overall time frame for analyses and integration may be defined/recommended by regulation, notably to account for some specific FEPs such as climatic and geological evolution. More specific time windows are then usually defined based upon the major thermal, hydraulic, mechanical, chemical, and gas related processes and the effects of their couplings.

The system description also includes a description of possible deviations in the implementation of the system (e.g. engineering mishaps), and uncertainties and detrimental phenomena that could potentially affect system evolution. It requires the identification of FEPs that may adversely affect the safety functions of the different components as well as addressing the questions about how, where and when this might happen. Ideally, if the detrimental phenomena result from a low-likelihood event, a probability or frequency can be assigned to the occurrence of that event to aid the evaluation of the risk of its potential consequences, but this is not always possible. If the event is highly unlikely but no probability can be assigned, its evaluation results may be useful in testing concept robustness.

5.3 Derivation of scenarios

Scenarios are being derived based on the safety concept including the safety functions and taking into account safety-relevant phenomena and uncertainties. Both safety concept and phenomenology depend on the system description and vice versa. Here the role of FEPs is most pronounced: on one hand, it is necessary to perform a thorough examination of what FEPs could “endanger” the safety functions. This might either concern the initial state of the system or its evolution, and uncertainties about when and where the phenomena may disturb the system have to be taken into account. On the other hand, an examination of about which FEPs contribute to maintain the safety functions can give support to the repository concept. Showing that a proper evaluation of both supportive and potentially deleterious FEPs has been done is an important part of confidence building.

In some assessments, scenarios are identified using a bottom-up approach that begins by assessing a range of external events or conditions (i.e. climate change scenario, intrusion scenario, initial defect scenarios) that may trigger changes in the disposal system or affect its performance. 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. 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. In reality either one of them is hard to imagine without the other.

Indeed, it is questionable whether an exclusively bottom-up approach has ever been successfully implemented – i.e. has a set of scenarios (or even an individual scenario) ever really been developed by piecing together individual features, events and processes (FEPs), as was sometimes claimed in the descriptions particularly of older safety assessments, or does one actually always begin from an integrated but preliminary conceptual understanding of system evolution and associated uncertainties, and use FEPs (together with interaction matrices, influence diagrams, etc.) to ensure that nothing is overlooked. Moreover, even the earliest, formally perhaps purely FEP-based approaches to develop scenarios were driven by the necessity to investigate repository performance (and, by that, safety functions) and its potential disturbance which was particularly visible in the FEP and scenario screening criteria applied in these approaches.

Safety assessments that claim to combine FEPs to scenarios sometimes lack any description of how exactly this is done. A combination of FEPs to derive scenarios certainly requires a first-cut description of the system and its evolution. It could be contended that the "top-down" approach described in recent safety assessments is in fact a more accurate representation of the approach that was in reality adopted (though not documented) in earlier safety assessments.

It could further be contended that "top-down" approaches to scenario development are, in fact, better described – at least in some cases and perhaps more generally – as "top-down/bottom-up". This is because, while the description of the initial state of the system and its expected evolution begins from an integrated "top-down" understanding of FEPs and their interactions, the identification of safety-relevant uncertainties starts from a "bottom-up" consideration of the impact of uncertainties in individual processes, system features, and a subsequent evaluation of whether the potential perturbations resulting from these uncertainties could significantly impact the safety functions. While the phenomena or FEP-based aspect of scenario development is less visible, it does, however, still exist in the wealth of phenomenological knowledge accumulated and documented in the safety cases.

In summary, each way, if seen in isolation, has advantages and limitations as explained in the following, and the limitations of each way could or should be compensated by the advantages of the other:

- FEP processing is an effective basis to understand and describe individual safety–relevant features and processes in a system, and also to identify factors that may trigger changes in the disposal system or affect its performance. Furthermore, FEP catalogues and the related process-describing documentation are important bases for modelling. However purely FEP-based or phenomena-based scenario development has difficulties concerning establishing an objective and formalised methodology and also of ensuring the comprehensiveness of the combinations of FEPs to be considered.
- Safety functions are useful to describe the initial state and evolution of a system in relation to the safety concept. Scenario sets derived from studying (scientific and technologic) uncertainties potentially affecting the safety functions (e.g. barrier performance) are perhaps not necessarily "complete", but better targeted to, and comprehensive with regard to, safety-relevant issues. However, for providing a sufficient scientific basis concerning the phenomenological knowledge needed to establish scenarios with confidence it will also be necessary to take advantage from systematic and comprehensive databases of the underlying THMC features and processes.

Finally, it should be noted that there is also a tendency to formally link the two ways in hybrid approaches, sometimes using formal tools linking FEPs to safety functions.

5.4 Structuring scientific knowledge and identifying safety-relevant phenomena and uncertainties

Structuring scientific knowledge and identifying safety-relevant phenomena and uncertainties is a prerequisite for safety assessment and in particular for scenario formulation. The main steps involved in the structuring of scientific knowledge and, from this, identifying safety-relevant phenomena and uncertainties can be extracted from the generic strategy flowcharts (see Section 4.2). Several tools have been developed and applied for this structuring, including system-specific FEP databases, interaction matrices, influence diagrams, assessment model flowcharts (AMF), phenomenological analysis of the repository system (PARS), storyboards, timelines with subdivision of time frames, and process description reports.

In all programmes, the starting point for the identification of safety-relevant phenomena and uncertainties is the development of a detailed description of the initial state of the system and its subsequent evolution. This description provides the basis for a main scenario, also termed normal-evolution, base or reference scenario.

The main scenario also provides a platform of discussion between phenomenological experts and safety assessors on what are the safety-relevant uncertainties that could significantly affect evolution and lead to deviations from this main scenario. Further tools are used to focus this discussion. Examples of such tools include:

- qualitative safety assessment (QSA) to identify which uncertainties in components and their evolution taking into account THMC interactions can affect safety functions (Andra 2005) and where it is determined whether the effects of residual uncertainties are minimal or their occurrence very unlikely, (e.g. addressing the uncertaintly explicitly by design options, by sensitivity analyses or specific hypothesis of scenarios);
- the identification and classification of phenomena according to (i) key contributors to the safety functions (ii) perturbing phenomena and uncertainties, and (iii), system attributes providing robustness against these phenomena and uncertainties;
- safety statements regarding what system/subsystem properties support safety functions where the statements form a hierarchy, with lower-level statements underpinning those at higher levels, and where the lowest level statements are directly supported by phenomenological understanding from the assessment basis;
- safety function indicators and associated criteria that give a quantitative test whereby it may be determined whether a particular uncertainty needs to be taken into account when analysing performance and safety.

It is noted that these tools generally make use of the concept of safety functions. In the future, it would be interesting to consider whether criteria related to the performance of key barriers can be defined for disposal systems other than where they now are defined.

5.5 Scenario probabilities

Since one of the purposes of scenario development is to explore the set of potential system evolutions, it is sensible to assign qualitative or quantitative statements about their probability or likelihood of occurrence to the scenarios developed. The first and most basic of such assignments is the qualitative categorisation of scenarios or evolutions as “main”, “base”, “normal”, “expected”, “likely”, or “reference” (as opposed to “altered”, “disturbed”, or “less likely”). As discussed in Section 5.6, some regulations require such a categorisation. The rationale behind this categorisation is the attempt to identify the way the system should perform (its design basis – “expected evolution”) as an important basis for further modelling, but also as a basis for communication to target groups of the safety assessment or safety case. The challenge is the necessity to demonstrate that this evolution is indeed the most likely one, or, correspondingly, that altered evolutions connected with less efficient safety functions are (much) less likely.

Regulations which allow “compensating” higher calculated consequences for some scenarios by lower probabilities or likelihoods associated to these scenarios might give rise to a more sophisticated, quantitative derivation of scenario probabilities, mostly based on probabilities to initiating or scenario-defining FEPs. Several conceptual questions have to be clarified if such an approach is chosen:

- Do the probabilities refer to the occurrence of a disruptive event (e.g. a seismic event), or to the existence (or otherwise) of a feature potentially jeopardising safety functions (e.g. an undetected fault or an unidentified mishap related to canister fabrication or to the construction of a geotechnical barrier)?
- Do they represent a probability per annum (often associated with an event) or one for the whole assessment time frame (e.g. presence or absence of a feature)?
- If events are considered: Can the event occur once (e.g. shaft seal failure) or repeatedly (e.g. seismic events)? In the latter case: What is the impact of such an event occurring more than once?
- What is the factual basis for assigning probabilities to FEPs?
- How can it be ensured that an exhaustive set of mutually exclusive scenarios will be addressed in the risk summation?

The answers to the first three of these questions have an impact on how safety indicators such as annual risk or mean dose per annum have to be calculated. For scenarios initiated by events the calculation requires integration of the consequence for each event multiplied by the probability density function for the event occurrence over the space of events. If a probability per annum can be quantified for “reasonably similar” events (e.g. for seismic events of a certain intensity), the integral can be simplified to a sum of the (usually time-dependent) consequences resulting from the event occurring in each year weighed with the annual probability. There is also the potential for repeating initiating events to lead to accumulating damage that erodes system safety over time so that the later occurrences lead to greater consequences than earlier occurrences.

If noteworthy consequences only occur for a time frame which is relatively small compared to the assessment time frame, this might result in so-called “risk dilution”. This effect is caused by the fact that the dose per annum a hypothetical individual living at a certain time in the future might be exposed to is strongly dependent on the point in time assumed for the initiating event. Averaging over these points in time (i.e. calculating the mean, its peak over time then being the “peak of the mean”) then results in a relatively low mean dose calculated for that individual although all conceivable pathways to this individual have been considered. Taking, however, the “culprit’s perspective” (i.e. “taking the position that an implementer wants to avoid any harm no matter when it might occur”), leads to considering total (instead of annual) scenario probabilities or to calculating the peak consequence over time for each simulation run and to average over these peak values (“mean of the peaks”). However, this value may be more difficult to interpret than the “peak of the means”. Risk dilution can also be addressed by a disaggregated presentation of calculation results (presentation of dose curves, empirical distributions, percentiles, etc.).

The fourth of the above questions is fundamental: factual bases for estimating scenario probabilities are rather rare. Conceivable possibilities include earthquake statistics (transferability to different time frames to be taken into account), detection accuracies for scenario-initiating features or statistics based on manufacturing practises. For example, destructive testing of sample canisters might indicate how many defective canisters will remain undetected by non-destructive testing which will later take place as part of the QA to be undertaken during canister production. Another example is that known resolutions of geophysical methods can give rise to estimating probabilities of undetected faults. In many cases, however, scenario probabilities are derived on the basis of expert judgement, the probabilities then representing a degree of belief that the scenario might occur.

Faced with difficulties connected with these options, organisations sometimes simply chose to overestimate the probabilities by a value of one for scenarios with low consequence. As long as consequences are sufficiently low, numerical compliance can still be ensured without taking advantage of weighing high consequences against low probabilities. If consequences are not low, either a more elaborate approach to determining probabilities (such as formal expert elicitation), or a more sophisticated and detailed consequence modelling effort, may need to be undertaken. Regulatory compliance may be possible with higher consequences from conservative approaches because regulators are experts who understand the basis for, the need for, and hence the acceptability of the results. These types of "what-if" evaluations and results are difficult to describe so they are not easily misinterpreted by non-expert audiences, especially those seeking reasons to oppose a disposal system.

5.6 Regulatory perspective

An appropriate system description, including a description of the corresponding uncertainties and of possible deviations in the implementation of the system, provides the foundation for the safety case, where what is "appropriate" depends on the stage of the programme. Early on, at the site selection stage, it is reasonable to make assumptions about general site characteristics of the geosphere and biosphere, to use data from roughly analogous locations and to consider generic design choices. However, the same is not true at the later stages of the programme, particularly at the licensing stage. At the licensing stage, the system description has to be based on traceable site-specific data with appropriate quality assurance qualifications and has to include a clear identification and description of system components important to safety (including their safety function or roles, their expected performance and evolution, and their design requirements). If data are transferred from "analogue" sites, it has to be shown that the processes of interest at the analogue site is (are) reasonable analogue(s) for comparable processes at the disposal site.

Data, whether from the site, the proposed engineered system, or an appropriate analogue, have to be adequate to justify safety arguments without the need for excessive assumptions. Taking data does not stop after licensing. Regulations often stipulate that the applicant should update its safety assessment to include any new information on site and design to determine whether such changes significantly affect the safety case or the licensing basis. Even if there is no specific updating directive in applicable regulations, a properly implemented nuclear-safety-culture requires the taking of data whenever unanticipated feature changes are encountered during the continuing underground development phase, whenever a significant change is made in the waste type accepted or its inventory, or whenever a modification is proposed for the engineered system. Such new information, whether quantitative or qualitative, ought to be evaluated for compatibility with the boundaries of the existing safety case. If there is significant incompatibility with the ranges of data, or the concepts, underlying the current safety case, a safety case update ought to be performed.

The objective of the system description is to provide sufficient detail so that the basis of the safety case can be understood and if needed the safety case can be reproduced by a qualified independent party. Because of the multiple disciplines involved and the rather long time needed to obtain a system description at varied space and timescales, the logical synthesis of information is unique to the repository programmes. Proper synthesis requires that data collected by various techniques at various scales in different disciplines is interpreted together to develop a coherent and consistent description of the system.

Safety assessment cannot be expected to produce a detailed, step-by-step description of the evolution of the whole disposal system over a million years, and sometimes longer, covering the full complexity of all the phenomena involved. Implementers are, however, requested to demonstrate comprehensive understanding of the safety functions like e.g. isolation and containment, i.e. of the processes central to repository safety (Vigfusson *et al.* 2007). The development and selection of scenarios entails a good qualitative understanding of the possible evolutions of the disposal system and therefore of the features, events and processes that may significantly affect these evolutions. It is commonly expected that these scenarios are described, developed and treated in a systematic way. Hence, some guidance on the classification and development of scenarios as well as on the objectives of the assessments associated with the different categories of scenarios is usually provided by regulators.

The extent to which regulators provide guidance on the classification of scenarios is directly related to the requirements on the approach to treat uncertainties on potential future evolutions of the disposal system. Requirements on scenario classification are indeed quite limited in countries where potential future repository evolutions are treated within a probabilistic framework as it reduces the need for defining different categories of scenarios. In that case, the dose calculated for individual scenarios is weighted as a function of their probability to develop an overall distribution of doses with time. Alternatively, requirements on scenario classification are usually provided by regulators fostering the use of deterministic or the combination of deterministic and probabilistic approaches to tackle the issue of uncertainties regarding the future evolution of the disposal system. Scenarios are often classified on the basis of their likelihood and the possibility of quantifying their likelihood (e.g. human actions). However, the objective of the assessment may also be considered to distinguish specific types of scenarios. Scenarios that do not have to be considered in the safety assessment may also be specified.

The categorisation of scenarios varies widely from one country to another but there are some common trends in the regulations considering different classes of scenarios:

- Central scenarios (also termed reference, likely or expected evolutions) include all the scenarios which are aimed at representing the foreseeable and expected evolution(s) of the disposal system with respect to the most likely effects of certain or very probable events or phenomena. Thus, the system can be considered as designed with a view to these scenarios.
- Plausible alternative scenarios represent less likely but still plausible modes of repository evolutions (e.g. barrier degradation more rapidly than expected, …) as well as scenarios portraying extreme natural events (e.g. extreme ice-age or a major seismic event) but that are still within the range of realistic possibilities (bounding cases). For some regulators, the influence of the declined performance of system components and/or the complementarities between the different components should be analysed by means of plausible altered evolution scenarios.
- A range of possible future human actions having the potential to breach the natural or engineered barriers or significantly impair the performance of a disposal system can be envisaged as particular types of plausible alternative scenarios. Because future human actions are unpredictable and scenarios that involve them need to make stylised assumptions, these are often considered as a specific scenario category. Human intrusions that directly damage the isolation/confinement performance are often systematically treated in regulations. A distinction is usually made between inadvertent and intentional human intrusion. Regulators generally consider that the only ones to be taken into account relate to inadvertent intrusion, most often associated with a loss of memory of the existence of the repository. Several regulations require considering the radiological impact on the intruder. However, it is generally considered that a person coming into direct contact with high-level waste might receive any radiation dose up to and including a fatal dose. The absence of

regulatory limits for that particular situation is somehow compensated by the necessity to minimise the likelihood of intrusion through deep disposal, site selection or by means of markers. The absence of regulatory limits also reflects the fact that the intruder receives an acute dose that can be detected, and perhaps treated, if the society in which this future person lives is as capable as our current society, a common simplifying assumption and sometimes prescribed by regulators. Many regulators consider that human intrusion will most probably result in a limited and local disturbance of the repository. Deferred radiological consequences associated with this disturbance have to be assessed and usually compared to a radiological criterion. A regulatory limit specific to this particular situation is sometimes prescribed by the regulator. A date of occurrence of intrusion is specified into some regulations as the earliest date for intrusion although maintaining memory as long as possible is viewed as an objective.

- The treatment of arbitrary scenarios other than those relating to human intrusion is considered or required by several regulators. These scenarios, often called "What if" scenarios, can be defined as imposed or conventional scenarios for which the occurrence of an event or random phenomenon is postulated. It is generally possible to exclude these scenarios from all plausible evolutions of the disposal system through design or the level of knowledge available. A typical example of this type of scenario is a postulated failure of a confinement barrier for undefined reasons. These scenarios are mainly used for assessing the robustness of the disposal system and the relative importance of some of its components or functions. Due to the arbitrary nature of these assigned or assumed perturbations, no regulatory criteria are associated with this type of evaluation.

The systematic development of scenarios for the safety case is considered by several regulators as of fundamental importance as it constitutes a key element of the management and analysis of uncertainties. In most regulatory environments, only a qualitatively sufficient set of scenarios is deemed necessary. Nonetheless, it is expected that these scenarios are comprehensive in the sense that they should illustrate the possible evolutions of the disposal system in a credible manner and their associated consequences should envelop all possible behaviours. The degree to which requirements or guidance on the development of scenarios is provided by the regulator varies significantly from one country to another. However, some common trends can be identified:

- Scenarios have to be developed in a systematic, transparent, and traceable manner.
- Although regulators usually specify events and processes that should as a minimum be considered in the scenario analysis, it is for the proponent to justify which events and processes to include in assessment models, and how to represent them in the models. Additionally, the proponent has to justify that all potential processes and events have been identified and that all possible future evolutions of the disposal system have been considered in the development of the scenarios.
- Stylisation may be regarded as appropriate in scenarios considering human intrusion, and in many cases stylisation is also accepted for the biosphere component of other distant-future scenario evaluations.

6. Modelling strategy

6.1 General

To assess the influence of a deep geological repository on humans and the environment, a spatial domain up to several kilometres and timescales from 10 000 years up to and exceeding a million years usually have to be considered. A wide range of features, events and processes are potentially relevant over this wide range of space and timescales. Therefore, an assessment of the performance of a repository can only be undertaken by simulation of the potential evolution of the repository system using mathematical or numerical models. Overall, there is wide consensus on the modelling strategies to support a safety assessment, and no major areas of disagreement have been identified.

The development of a model involves four main stages: i) derivation of a conceptual model, ii) formulation of the accompanying mathematical model, iii) transfer of the mathematical model into a numerical model and iv) qualification of the model. In practice, these stages are iterative. It should be noted that steps i) – iii) refer to stages of abstraction, while step iv) is conceptually different. Moreover, the actual coding of a numerical model may also be seen as a separate step following step iii). The models usually become more detailed over time as more data and understanding become available and additional needs are identified.

In repository safety assessments, modelling is used for a variety of purposes. However, the models used in safety assessment can generally be classified due to their level of detail of representation of processes, and their overall level of integration. Although nomenclature is not harmonised internationally, in many safety assessments at least two levels of models, process-level models and integrated or system-level models, are distinguished. In addition, a third class of models is used in many assessments, namely simple models that can be summarised in a few fairly transparent mathematical equations. Simple models include only main processes and give rough estimates of the results in question.

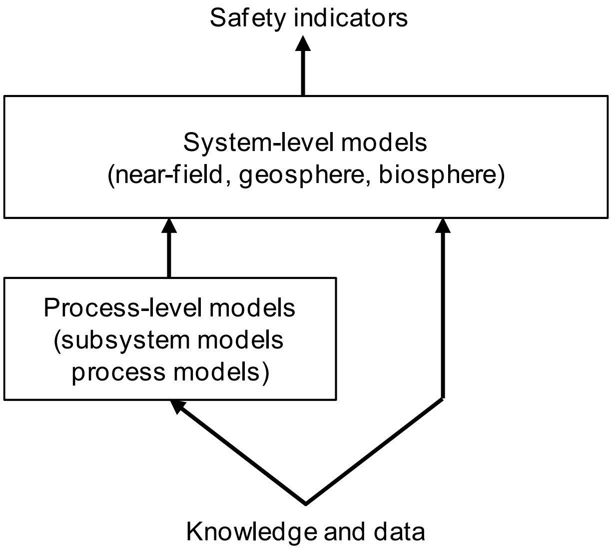
A generalised approach for the use of the different kinds of models in a safety assessment, which of course does not cover all details nor all repository programmes, is illustrated in Figure 6.1. At the bottom of the figure all the necessary data for the safety assessment are depicted. Most of the data are not directly used in the system-level models but are interpreted by process-level models, which in turn generate input data and aid the development of conceptual models incorporated in integrated or system-level models. At the highest level are the integrated or system-level models, which simulate the entire repository system and quantify consequences by calculating indicators for safety, such as radiological risk, dose or another kind of safety indicator. In addition simple, often analytical, models might be used at each modelling level.

6.2 Process-level models

Process-level models are developed in order to gain a solid understanding of some aspect or part of the repository system. This includes identifying the parameters and processes governing the performance of specific repository components, to evaluate the performance of these components, or to identify critical uncertainties. These models are very important to the safety assessment since they represent our best understanding of the processes. In many cases these process-level models form the basis for conceptual models incorporated into, and parameters used in, system-level models. Process-level models may also help provide justification for simplifications of processes incorporated in system-level models.

Over the past 20 years, an increasingly important role of process-level models has arisen in the treatment of process couplings and in transient phenomena. Typically, in their early stages waste disposal programmes developed models for individual processes; more recently models that include couplings have been developed. This reflects both increased knowledge as well as increased computer capabilities. Within this context, today THMC models are increasingly being applied to consider temperature, hydraulic, mechanical, and chemical processes and their interactions (e.g. NEA 2007b), although such models usually do not consider all conceivable interactions, only those judged important. Due to the complexity of the investigated processes and their limitation of relevance in time, process-level models are often applied for a certain time window of the overall assessment time frame.

Figure 6.1: Hierarchy of models used in a safety assessment



6.3 Integrated or system-level modelling

The central part of the safety assessment consists of integrated or system-level models, which are used to assess the performance of the disposal system as a whole and to evaluate the potential environmental impact through performance measures such as dose for the whole assessment time frame. Such a system-level model describes the evolution of, and the radionuclide transport through, the entire repository system. For each selected scenario, a suitable system-level model has to be applied – this could be one and the same system model if sufficiently flexible, or additional scenario-specific system-level models.

When modelling a complex system such as a deep geological repository, simplifications are unavoidable. This simplification of process-level models into system-level model has important consequence in terms of level of conservatism and representativeness of the modelling results. Consequently it was noted in the 1991 safety assessment review as a key element of the modelling strategy (NEA 1991). It continues to be so today. A first type of simplification is introduced when the results of process-level models are converted into system-level model inputs. At this stage, the modeller needs to address which are the essential processes that dominate the system evolution or the performance of the repository system, and on the other hand, which processes can be neglected because they have a negligible (or a limited positive) influence on the performance of the repository system. A second type of simplification can be introduced at the stage of developing numerical models. A third type of simplification is often needed to overcome limitations in the features presently available in computer codes or in the calculation capacity of the computers. The availability of more powerful computers in recent years has to some extent reduced the need to use such simplifications in deterministic calculations. However, the desire to include more processes, as well as to conduct probabilistic calculations, means that there is still a need for simplifications.

Integrated assessment calculations can be carried out in two principally different ways. A deterministic analysis is a calculation performed with a single set of parameters, and may provide a best estimate, conservative or extreme estimate (e.g. what-if cases) of system performance. In a stochastic or probabilistic analysis, relevant parameters are simultaneously varied to address the range of their uncertainties, constrained, of course, by dependencies or correlations between these parameters. Since the 1991 review, there has been an emerging consensus on the use of deterministic and probabilistic approaches. In most safety analyses, deterministic and probabilistic calculations are now seen as complementary and both approaches are applied. Deterministic calculations are more appropriate for detailed calculations and communication purposes. Probabilistic calculations are especially appropriate to deal with parameter uncertainty. Stochastic sensitivity analyses can provide much information on the key parameters controlling the repository system behaviour.

Significant differences exist between countries regarding the extent to which regulations allow simplified handling of the biosphere in the safety assessment. Some regulations provide specific guidance, for example, by prescribing stylised approaches for converting geosphere releases into dose, defining how to handle future climate changes, and how to address potential changes in future human behaviour. Therefore biosphere modelling varies to a large extent. In many system-level models, dose conversion factors are used, which have been derived from biosphere process-level models and provide a simple way to transfer radionuclide surface fluxes or concentrations into dose. Other system-level models implement a full biosphere model, describing radionuclide transfer between different compartments. The use of evolving landscape models is relatively recent, at least with respect to system-level models, and its utility remains to be fully explored.

There is a clear trend that models are getting more complex, due to both more powerful computers and our improved understanding of the processes. During the 1991 review, one issue identified was the balance between more complete but also complex models, and our ability to understand the results. This issue remains. However, in general the use of more complex models does not seem to have hurt our ability to understand the results. Possibly this is in part because the greater complexity is balanced by the greater completeness of the model, which in itself eliminated some uncertainty over the results. This is probably most noticeable with the better representation of geometry in more complete models. This greater complexity also can be balanced by the use of simple models that provide a demonstration that the salient processes and features of the complex model are understood.

A total system model can successfully be built by linking appropriate process-level models. This is not usually done because of the complexity of the disposal system as noted. However, if the geological disposal system is relatively simple and unchanging over the time period of interest it is possible to build a system model in this manner and still run it efficiently in a fully probabilistic fashion. This is the case for the operating deep geological repository in New Mexico, USA, called the Waste Isolation Pilot Plant. It is a repository for non-heat-emitting waste, in a salt host rock where engineered system degradation is not an issue, where there is no significant long-term seismic risk, and for which the regulatory performance-measures are prescribed by regulation and stylised.

Late in 2010 this repository was given its third five-year recertification by its long-term safety regulator, the US Environmental Protection Agency. The system-level modelling approach is relatively unusual in that it is fully probabilistic and yet involves linked system-level models with only a limited simplifying level of abstraction. Over the regulatory time frame of interest the only releases are from the human intrusion scenario, which is highly stylised in conformity with regulatory direction.

6.4 Computer power and software

The desire for more complex models is in part supported by the advances in computing power and software. Key advances during the 1990s that affect the modelling strategy are increasing computer power, and advances in software and numerical methods.

The improvement in processor speed and memory capacity directly allows more complex calculations to be performed, involving more variables and more time steps. The increase in parallel processing capability is not yet widely exploited in repository safety assessments.

Developments in numerical methods have been more subtle. In many respects, the increased computer power noted above has simply allowed current numerical techniques to be extended to tougher problems by brute force – i.e. allowing the model to be represented with much finer mesh spacing or time steps, and thereby avoiding numerical instability issues. However, there have been notable improvements in the numerical techniques used for discretisation and solvers, which allow for the adaptive refinement of the discretisation and therefore the assessment of more complex models.

Another important aspect for safety assessment has been the large improvements in software visualisation methods and graphical user interfaces. This provides benefit in the preparation of input files, preparation of models and presentation of calculation results.

With respect to preparation of input files, the large multi-dimensional input files with thousands or even millions of nodes are only practical to create because software tools allow the user to define complex geometries, and then to rely on the software to generate the input files. With respect to preparation of models, the main development has been software platforms in which the user defines the model more directly in terms of connected blocks or icons or mathematical formulae, rather than in a source code such as Fortran or C++.

6.5 Data gathering and management

Data gathering and management remains a prerequisite for modelling. Site characterisation, technical developments of the barriers with associated experiments and waste characterisation generate large amounts of data, and the traceability from the safety assessment back to these data requires planning. Approaches currently used to help with this include data clearance procedures, site descriptive models, and reference datasets.

When identifying data for use in safety assessment models it is important to consider the quality of the data, its relevance to the spatial and temporal scale of the model (for example whether upscaling or extrapolation is required), the level of uncertainty associated with the data, and the purpose of the model (affecting for example, how conservative the data should be).

All modelling work is underpinned by data from a variety of sources, including laboratory experiments, field tests, large-scale experiments, site investigation, literature searches and comparisons with natural phenomena. Not all data will be obtained in the format required by the models and it is unlikely that a “complete” data set will be available for evaluating a complex system over very long times, especially when that system has not yet been built. The goal is to create a data set that is sufficient for the decision point for the repository system that is currently under consideration.

Some data will require processing prior to use in models. Some data will require extrapolation or interpolation because the actual data available are incomplete or do not relate to the exact conditions experienced by the repository system. Expert judgement may be combined with the available empirical data to elicit a full data set or manage the consequences of uncertainty associated with the available data, in particular the selection of probability density functions (PDFs) for certain parameters to facilitate probabilistic evaluations.

Documentation, record keeping and quality management are key requirements to the provision of information. To be useful for licensing purposes, the data must ultimately be controlled within the context of a specific project, as a controlled reference dataset. Such a reference dataset may be frozen for a particular time span by the application of a formal data clearance procedure. This guarantees that all model applications in this time span are based on the same dataset and that, therefore, the results are consistent. It will also be important to maintain good records of all the relevant information over the lifetime of the repository project and beyond. This includes the waste inventory, its radiological and chemical characteristic, the design basis, and the site geoscientific data.

6.6 Model qualification

As programmes have matured and shifted towards more site-specific assessments, there is a trend to apply more formal software quality assurance to what were previously research-type codes. The full implementation of this within the radioactive waste community has not yet been established, as many codes do not as yet ascribe to a formal software quality assurance standard.

Conventional software quality assurance is divided into verification and validation. Verification aims at showing that the computer code, via the numerical model, correctly implements the intended mathematical model. Validation on the other hand should demonstrate that the model correctly represents reality. Validation is the harder task.

Due to the long time and spatial scales involved in geological disposal, a complete comparison between safety assessment model predictions and experimental results cannot be done. The limitations of conventional validation are acknowledged in the NEA review (NEA 1991). Since strict validation of the models used for safety assessments is in most cases impossible, alternative terms have been introduced in some countries. In particular in some programmes, the term model qualification has been introduced. The intent of model qualification is to demonstrate that the model is consistent with the scientific understanding within the assessment basis, and that it adequately represents the considered phenomena and interactions relevant to the assessment case. In other countries the concept of model validation is retained, although not viewed as a specific end point that is met, but as an ongoing, iterative and progressive process that builds confidence in the model. In either case, the modelling strategy should include elements of the following with respect to testing of the safety assessment models:

- independent peer review of the theory, including the conceptual and the mathematical models;
- a software quality assurance process that ensures that software changes are implemented in a formal manner with appropriate review of each step;
- verification that the computer codes accurately implement the mathematical models, i.e. by comparison with analytical solutions;

- benchmarking of new codes against the results of older codes (and the strategy with respect to maintenance of the older codes);
- testing of specific phenomena within the safety assessment model against experimental (laboratory scale) data, field data, natural analogues and/or detailed process models;
- comparison with similar models;
- comparison with field-scale tests that can be conducted within the bounds of underground research laboratories;
- calibration to conditions at a specific site.

It should also be noted that the difficulties associated with model validation have contributed to the development of the safety case concept, with its emphasis on multiple lines of reasoning. Within a safety assessment, it is possible to adopt strategies that do not reduce model uncertainty but can bound the implications of the uncertainty, see e.g. Section 8.

Overall, the topic of model qualification is reasonably well understood. International collaboration on large-scale tests and on data is, when practical, already widely practiced.

6.7 Regulatory perspective

The aim of modelling studies is to first help in understanding the characteristics and behaviour of the repository system and its component parts, and ultimately to assess the performance of a repository under various scenarios to support a licence application. Consequently, the developer's modelling strategy, and the resulting presentation in the safety case, is closely aligned with the relevant regulations and regulatory guidance i.e. it is based around the time frames, scenarios, indicators and criteria discussed in Section 7.

Regulatory bodies consider that implementers need to provide support for confidence in their models but recognise that there is no single "best" or "correct" way to carry out modelling studies. Consequently, regulations tend not to be too prescriptive in defining particular modelling approaches to use. However, some regulators provide quite specific guidance on how to carry out certain parts of the safety assessment, for example on how to treat the biosphere (e.g. by prescribing stylised approaches for how to determine exposed groups of people, how to convert geosphere releases into dose), how to handle future climate changes, and how to address potential changes in future human behaviour.

The need to evaluate and manage the various types of uncertainties in safety assessments is an important regulatory requirement. With respect to modelling, there are a number of conclusions that can be made from examination of national regulatory documentations:

- There is now a better overall appreciation of the limitations of modelling studies, in particular the large uncertainties associated with predicting far into the future and the consequential need for more qualitative based reasoning and complementary evidence to demonstrate safety at longer times; the need to avoid over-interpreting model results; and the need to manage the uncertainties introduced through the simplifications necessary in developing models of real systems.
- Justification for the choice of model or interpretation is sometimes an explicit requirement.

- There is agreement on the need to justify the range of applicability (scales in space and time, heterogeneity) of models chosen and the underlying parameter values, and in some cases there is a requirement to carry out sensitivity analysis.
- The desire to avoid underestimation of the radiological impact from a repository is common to all regulations. However, there are slight differences in the way this is translated into regulatory requirements and also the terminology used. In practice, safety assessments usually employ a combination of the best estimate approach with the strategy of conservatism, in that certain conservative assumptions are necessarily made even during "best estimate" scenario analysis (Vigfusson *et al.* 2007).
- The modelling approach adopted in practice includes many stylised elements (e.g. in relation to the biosphere or future human actions), which seek to err on the side of conservatism. Stylisation is a way of bypassing unquantifiable uncertainties. Stylisation needs to be avoided, however, for those components of the repository system where avoidance is possible.
- Regulatory prescription regarding probabilistic and deterministic assessment methods is varied. For some countries the use of both methods is required or encouraged, and guidelines are given. However, in many regulatory documents the choice of one or other or both is left to the developer.

The perception that dose-based regulations ask for deterministic and risk-based regulations ask for probabilistic approaches is not necessarily true (Röhlig and Plischke 2009). Dose values can also be calculated by probabilistic assessments and risks by deterministic assessments. It is therefore possible and – with regard to the specific shortcomings of each approach – also advisable to use a mixture of deterministic and probabilistic analyses. In fact, most regulations either follow this strategy or do not prescribe this at all. Whatever approach is chosen, probabilistic or deterministic, the proponent should show where the uncertainties come from, what their implications are and that the uncertainty space has been reasonably well explored.

Regulators often decide to use or develop independent models (Winterle and Campbell 2008). In this context it is important that the regulator has the technical capability to adapt or develop its models and that the applied codes provide sufficient flexibility to evaluate changes in data and understanding over time.

The assurance of data and information quality as well as of model and software development quality is a common theme across national regulatory documentation. In particular, the need for "traceable" and "transparent" links to the source data and references is seen as essential by most regulators. Also considered to be of particular importance (Vigfusson *et al.* 2007) is the traceable and transparent documentation of the elicitation of scientific knowledge underlying the modelling, of the transfer of this knowledge to conceptual models and from there to numerical models, and of measures enhancing the basis for finding where there can be confidence in models (e.g. benchmarking, comparison with laboratory or field tests or to observations in nature).

7. Indicators for safety assessment

7.1 General

Most national regulations relating to repositories for nuclear waste give safety criteria in terms of dose and/or risk, and these indicators are evaluated for a range of evolution scenarios for the disposal system using quantitative analyses. In recent years it has become evident that this comparison for an overall system safety assessment can be augmented with additional analyses and indicators in the safety case. It is now internationally accepted that the robustness of the safety case and the resulting confidence in the repository concept is strengthened by the use of multiple lines of evidence which includes complementary (also qualitative) safety arguments that can compensate for shortcomings in any single argument. One type of argument in support of a safety case is the comparison with safety indicators complementary to dose and/or risk (e.g. NEA 2004; IAEA 2007; PAMINA 2006-2009).

Such complementary indicators can avoid to some extent the difficulties faced in evaluating and interpreting doses and risks that may occur in a far future. In particular the individual human behaviour as well as near-surface processes, which are an important basis for calculation of dose and risk, are difficult or impossible to predict over long timescales. In contrast the possible evolutions of a well-chosen host rock and geological site can be bounded with reasonable confidence over much longer timescales of up to about one million years into the future (depending on the site). Hence, there is a trend in some recent safety cases towards evaluating indicators in addition to dose and risk, which show more clearly the repository´s intrinsic performance without requiring any assumptions about the future surface environment and biosphere.

The concept of safety and performance indicators has undergone considerable development during the last decade. While there is a consensus that using different indicators in addition to dose or risk in safety assessments is a good way to improve the understanding of the system and to support the safety case, concepts and perceptions vary between countries and organisations. Different approaches and levels of detail in regulatory guidance might have contributed to this variability.

7.2 Classification of indicators

There have been a number of systematic classification schemes and formal definitions proposed for complementary indicators on the basis of how they may be applied in a safety assessment. These proposed classification schemes have not been universally adopted, however, in part because they are not consistent with the assessment methodologies applied in all national disposal programmes. Setting aside the proposed classification schemes, a review of the complementary indicators used in safety assessments to date shows that they can roughly be divided into three groups on the basis of their nature and the information they provide:

- concentration and content related indicators, that provide information on the radionuclide inventory and its distribution within compartments of the repository system and the environment (e.g. total radioactivity content of the wasteform or radiotoxicity concentration in groundwater);

- flux related indicators, that provide information on the transport of radionuclides between compartments of the repository system and their release to the accessible environment (e.g. radioactivity flux from the engineered barriers to the geosphere or total integrated radiotoxicity flux from the geosphere to the biosphere over time); and
- status of barriers related indicators, that provide information on the functioning and containment capability of the barriers in the repository system (e.g. container life time or buffer swelling pressure).

These three groups are not fully independent. In particular, the status of a barrier could have a significant impact on the flux of radionuclides across it and, consequently, the content of radionuclides in the compartments on either side.

Another, frequently adopted classification scheme is according to the specific purpose of the indicator. Typical purposes are:

- the quantification of the post-closure safety of the repository in the long term;
- the characterisation and illustration of the performance of the system or subsystems;
- the judgement whether a safety function is fulfilled or not.

Safety indicators give an indication on the safety of the repository and, particularly dose and risk are suitable for comparison with established acceptance criteria. Performance indicators are in particular suitable for understanding and evaluating system behaviour. Safety function indicators are suitable for evaluating key parts of a repository system in a disaggregated fashion. This classification is based on experience from international fora, notably IAEA (2007) and projects such as SPIN (Becker *et al.* 2003) and PAMINA (Becker *et al.* 2009). Safety function indicators have been introduced in the Swedish programme for a final repository for spent nuclear fuel (SKB 2006). This classification was also the basis for the structure of the assessment defined within MeSA.

Generally, there may be additional ways of grouping complementary indicators. Each organisation may choose their own approach to be consistent with their specific assessment context, and the expectations of regulators and stakeholders. Throughout the development of a repository and refinement of its design (e.g. to optimise the design to account for the geological conditions at a chosen site), the definitions of the indicators in use could also be progressively refined as the assessment evolves from a generic to a site/design-specific basis. It is important, however, that whatever classification or categorisation scheme is adopted, the chosen definitions are appropriately and clearly defined.

7.3 Safety indicators

A safety indicator should give an indication of whether a repository can be considered safe regarding some safety aspect. Such a safety statement requires a numerical measure as well as a reference value defining a safe level. Therefore a safety indicator might be defined, as most recently done in the PAMINA project, as a quantity, calculable by means of suitable 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.

The most commonly used safety indicators in addition to the annual effective dose are radiotoxicity concentrations in the biosphere water and radiotoxicity fluxes out of the geosphere. Safety statements derived from these indicators might be as follows:

- Annual effective dose [Sv/a]: Human health is not jeopardised by radionuclides released from the repository. Under certain assumptions concerning the biosphere and human habits, all biological effects to a human individual, i.e. the incorporation of radionuclides by humans via different exposure pathways remain so small that they have no adverse impact on human health.

- Radiotoxicity concentration in the biosphere water [Sv/m3]: The hazard from the ingestion of the biosphere water that contains trace amounts of radionuclides from the repository does not exceed the one from the ingestion of average drinking water (regarding the impact of radionuclides).
- Radiotoxicity flux from the geosphere [Sv/a]: The radiotoxicity flux from the geosphere to the groundwater is below the present natural radiotoxicity flux in the groundwater.

7.4 Performance indicators

Safety indicators are useful for assessing the level of safety of the total system, but they usually do not provide much information about how the system works and how the level of safety is reached. Such information, however, is of high value for the safety case. It is essential to understand how the different barriers work together, where the radionuclides are mainly retained and how the system might be optimised. This kind of information is provided by performance indicators, which have been defined most recently in the PAMINA project as quantities, calculable by means of appropriate models, that provide a measure for the performance of a system component, several components, or the whole system. Performance indicators are typically concentrations or fluxes of radionuclides in or between specific parts of the repository system, or other descriptive measures that demonstrate specific properties of the system.

Most performance indicators developed or considered within the SPIN and PAMINA projects are based on compartments. The considered compartments are the results of a division of the repository system into sub-systems, for which it is considered interesting to show the evolution of the performance indicators. Compartments can correspond to a component of the repository system, e.g. buffer or host clay layer. Some compartments can contain other compartments, e.g. the canister compartment can contain the waste matrix, the water in the canister and a precipitate.

Also very useful is the additional analysis of single radionuclides. By comparing radionuclides with different characteristics (e.g. different solubility limits or sorption coefficients), additional processes or effects in the repository system can be studied and explained.

7.5 Safety function indicators

Safety function indicators are associated with safety functions that may be defined as a role which a particular part of a repository system plays in assuring safety. A safety function indicator is defined by SKB (2006) as a measurable or calculable quantity that quantitatively characterises the extent to which the safety function under consideration is fulfilled. Compared to performance indicators as defined in the SPIN project to characterise the efficiency of given barriers to impede release of radionuclides to the environment, safety function indicators characterise additional properties of safety relevant elements. While calculated values of performance indicators as defined in the SPIN project do not only depend on the performance of a certain barrier or component but also on the question about whether or not a radionuclide flux enters a barrier or compartment (i.e. on the performance of "previous" barriers), most safety function indicators do not depend on such a prerequisite.

Once basic safety functions for disposal are defined for the system concept, understanding and evaluating repository safety in a detailed and quantitative manner requires a more elaborate description of how the main safety functions of isolation, containment and retardation are upheld by the components of the repository. Based on the understanding of the properties of the components and the long-term evolution of the system, a number of safety functions subordinate to containment and retardation can be identified.

In order to quantitatively evaluate safety, it is desirable to relate or express the safety functions to measurable or calculable quantities, often in the form of barrier conditions. In order to determine whether a safety function is upheld or not, it is desirable to have quantitative criteria against which the safety function indicators can be evaluated to aid barrier evaluation for design or optimisation purposes. The situation is, however, different from safety evaluations of many other technical/industrial systems in an important sense: The performance of the repository system or parts thereof do not, in general, change in discrete steps, as opposed to e.g. the case of a pump or a power system that could be characterised as either functioning or not. The repository system will usually evolve continuously and in many respects there will be no sharp distinction between acceptable performance and a failed system or a sub-system or regarding detailed barrier features.

Nevertheless, at least for the KBS-3 concept, there are some crucial barrier properties on which quantitative limits can be put (SKB 2006). Regarding containment, an obvious condition is the requirement that the copper shell should nowhere be penetrated, i.e. there should, over the entire surface of the canister, be a non-zero copper thickness. In addition to this direct measure of containment performance, a number of quantitative supplementary criteria can also be defined. These relate, for example, to the peak temperature in the buffer and to requirements on buffer density and buffer swelling pressure giving favourable buffer properties for maintaining containment. Most of these working criteria are used to determine whether certain potentially detrimental processes can be excluded from the assessment. A safety function indicator criterion is thus a quantitative limit such that if the safety function indicator to which it relates fulfils the criterion, the corresponding safety function is upheld. It is emphasised that the breaching of a safety function indicator criterion does not mean that the repository is unsafe, but rather that more elaborate analyses and data are needed in order to evaluate safety.

7.6 Reference values

A reference value is a yardstick against which an indicator can be compared and repository safety and performance evaluated (IAEA 2003).

The need for reference values depends, to a large extent, on the purpose of the indicator and the assessment context. For indicators that are used to make a safety statement a reference value is essential because, without one, the impact of the repository cannot be judged to be acceptable or not. The same is true for safety function indicators when they are used to make explicit judgements about the functional performance of the repository. On the other hand, for indicators used to increase understanding of repository behaviour (rather than judge performance) or to compare between different design options then reference values may not be necessary, although they could still be useful for providing context.

Reference values for the effective dose rate and risk are usually defined by the regulator, whereas reference values for complementary indicators other than dose or risk are not always provided by the regulator. In most cases, it is the responsibility of the developer to propose and justify the values used. In this case, when used to make a safety statement, it is important to take account of a specific safety aspect when determining a reference value. The same numerical measure for repository safety, even when calculated in exactly the same way, can yield different safety statements if referred to different safety aspects and combined with the appropriate reference values.

A review of the use of complementary indicators in safety assessments to date shows that the definition of appropriate reference values is the most difficult aspect of their application. Reference values can be valid globally like the concentration of radiotoxicity in drinking water that is harmless for human health. Other reference values have a very local character and are only valid in a specific environment, e.g. natural radiotoxicity flux or concentration in groundwater. Several safety assessments have used proxy data from other sites or global or regional-scale average values when actual site-specific data are unavailable. Within the IAEA project "Natural activity concentrations and fluxes as indicators for the safety assessment of radioactive waste disposal" (IAEA 2005), several approaches for gathering local and regional data and using them – if necessary by averaging – for the derivation of reference values were investigated. When indicators are used to increase understanding of repository behaviour or simply to set a context for the impact of the repository, then it is possible to compare the indicator with a number of different reference values, and not one single value, to provide greater context and to illustrate the variability in natural systems.

7.7 Timescales

An original intent of using complementary indicators was to avoid some of the uncertainty inherent in calculations of dose and risk based on assumptions for human behaviour and climatic conditions in the very far future. As such there was anticipation that complementary indicators, particularly those that can be considered as safety indicators, would be most usefully applied to time periods in the far future. For example, the radiotoxicity concentration in biosphere water is a more robust indicator for time frames in the far future than the dose rate. Another aspect relevant to timescales is that complementary indicators can be used to justify the cut-off time for the assessment by explicit comparison of the changing hazard posed by the waste (due to radioactive decay) with the hazard due to naturally occurring materials and, in particular, uranium ore bodies.

This timescales approach is, however, only reflected to a limited extent in existing regulatory guidance documents. Nonetheless, a few regulations do explicitly address the issue. Furthermore, despite the advantages of complementary indicators in assessments of far-future impacts, a review of their use in safety assessments to date shows, however, that most organisations calculate all indicators (dose/risk and complementary indicators) for all assessment time periods, and do not apply any preferred bias or weighting. There may be a number of reasons for this but primarily the growing interest in using complementary indicators to evaluate sub-system performance and the evolving status of barriers over time (expressed as performance indicators or safety function indicators) means that they add value to the assessment at all time periods and not just in the far future.

7.8 Transferability

The safety indicator annual effective dose or a corresponding risk is a generally applicable indicator, because the interrelation between a certain dose rate and human health is always the same, independent of repository concept, host rock type and waste type. The same conclusion must consequentially be true for all indicators, which depend in an unequivocal way on the annual effective dose or vice versa. Therefore, the general applicability of the indicator annual dose is also existent for the safety indicator radiotoxicity concentration in the biosphere water, because the annual dose can be calculated from the radiotoxicity concentration in the biosphere water. A slightly different implication is deduced for the safety indicator radiotoxicity flux from the geosphere. Because natural radiotoxicity fluxes (as absolute flux through a given cross-section in Sieverts per time) can differ by several orders of magnitude depending on geology and location, the safety statement derived from this safety indicator is not in all cases the same, but it depends on the employed reference value.

In contrast to safety indicators, the applied performance indicators depend much more on the respective repository concept and therewith also on the host-rock formation. This dependence is an important reason for the different safety and repository concepts for repositories in different host-rock formations under consideration and the different structures of models used, especially for concept-specific near field calculations.

The potential usefulness of safety function indicators is related to the repository concept under consideration and must be evaluated in the context of the particular concept. While the general approach is transferable, specific safety function indicators are concept specific and thus hardly transferable between concepts.

7.9 Regulatory perspective

The time frame over which the safety indicators have to be evaluated, varies considerably between national regulations and sometimes has to be determined and justified by the proponent as adequate for the wastes and repository system concerned. In the last decades, there has been a development of the view of ICRP and national regulators on the meaning of dose and risk constraints for times very far in the future. Firm predictions of doses and risks to humans beyond times around several hundred years into the future are now regarded as impossible or at least very difficult, due to the large uncertainties that are connected to human behaviour, needs, and skills. Also the uncertainties regarding the climate and biosphere increase considerably with time. Calculated values of dose and risk for times far in the future are therefore not perceived as predictions but as indicators which allow judgements to be made of the the capability of the proposed system to provide isolation of the waste and containment of radionuclides.

In view of the uncertainties connected to very long time frames, especially with regard to predictions of the biosphere, dose and risk indicators have to be quantified on the basis of stylised assumptions or scenarios, although the perception of how much stylisation is required and how much predictive modelling is possible varies from country to country. The definition of stylised assumptions or scenarios is an important regulatory task since it might be very difficult for a proponent to defend their own stylised assumptions with well founded scientific-technical arguments in a licensing procedure.

National regulations always establish at least one safety indicator, usually dose or risk, which provides an indication of whether the disposal system is able to comply with the given safety objectives. The effective dose (defined in ICRP Publication 60), which specifies the expected overall effect this radiation has on the body, has been implemented into legislation and regulations in many countries worldwide, and provides a practicable approach to the management and limitation of radiation risk in relation to both occupational exposures and exposures of the general public.

Despite the fact that the effective dose is a frequently used safety indicator, other indicators that are able to serve as safety indicators, and the practices of how these safety indicators are defined and used, vary considerably across the countries. Similarly, national differences can also be found with regard to acceptance criteria. For example, the NEA's Regulators Forum project on long-term safety criteria (LTSC) found a significant variation among the current criteria, which not only differ in their magnitude, but also with respect to the time frame over which they are envisioned to apply. Also the bases for setting the criteria vary. This implies that numerical criteria of different countries cannot be compared in a meaningful way without considering the underlying country-specific reasoning on what is an acceptable level of consequences today and in the future and how it should be evaluated (NEA 2007b).

The need for complementary indicators is recognised by several regulators. However, whether the use of complementary indicators is prescribed or only recommended in regulations differs from country to country. Although, from a methodological point of view, performance and safety indicators provide different kinds of statements, regulations often do not distinguish explicitly between these two types of indicators. Usually, regulations provide no quantitative criteria for performance indicators, but regulators follow with interest the use a proponent makes of self-imposed performance indicator criteria or targets, and the reaction of a proponent organisation to a calculated value that lies beyond such a self-imposed goal. Observing the response to such an event may be a way of judging the seriousness of a proponent organisation's adherence to a nuclear-safety culture, for example.

Regulations usually do not specify which safety functions the proponent should assign to technical components nor do they specify respective safety function indicators and criteria. The main reason for this is that, for technical components, the choice of safety functions and safety function indicators often depends on the repository concept so that a specification on the part of the regulator can hinder the development of an optimal system which a proponent should be free to develop based on available technology. Another way to state this principle is to say that a very prescriptive approach to regulation is overly restrictive since it embeds a perhaps unstated but assumed conceptual model of the way the proposed system functions. That specificity is a potentially counterproductive constraint on system optimisation.

8. Treatment of uncertainties

Already in the NEA (1991) brochure it was observed that uncertainties are, and always will be, associated with assessment results. In the safety case, the connection needs to be made between key uncertainties that have been identified and the specific measures or actions that will be taken to address them, especially with regard to the R&D programme, in order eventually to arrive at a safety case that is adequate for licensing. Uncertainties can partly be reduced by collecting additional and more accurate data, by design changes, further research, or by additional model development. Since uncertainties will persist reflecting the limits in system understanding and the resulting variability in present and possible future states of the system, statistical methods are typically employed for evaluation of the impact of uncertainties on safety statements.

8.1 Classification of uncertainty

Internationally, there is now a high level of consensus on the type or source of uncertainties in safety assessment, although somewhat different terminology may be used. Typically, the uncertainties considered in safety assessment are classified in the following way:

- Scenario uncertainties: These uncertainties are associated with significant changes that may occur within the engineered systems, physical processes and site over time.
- Model uncertainties: Such uncertainties arise from an incomplete knowledge or lack of understanding of the behaviour of natural and engineered systems, physical processes, site characteristics and their representation using abstractions to set up assessment models and calculate them with the aid of computer codes.
- Data and parameter uncertainties: These uncertainties are associated with the values of the parameters that are used in the implemented assessment models, since data may be incomplete, cannot be measured accurately or are not available.

One must be aware, though, that the classification system above essentially arises from the way safety assessment is implemented. All three classes of uncertainties are related to each other, and particular uncertainties can be handled in different ways, such that they might be dealt with in one class or another.

In the last decade, the increased number of parameter data, along with the improved and deeper understanding of the FEPs governing the evolution of a disposal system has allowed achieving a more realistic understanding of the disposal system or parts thereof as compared with the initial early conservative representations. The increased level of understanding and the unavoidable associated increase of awareness of phenomenological uncertainties cannot be grouped straightforwardly into the three classes of uncertainties mentioned above.

In response, a representation of the FEPs and their associated uncertainties from a phenomenological perspective has gradually emerged. Following this approach, the phenomenological description of the disposal system and its associated uncertainties are not integrated (structured) into a safety perspective, e.g. into the safety functions or safety-relevant FEPs, but rather they are being classified as being specific to key THMC conditions as they evolve in the evolution of the system. This phenomenological description has provided the basis for the analysis of the uncertainties on the post-closure safety of the disposal system, and only after that analysis is there an attempt to classify the evaluated uncertainties into scenario, model and parameter uncertainty classes. This classification then allows these uncertainties to be interpreted and discussed in terms of effects on post-closure safety in the long term.

It is widely recognised that each uncertainty has a specific nature regardless of its classification. In this respect, irreducible (aleatory) and reducible (epistemic) uncertainties can be distinguished. Even though the different nature of uncertainties is generally acknowledged in safety assessments, the distinction between epistemic and aleatory uncertainties is usually not made because many uncertainties are best described and understood to be a result of the interaction of both types. For example, the calculated degradation rate of an engineered barrier component, an epistemic uncertainty, may be accelerated by a disruptive event (an aleatory uncertainty). From a total system safety perspective, over long times what matters is the cumulative effect of both types of uncertainty on the integrity of this component as a function of time.

8.2 Strategies for treating uncertainty

Strategies of treating uncertainties within the safety assessment are well established. Generally, these fall into one or more of the following five strategies:

- demonstrating that the uncertainty is irrelevant to the safety assessment;
- addressing the uncertainty explicitly – for example through a probabilistic approach or through a series of sensitivity studies;
- bounding the uncertainty – for example by making a number of simplifying assumptions taking a conservative view, i.e. assumptions are made such that the calculated safety indicators such as dose rate or radiological risk will be overestimated;
- ruling out the uncertain event or process – for example ruling out uncertain events on the basis of very low probability or because should the event happen, there will be more serious consequences elsewhere;
- using an agreed stylised approach to avoid addressing the uncertainty explicitly – for example, biosphere uncertainties and uncertainties regarding future human behaviour patterns may be addressed used a stylised “reference person” and an agreement that the assessment should be based on present day conditions and technologies.

As integrated safety assessments develop, the assessments themselves are used to identify which areas of uncertainty most need to be reduced in order to increase confidence in the overall assessment results, for example through sensitivity analyses. This iterative link between the safety assessment and the research on THMC processes, on material for engineered barriers and on waste characteristics as well as site characterisation programmes is an important aspect of developing overall confidence in the safety case. The understanding developed from research and development programmes can be fed directly into safety case arguments and can help to put the uncertainties associated with assessment results into a proper context.

8.3 Mathematical techniques

Mathematical methods for assessing quantitatively the influence of uncertainties on the calculated indicators are available and are well established. The understanding of advantages and drawbacks of specific methods has increased considerably in the last years. A variety of methods, both quantitative and qualitative, provide insight into the effect of uncertainty on system performance. Use of a variety of methods is helpful for gaining more comprehensive understanding. The development of new methods is actively pursued.

There is a wide consensus that sensitivity and uncertainty analysis is an important part of the safety assessment for radioactive waste repositories, and with that, of the safety case. The approach to uncertainty analysis may be either essentially deterministic or probabilistic. The choice between the various approaches is primarily driven by regulations. Many programmes consider that these approaches complement each other. More generally, in several programmes alternative methods are applied in parallel to increase the confidence in the results obtained.

In order to perform probabilistic uncertainty and sensitivity analyses, each uncertain parameter has to be assigned an adequate probability density function (PDF), which is used in the random sampling process. However, a general procedure for systematically deriving PDFs is not yet established internationally. Not all uncertainties have an important impact on the final result of the performance assessment, hence not all uncertainties need to be evaluated in a system uncertainty assessment, but an argument needs to be made and documented for excluding such uncertainties in the uncertainty evaluation.

8.4 Regulatory perspectives

Assessment strategies are strongly motivated by the need for an adequate treatment of uncertainties. Sources of uncertainties which are inherent to the concept of final disposal in geological formations are the considerable length of the assessment time frame and the incomplete knowledge of the natural system, its evolution, and interaction with the materials of the repository. This leads to uncertainties in data, assumptions, conceptual and physical models which have to be considered in the safety assessment.

Regulators expect uncertainties to be identified, to the extent possible quantitatively characterised or bounded, and their impact on safety clearly articulated in the safety case. Moreover, the way uncertainties are treated and propagated in the safety assessment should be traceable and substantiated. Complementary strategies like scoping and bounding assessments, deterministic and probabilistic approaches, realistic best estimates, conservative estimates, and alternate lines of evidence may be prescribed by regulations for specific assessment objectives. The requirement to simply build all scenarios into a single overall probabilistic assessment is nowadays considered to be insufficient by many regulators (Vigfusson *et al.* 2007) without demonstrating that there is an adequate basis and quality assurance pedigree for the complex model and the results.

Regulators expect that uncertainties which cannot be shown to be irrelevant are avoided or reduced as far as possible e.g. by means of site selection, site characterisation, repository design, and process-oriented research in order to increase the knowledge of the system's properties, state and behaviour, although it is acknowledged that some uncertainties will always remain. Uncertainties connected to the assessment results can be placed into an understandable context that enhances the ability to evaluate its importance by reference to multiple lines of evidence either as a complement to the entire safety assessment or to parts of it. In order to reduce uncertainties concerning the quality of procedures used for data collection and assessments, regulators often require the application of auditable quality assurance measures to avoid inconsistencies or errors in the data or models (Vigfusson *et al.* 2007) and the use of systematic approaches in avoidance of methodological mistakes. Internal and external, but in either case independent, expert reviews of the building blocks and process leading to the system model, and the interpretation and evaluation of the modelling results, can be very useful to the regulator in evaluating the confidence that can be assigned to the modelling effort.

When conservative estimates are required care has to be taken that conservativeness is not inherent to a single assumption but is instead judged with regard to appropriate specific safety indicators. The judgement whether an estimate is conservative requires a good understanding of the system (Vigfusson *et al.* 2007). Conservative approaches therefore are always either implicitly or explicitly connected to best-estimate approaches which try to approximate the most likely system behaviour.

Expert judgement is a ubiquitous but not always visible ingredient in the treatment of uncertainties. Regulators usually recognise that expert judgement may be useful in both the quantification of uncertainties and in their qualitative treatment where reliable quantification is not practical. It is usually considered that it is a matter for the proponent to decide whether, where and how to use expert judgement. If expert judgement is used though, it has to be documented in a traceable and transparent way and the proponent must apply appropriate quality standards. The role of the experts is not seen as a substitute for scientific research, but instead to synthesise disparate and sometimes conflicting sources of information to produce an integrated picture (Vigfusson *et al.* 2007). Uncertainties originating from any differing or contradictory expert elicitation have to be explained and treated in the safety case.

The safety assessment also has to deal with irreducible uncertainties that are not amenable to quantification. There is e.g. uncertainty about the likelihood of human intrusion, uncertainty whether calculated doses have the same radiological impact on future species as on present species, and uncertainty whether all relevant processes, events, evolutions and uncertainties have been identified and considered in the safety assessment. The confidence in the safety of the disposal system relies on the subjective judgement that such uncertainties are sufficiently low in view of the measures that have to be taken to reduce them. The regulator has to give guidance regarding the circumstances under which it is acceptable to have known uncertainties that cannot be quantified. Many regulators prescribe stylised approaches regarding future dose receptors, biospheres, or human intrusion scenarios that obviate the need to argue such unquantifiable uncertanties in a licensing proceeding. In addition some regulators may accept the possibility of human intrusion and its potential consequences on the condition that it is demonstrated that the repository has been placed at a sufficiently great depth and away from natural resources, the two main counter measures against human intrusion. Also, the repository may be designed to reduce the likelihood of human intrusion or the possible consequences.

The possibility that relevant FEPs might not have been discovered at a certain stage of the repository development process may be accepted on the condition that systematic procedures for FEP screening, which aim at comprehensiveness, have been applied, or that the state of the art in relevant science disciplines and technology is evaluated periodically.

9. Conclusions and recommendations

Key conclusions from the MeSA project include:

- Safety assessment forms a central part of the safety case. However, the results of such assessments must be placed in context and augmented by additional information (i.e. in a safety case) to support decision-making.
- Safety assessment provides key information to focus research and site characterisation programmes, as well as engineering design and testing. Conversely, these aspects of repository development produce the data (and interpretations of that data) that support a high quality assessment. Given these links, an important aspect of repository planning is to ensure clear and effective information flow among the various groups and stakeholders involved with repository development.
- Generic safety case and safety assessment flowcharts were developed. At a higher level, key assessment activities are "freezing of key data", comprehensiveness checking, a synthesis of evidence, arguments and analyses, and feedback to programme management. At a more detailed level, safety assessment generally starts with the development of an integrated description of the expected initial state of the disposal system and of its evolution.
- Scenarios represent specific descriptions of a potential evolution of the repository system from a given initial state. They describe the compilation and arrangement of safety relevant features, events and processes as a fundamental basis for the assessment of post-closure safety which includes assessing the potential consequences on humans and the environment. The development of scenarios for the safety case is of fundamental importance as it constitutes a key element of the management of uncertainties.
- An assessment of the performance of a repository can be undertaken by simulation of the potential evolution of the repository system using mathematical or numerical models. Overall, there is wide consensus on the modelling strategies to support safety assessment, and no major areas of disagreement have been identified. In most safety analyses, deterministic and probabilistic calculations are now seen as complementary, and both approaches are applied.
- The concept of using various types of indicators to complement dose and risk has developed considerably during the last 15 years and has become internationally accepted. However, the terminology used for indicators by different organisations is rather inhomogeneous and not consistent between national programmes; identical or very similar concepts are sometimes denoted differently, while in other cases the same term is used with different meanings.
- Uncertainties are, and always will be, associated with assessment results. Internationally, there is now a high level of consensus on the types and sources of uncertainties in safety assessments, although somewhat different terminology may be used. Typically, the uncertainties considered in safety assessment are classified into scenario uncertainties, model uncertainties, and data and

parameter uncertainties. Strategies for treating uncertainties within the safety assessment are well established.

- Regulations and regulatory expectations have evolved considerably since the issuing of the NEA brochure on the methodology of safety assessment in 1991 and nowadays recognise more clearly the implications of the long assessment time frame for the demonstration of compliance on the assessment methodology that should be used. Regulators expect that the proponent not only assesses compliance with quantitative radiological criteria, but also demonstrates that the repository system is robust and that its possible evolution is well understood. Also, assurance of data and modelling tool quality, appropriate quality management and transparency and traceability of the assessment process are considered essential.

The MeSA project led to several suggestions on areas related to the safety case in which further development work might be conducted. These included:

- A suggestion to update the NEA brochure on the safety case concept and, in doing so, to emphasise more clearly the essential role of safety assessment within the safety case.
- A suggestion to update and enhance the NEA database of features, events and processes (FEPs) relevant to safety assessment for geological disposal.
- A suggestion to initiate a project that would foster the exchange of information and best practice on scenario development.
- A suggestion to develop a "state-of-the-art" report on safety indicators in safety assessment, based on further evaluation of responses to a questionnaire survey conducted during the MeSA project.
- A suggestion to develop guidance on a general scheme for performing sensitivity analyses in safety assessments for geological disposal systems and interpreting results.
- A suggestion to develop guidance on when formal approaches to expert judgement and elicitation may be warranted in safety assessment in general, and on disposal system description and scenario development in particular.

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Part II

Issue papers

11. Safety assessment in the context of the safety case

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Abstract

This paper reviews safety assessment in the context of the safety case. The paper provides definitions and illustrative examples of the various roles played by safety-assessment in a radioactive waste disposal programme. This paper discusses the general issues that need to be addressed in order to produce a credible safety assessment that then becomes a central component of an overall case for long-term safety. This is the first in a series of papers in an overall structure called the Methods for Safety Assessment (MeSA) project. The second through sixth papers delve deeper into the roles of safety-assessment, and the final paper gives a regulatory perspective on the topic addressed in papers one through six. Topics addressed in papers two through six are: (2) Safety assessment and safety case flowcharts, (3) System description and scenarios, (4) Modelling strategy, (5) Indicators for safety assessment, and (6) Treatment of uncertainties. The seventh paper addresses regulatory perspectives on all relevant topics from other papers. The purpose for this series of papers is to document the current state of the art respecting the safety assessment's role in geological repository programmes.

Keywords: Safety assessment, safety case, geological repository, radioactive waste, disposal.

11.1 Introduction and definitions

11.1.1 The MeSA project

The MeSA project, under the auspices of the NEA Integration Group for the Safety Case (IGSC), examines and documents Methods for Safety Assessment for long-term safety of geological repositories for disposal of radioactive waste. In 1991, IGSC's predecessor, the Performance Assessment Advisory Group (PAAG), compiled the state-of-the-art at that time in a brochure called "Review of Safety Assessment Methods". The evolution since that time is characterised by (see NEA 2007):

- the development of the safety case concept, in which safety assessment is brought into a broader perspective;

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- the submission of numerous safety cases containing a variety of safety assessments with commonalities, differences, and new methodological developments;
- a considerable number of national and international activities devoted to the further development of several aspects of methodologies for safety assessments;
- a number of peer reviews of safety assessments and safety cases.

This state of the art is currently undergoing further development, for example, through the European Commission's (EC's) Performance Assessment Methodologies in Application to Guide the Development of the Safety Case (PAMINA) Project. Most contributors to this series of MeSA papers are also involved to some degree in that EC Project and the aim is to provide a series of papers here that complement and are synergistic with the products being generated through the PAMINA Project.

The goals of the MeSA project are to review and summarise developments regarding safety assessment methods in order to:

- describe the state of the art;
- discuss the variety of methods and overall approaches;
- and confirm or establish a joint view about what are considered the necessary elements and agreed methods of modern safety assessments.

As noted above, the emergence and definition of the concept of a safety case has provided a new and different context in which to understand the role of safety assessment and to interpret the results. This paper provides definitions of safety assessment and safety case, and explores the relationship between them. The paper describes the long-term safety assessment in terms of its purposes and uses in planning and implementing a radioactive waste disposal system.

Other important aspects of safety assessment are explored in a series of related papers that address:

- Issue Paper No. 2: Safety assessment and safety case flowcharts (Schneider *et al.* 2011).
- Issue Paper No. 3: System description and scenarios (Röhlig *et al.* 2011).
- Issue Paper No. 4: Modelling strategy (Gierszewski *et al.* 2011).
- Issue Paper No. 5: Indicators for safety assessment (Noseck *et al.* 2011).
- Issue Paper No. 6: Treatment of uncertainties (Mönig *et al.* 2011).
- Issue Paper No. 7: Regulatory issues (Navarro *et al.* 2011).

Cross-references to the other papers are provided in the text where appropriate.

11.1.2 Definitions

Over time, various definitions have been put forward for "safety assessment", "safety case" and related terms (see e.g. NEA 1997, NEA 1999a, NEA 2004). The MeSA project focused on long-term safety; that is, safety in the period after disposal facility closure and beyond the time when active control of the facility can be relied on. In this context the MeSA project used the following basic definitions:

> *Safety assessment* is a systematic analysis of the hazards associated with geological disposal facility and the ability of the site and designs to provide the safety functions and meet technical requirements. The task involves developing an understanding of how, and under what circumstances, radionuclides might be

> released from a repository, how likely such releases are, and what would be the consequences of such releases to humans and the environment.
>
> The *safety case* is an integration of arguments and evidence that describe, quantify and substantiate the safety of the geological disposal facility and the associated level of confidence. In a safety case, the results of safety assessment – i.e. the calculated numerical results for safety indicators – are supplemented by a broader range of evidence that gives context to the conclusions or provides complementary safety arguments, either quantitative or qualitative. A safety case is the compilation of underlying evidence, models, designs and methods that give confidence in the quality of the scientific and institutional processes as well as the resulting information and analyses that support safety.

These definitions are based on those in the 2004 NEA brochure that documented the concept and elements of the safety case – which, in turn, closely match and elaborate on those incorporated in safety requirements published jointly by the International Atomic Energy Agency and the Nuclear Energy Agency (IAEA 2006).

As noted above, there have been some differences in terminology over time and across national programmes, so the definitions given above may not match precisely what is used in different countries. A term often used interchangeably with safety assessment is performance assessment. There are varying perceptions about the relationship between safety assessment and performance assessment. For instance, according to the IAEA Safety Glossary, safety assessment is the assessment of all aspects of a practice that are relevant to protection and safety (including siting, design and operation of the facility), whereas performance assessment is defined as the assessment of the performance of a system or subsystem and its implications for protection and safety. From that perspective performance assessment may be considered a component of safety assessment, but there is not universal agreement on this point. The term safety analysis is also used in some programmes. For the purpose of this project, the term "safety assessment" is used as it is defined above.

Similarly, and depending on the context, slightly different terms have been used in different programmes for the safety case (e.g. "a post-closure safety case", a "long-term safety case", a "safety report", or part of a "license application").

11.2 The safety case as context for safety assessment

11.2.1 The concept and role of the safety case

As defined in the preceding section, the safety case is an integration of arguments and evidence that describe, quantify and substantiate the safety, and the associated level of confidence, of the geological disposal facility. It is a generally accepted principle that the safety case for a geological repository should show that repository will be safe without relying on future generations to maintain active control of the facility. A safety case is presented, most often by organisations responsible for implementing waste disposal solutions, at specific points in the process of repository development. 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 or repository, or with the aim of developing and testing the methodology for developing a safety case.

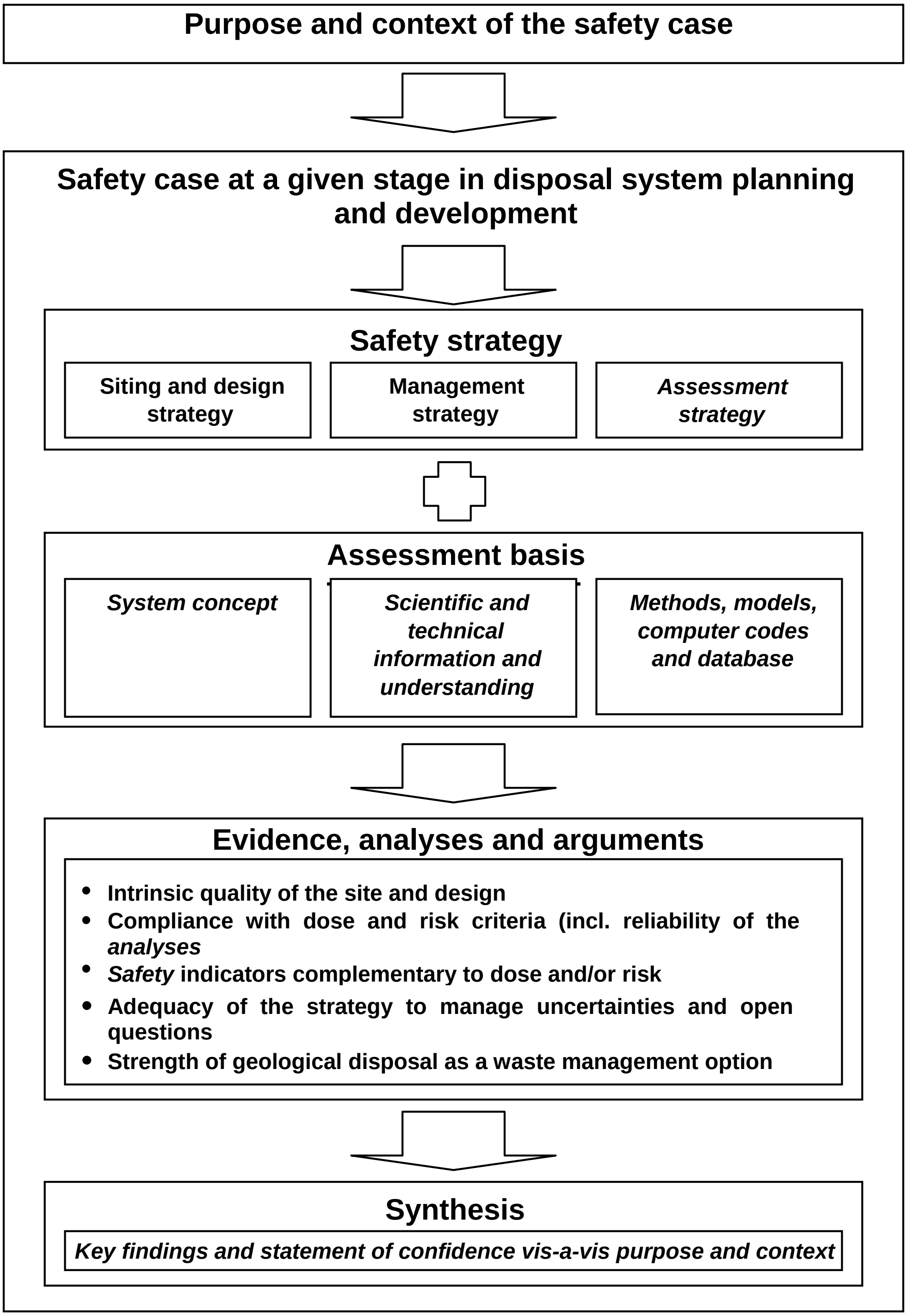
A key function of the safety case is to provide a platform for informed discussions whereby interested parties can inform their level of confidence in a project at a given stage, including any issue upon which further work is warranted. That is, the safety case is a basis for decision-making (NEA 2004a, p. 46). An iterative development process, in which the safety case is presented and reviewed at key decision points, is expected to result in a comprehensive and cogent safety case and in high, shared confidence in the quality of the decision it is designed to support.

11.2.2 The elements of the safety case

The NEA Safety Case Brochure (NEA 2004a) described the essential elements of a safety case, which can be summarised as follows:

- A clear statement of purpose provides context for the safety case. The content of the safety case should be adapted to the decision context.
- The safety strategy is the high-level approach adopted for achieving safe disposal, including an overall management strategy, a siting and design strategy and an assessment strategy. It incorporates good management and engineering practice, and provides sufficient flexibility to cope with new information and technical advances. Appropriate strategies tend to favour robustness and minimise uncertainty, for example by selecting a site with assessable features and by tailoring repository design to its geological setting.
- The assessment strategy ensures that events and processes relevant to safety are identified and guides how their consequences will be quantified. The assessment strategy involves the definition of conceptual models and mathematical approaches to be used to evaluate them, and is an integral part of 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 and its geological setting; 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 depends on the quality and reliability of the assessment basis. The assessment basis should be tailored to provide the necessary information and supporting evidence, analyses and arguments for safety to support the decision step under consideration. The description of the process that leads from evidence to a safety evaluation is an important part of the safety case.
- Evidence, analyses and arguments for safety must be compiled into a safety case. Results of analyses are typically compared against safety criteria, often in terms of radiological dose and/or risk, but there may also be other performance measures applied either for regulatory compliance or as indicators of performance that provide insights into system behaviour (see Issue Paper No. 5, "Indicators for safety assessment"). The evaluation of these performance measures or indicators, using mathematical analyses (i.e. safety assessment) is typically accompanied by more qualitative arguments that provide a context or support for the performance-calculation results. A series or range of appropriate evolution scenarios may be addressed for the disposal system. Evaluating system performance under various scenarios may provide an opportunity to optimise the system to increase the robustness of the case for safety. Robustness of the safety case may also be strengthened by the use of multiple lines of evidence, leading to complementary safety arguments, to compensate for any shortcomings in confidence in any single argument.
- A synthesis of available evidence, arguments and analyses, as supported by the quality and reliability of the assessment basis, leads to a statement by the implementer of the degree of confidence that exists regarding whether to proceed with the next stage of planning or implementation of a disposal system.

Figure 11.1: An overview of the elements of a safety case



Note: Aspects which relate directly to safety assessment are italicised.
Source: NEA 2004, p. 2.

Figure 11.1 shows the elements of a safety case as defined in the 2004 NEA brochure. It can be noted that safety assessment, per se, is not identified as a separate "element" of a safety case. Its essential role in the safety case means that aspects of safety assessment relate to numerous elements of the safety case. Those aspects which relate directly to safety assessment have been italicised and underlined for emphasis. Based on the figure from the 2004 NEA safety case brochure, safety assessment involves elements of the safety strategy, the assessment basis, and the evidence and arguments for safety.

11.2.3 The relationship of safety assessment to the safety case

As has been suggested already by the definitions in Section 11.1.2 of this paper, the safety assessment is central to the safety case. It provides an important platform for integrating information; for organising and testing conceptual understanding of a disposal system; for assessing the relevance and significance of uncertainties; and for quantifying performance and safety in a format that is readily comparable to established safety criteria. The safety assessment by itself does not comprise a safety case, but it is an indispensable component.

It would be convenient to be able to say unequivocally that all italicised items in Figure 11.1 are related to the safety assessment, and that all others are the additional elements needed to build a safety case. However, experience since publication of the 2004 NEA brochure has shown that the dividing line between safety assessment and safety case is not sharply drawn. There may, for example, be information that serves roles in the safety assessment as well as supporting other, usually more qualitative, arguments for safety. In addition, national programmes have different interpretations and expressions of the elements of safety assessment, which overlap to various degrees with the definitions above. Furthermore, there are steps or components of safety assessment – notably, for example, the process of identifying relevant scenarios and processes– that do not appear at all, as least as distinct items, in the 2004 diagram of the safety case.

Another example of such differences is whether or not programmes present the system description and conceptual models as part of the safety assessment. Some recent safety cases contain dedicated reports presenting what is termed the safety assessment, with separate reports dedicated to the system description (e.g. geosynthesis, layout and design description, process description). With such a structure, the initial system description and "assessment basis" may be seen as an input to, rather than a part of, the safety assessment.

The ease or difficulty of delineating between safety assessment and the safety case may also depend on the stage of programme development. In later stages of repository development, when a safety case is presented to a decision maker or another audience, the boundary between safety assessment and the safety case is often clearly identifiable because the various lines of evidence are well defined and described. This might be the case only to a lesser extent, during earlier stages of repository development. Several of these important links are discussed in Section 11.4 of this paper.

Thus, it is difficult to draw a clear dividing line between safety assessment and the safety case. Nor is it necessarily useful to make a sharp delineation, especially in view of the variety of definitions used internationally. Instead, we can conceive of a "dividing area" between the two concepts. What is important is that: firstly, safety assessment – a systematic and scientifically-supported analysis of repository performance – forms a central part of the safety case; and secondly, that the results of such assessments should be placed in context and augmented by additional information in a safety case to support decision-making. Issue Paper No. 2 in this series discusses the elements and process of safety assessment, and their relation to the safety case, in greater detail.

11.3 The scope and basis of safety assessment

11.3.1 The scope of safety assessment

The "scope" of safety assessment is largely established by its very definition. That is, as noted earlier, a safety assessment considers the overall performance of the waste disposal system in terms of impact such as risk or some other global measure(s) of impact. Still, within this framework, there can be variety concerning the time frame(s) considered relevant, the level of detail, the range of issues considered, and the degree of precision required for input data and in resulting calculations. Setting the scope and designing a safety assessment entails addressing the attendant technical aspects above, and usually also involves policy and practical considerations. The degree of programme development often dictates the purpose, scope and degree of detail needed in safety assessment.

The time frame over which the safety indicators have to be evaluated varies considerably between national regulations and sometimes has to be determined and justified by the proponent. Cut-off times specified in national regulations are derived from the declining radiological toxicity of the waste, from peak radiological consequences, from increasing uncertainty with time, or from the need for adequate coverage of transient or perturbing processes (NEA 2007; MeSA Issue Paper No. 7 – Navarro *et al.* 2011).

The selection of the time frame influences many aspects of safety assessment, including the range of scenarios that might occur and the level of uncertainty that must be accommodated. Furthermore, the time frame under consideration has a significant effect on how the results of safety assessment can be interpreted. In this context it is important to note this caution in the IAEA/NEA safety requirements (IAEA 2006, Section 2.12):

> It is recognised that radiation doses to people in the future can only be estimated and the uncertainties associated with these estimates will increase for times further into the future. Care has to be exercised in applying the criteria for periods beyond the time where the uncertainties become so large that the criteria may no longer serve as a reasonable basis for decision-making.

The safety assessor must also decide on what calculational endpoints to address. Where there is clear regulatory guidance it is to be followed, of course. However, there may be additional benefit from the use of alternative, complimentary performance or safety indicators (IAEA 2006 Sections 2.18, 3.35, 3.48, as well as MeSA Issue Paper No. 5 – Noseck *et al.* 2011). The issue of timescales in safety assessment and in safety cases is discussed extensively in several NEA reports (e.g. NEA 2004b; 2009c).

Another significant aspect in designing a safety assessment is to define the range of scenarios and how they will be addressed. The assessment strategy typically establishes conditions that define a base case representing "expected performance," meaning that it addresses a range of conditions and evolutionary scenarios that are reasonably likely to occur over the time frame of interest. The safety assessment also takes account of disruptive events and scenarios of lower probability. Lastly, some safety cases include "what-if" scenarios that are considered implausible, but assessment of which can provide information regarding, for example, the robustness or reserve safety features of the disposal system.

Ultimately, it is necessary to establish a boundary, delineating events that lie outside the scope of safety assessment, in order to limit the complexity and uncertainty in safety assessment, as well as to encourage attention on those aspects most relevant to safety. This may be done on the basis of probability cut-offs or other criteria, which raises the issue of uncertainties regarding the nature and probability of occurrence of key events and processes. There are several approaches available to do this type of uncertainty evaluation, usually employing a mix of probabilistic and deterministic approaches.

Even after criteria have been established with which to define the set of scenarios to be considered, there remain uncertainties in establishing how these scenarios should be modeled. Significant issues in this category relate to the treatment of the biosphere and human intrusion scenarios. Often, these are treated using "stylised" scenarios and approaches. In particular, it is common practice to assess the potential consequences of human intrusion by undertaking deterministic calculations separately from other aspects of performance and safety assessment.

Sometimes criteria for identifying scenarios, and guidance on approaches to modelling scenarios, are specified in regulation (see MeSA Issue Paper No. 7 – Navarro *et al.* 2011). If not, these aspects are determined by the implementer. In the absence of clear regulatory stipulation, the implementer may need to make a case for a preferred approach to evaluating scenario-uncertainties and this may be based in part on international requirements and recommendations from IAEA and/or NEA (e.g. NEA 1999b).

11.3.2 Importance of the assessment basis

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 [including the wastes to be disposed of, the engineered aspects including excavations and engineered barriers (e.g. EC and NEA 2010), and the host rock and surrounding geological environment] and their safety functions (see e.g. MeSA Issue Paper No. 3 – Röhlig *et al.* 2011).
- The scientific and technical data and understanding relevant to the assessment of safety – see MeSA Issue Papers No. 2 (Schneider *et al.* 2011) and No. 3 (Röhlig *et al.* 2011), as well as Section 11.4 of this paper.
- The assessment methods, models, computer codes and databases for analysing system performance (see MeSA Issue Paper No. 4 – Gierszewski *et al.* 2011).

Obviously, the quality of the safety assessment depends on the quality of the assessment basis. The information base should be consistent, well-founded, transparent and adequate for the purpose of the assessment and associated stage of repository development.

11.3.3 Uncertainties and safety assessment

Uncertainties regarding long-term safety assessment "… are unavoidable due to the complexity of the phenomena of concern and the scales in time and space under consideration, and their management is central when developing a repository system and assessing its safety" (Vigfusson *et al.* 2007). These include uncertainty about whether all the relevant features, events and processes have been considered, uncertainty in their description and how they should be modeled, and uncertainty in the data that is needed in an analysis. The safety assessment methodology must account for uncertainties, and various approaches can be taken. Thus, safety assessment needs to be integrated within the uncertainty management strategy. Importantly, safety assessment itself is also a valuable tool with which to evaluate uncertainties regarding system behaviour.

Uncertainties relevant to safety should, where possible, be quantified and/or bounded (see, e.g. MeSA Issue Paper No. 6 – Mönig *et al.* 2011) in the conduct of safety assessment. There are instances where this is not possible, however, and in such cases the uncertainties should be acknowledged and managed to the extent practicable. The assessment methods and tools must also be clearly and systematically presented (refer again to MeSA Issue Paper No. 3 – Röhlig *et al.* 2011), and implemented under clear quality-management systems.

The role of the safety case, however, goes beyond a pure quantification and assessment of uncertainties. Safety assessment is, amongst other things, a tool to identify uncertainties and judge their significance for safety. When a safety case is compiled and presented at major decision points, the assessment basis can be considered "frozen" for a particular point in time. At such a decision point, an essential aspect of judging confidence in the safety case is to assess the relevance and significance of remaining uncertainties. The use of this information varies depending on the stage of repository development.

In early stages of repository development, the results of safety assessment provide essential input for research and development. Uncertainties can be identified and their significance to safety can be assessed. For those that are deemed significant, measures can then be designed to manage them. Some uncertainties can be avoided or reduced. Typical means for reducing uncertainties are research and site investigation programmes, or modifications to site layout and repository design. For example, successive safety reports in the French programme were used to refine site investigations and focus on those features of the host rock found to be most significant in fulfilling its performance as a barrier (Lebon 2008). A possibility to mitigate the effects of uncertainties by design measures is the Belgian concept of the so-called "super-container" which, amongst other things, is meant to circumvent uncertainties concerning near-field corrosion processes (NEA 2011).

Ideally, the information comprising a safety case should be summarised and synthesised into a concluding statement regarding the degree of confidence that exists at the given stage of repository development and which, amongst other things, should address the remaining uncertainties and how they might be managed. The implementer/applicant should state:

- which of the identified uncertainties are significant for safety;
- whether and why it is appropriate to move to the next stage of repository development despite these uncertainties; and
- which strategies (e.g. R&D programmes, site investigation programmes, repository design refinements) should be employed to address them.

As a programme matures, studies will increasingly focus on key safety-relevant uncertainties and stakeholder concerns, and the specific data and measurements needed to resolve these.

In the later stages of repository development, the safety assessment is an important tool for providing feedback to detailed design and for assessing the possibilities of further enhancing safety, in addition to being a tool with which to develop confidence and to provide assurance that uncertainties significant to performance have been adequately addressed. A decision to move to the next step of repository development is an expression of confidence in the proposed concept based on the findings of the safety assessment and the safety case, despite the existence of uncertainties, some of which will inevitably remain.

11.4 The safety assessment and safety case in repository development

11.4.1 Evolution of the safety assessment and the safety case over time

As already suggested in Section 11.2.1, a given safety case exists in a specific context in terms of the decision being considered and the modelling tools, data and design information that are available at that time.

A 2008 NEA symposium on the safety case demonstrated a wide range in the degree of sophistication for safety assessments and safety cases from national programmes. This exemplifies the progression that programmes go through to reach maturity in the safety case (NEA 2008, pp. 18-19). Safety cases may need to be prepared from the earliest stages of planning at time intervals up until (and sometimes even after) a repository is closed, spanning a period of several decades up to centuries. As investigations continue, data availability increases and the models used for safety assessments are re-evaluated in terms of appropriateness in the context of new information. As programmes are implemented it is likely there will also be differences between what was assumed in earlier safety assessments and what has actually been built and placed in the repository. Deviations from original plans and assumptions need to be identified, evaluated, and in some cases justified.

Given the long time frames of repository development and, thus, safety assessment iterations, care must be exercised to preserve key data and ancillary information that establish the quality of those data.

11.4.2 Feedback and links with other aspects of repository development: site characterisation, testing, engineering, design

It has been noted that there is not always a clear dividing line between safety assessment and other elements of the safety case. This is due in part to the fact that there is significant interaction and iteration between safety assessment and other aspects of repository development, notably site characterisation and repository design. In some cases, preliminary safety assessment results are key inputs to guide these activities (see Section 11.3.3. of this paper). In other cases, the results of these activities are key inputs to safety assessment. It is not uncommon, especially in early phases of repository development, that both will be true and that there will be iterative information flow to and from safety assessment.

One of the most prominent examples in repository development is the information flow between safety assessment and site characterisation. Preliminary system models are typically developed and used to some extent in defining the site characterisation process. Later characterisation of the site will then allow refinement of the preliminary modelling to reflect actual field conditions based on the information gained: after all, this is the purpose of site characterisation. That is, site investigation tests and observations provide the fundamental data that underpins the development of conceptual models, provide data to derive parameter values, and help define the relevant processes and scenarios in safety assessment (NEA 2009b, pp. 36-37).

As understanding of the system further matures, safety assessments should be useful in indicating what processes are most important to performance and, therefore, the data needed to quantify these processes.

There is also two-way feedback between safety assessment and the design of the engineered barriers of a repository system. In early stages of development, safety assessment can be useful in selecting between various options or conceptual designs for disposal. Safety assessment also provides important input to establishing engineering design requirements. As has already been discussed in Section 11.3.3, modifications may be made to repository layout or design in order to avoid or compensate for uncertainties that are shown by safety assessment to be relevant. Conversely, engineering and design details are important inputs to ensure that the disposal system is being appropriately modeled in safety assessment. Testing of engineered materials and designs provides crucial information to confirm modelling assumptions (e.g. regarding container lifetime or permeability of barriers) and to demonstrate that the system can be built as intended and as reflected by modelling.

Safety assessment also provides a means with which to integrate information and understand the interactions between various parts of the disposal system or between different sets of requirements. For example, the performance of the engineered and natural barriers may be evaluated as one system, or they may be evaluated separately by varying the properties of some components while holding properties of the other system constant to evaluate the robustness of the entire system for different assessment cases or scenarios. Furthermore, some requirements may compete with one another or imply opposing options. While long-term safety is a main driver in repository design, operational safety and engineering feasibility are also 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 and one for which safety assessment is a valuable tool (NEA 2009a, p. 52). Safety assessment similarly provides assurance that a change made to solve one problem, such as avoiding the consequences of an uncertainty through a robust design, does not introduce other, more serious problems or uncertainties. In these ways, safety assessment can make an indispensable contribution to the continuous optimisation of disposal system design and implementation.

Thus, it is clear that safety assessment provides key information to drive research and site characterisation programmes as well as engineering designs and testing. Conversely, these other aspects of repository development produce the data (and interpretations of that data) that support a high-quality assessment upon which the quality of the safety case depends. Given these links and mutual dependencies, an important aspect of repository planning as well as a sound safety assessment is to ensure clear and effective information flow among the various components of repository development. This can be achieved with various approaches, which have been described in other NEA documents. (NEA 2009a, p. 52). For example, in some programmes (e.g. Belgium, France, Sweden) safety functions serve as a tool for establishing the necessary linkages and facilitate interaction and communication between the relevant work teams.

11.4.3 *Regulatory expectations*

Safety regulations for geological repositories commonly address safety assessment, but to different degrees and at varying levels of detail. Issue Paper No. 7 in this MeSA series (Navarro *et al.* 2011) addresses regulatory expectations in more detail.

As a generality, from a regulatory perspective, it has long been established that providing the evidence to support the claims made in the safety assessment is just as important as the safety assessment calculations themselves (NEA 2009a, p. 11). This suggests that regulators have always called for a safety assessment to be accompanied by the type of supportive and ancillary information that puts it into the context now being called a safety case.

Furthermore, from a regulatory perspective, it is expected that there will be a systematic and clear treatment of uncertainties in safety assessment. In some cases, the treatment of uncertainties encompasses the treatment of contradictory expert opinions. A number of methods can be used to handle differences of opinion between experts, as well as other types of uncertainties (see NEA 2009a as well as Issue Paper No. 6 in this series).

It must be appreciated that the regulator of a geological disposal facility for long-lived radioactive wastes is challenged with having to review first-of-a-kind methods and information (NEA 2009a, p. 43). The safety assessment represents one of these types of information, but at the same time provides the means to assess other aspects, such as to understand to what extent it would be possible to modify an existing design choice or related programme decision.

From a regulatory perspective it is also important to keep in mind that safety assessment results are often reported in various documents or at several levels of technical sophistication (see Section 11.5 of this paper for further discussion of this issue). Regardless of the level of detail, the various presentations must be consistent;

that is, they must rely on the same safety arguments and reach the same conclusions regarding long-term safety. A regulator would be placed in an awkward position in reviewing a license application that, for example, reached different conclusions (or on a different basis) than those in an accompanying environmental impact assessment or other report. This issue, along with its implications in terms of the regulator's responsibilities, is addressed in MeSA Issue Paper No. 7 (Navarro *et al.* 2011).

11.5 Interpretation and presentation of safety assessment results

The results of safety assessment may be compared against agreed criteria for safety and performance indicators, which usually include radiation dose and/or risk, and possibly other measures of the performance or possible consequences of releases from the disposal system (see MeSA Issue Paper No. 5 – Noseck *et al.* 2011). These comparisons provide one of the main lines of evidence in a safety case, but must be supplemented by additional evidence and information. For example, when practical, comparisons with what is known from analogous systems play a part in underscoring that all meaningful scientific knowledge available has been consulted in the site characterisation, materials selection, design and modelling of the overall system. Bringing all of that supportive information into a document that also describes and shows the output of a safety assessment makes for a comprehensive safety case.

The uncertainties in safety assessment and, consequently, in the interpretation of results may complicate the communication of safety assessment results. There are large bodies of research devoted to risk communication in itself (see to NEA 2004a, pp. 29-30 for further discussion of this issue). The comparison of safety assessment results with safety criteria are not necessarily simple to explain, especially to a non-technical audience. Nor are they always those of most interest to a given audience (NEA 2004a, pp. 21-22):

> The presentation of a safety case to the public needs to emphasise issues that are likely to be of greatest public concern. It also needs to adopt a style that is accessible to an audience with a broad range of technical and non-technical backgrounds. The public audience is typically neither expert nor specialist, and needs a yet more transparent, understandable safety case in which the arguments for safety are presented in clear and, most likely, more qualitative terms. Alternative media to enhance the visual presentation of concepts unfamiliar to non-specialist audiences may be appropriate to illustrate complex technical content.

Thus, different audiences may be presented with a different emphasis on aspects of the safety case, or may be presented with differing levels of technical detail. As noted, safety assessments, and their level of detail and complexity, will change through iterative cycles over time. In addition, publications and presentations at a given decision point may be adapted or extracted, for example, to make information more accessible to non-specialists. A strategy that may be used to convey key results in a simplified way, while retaining the detailed technical basis, is through "tiered documentation", in which different documents provide different levels of detail and are aimed at different audiences. "Higher-level" documents provide key messages to non-technical audiences. This requires translating highly technical information into language that a reasonably well-informed adult can understand. The results should be related clearly to the stage of the repository decision-making process. Care must be taken not to oversimplify the safety assessment results and their meaning. It is important to express confidence in the assessment basis and results, but caveats will always apply and uncertainties need to be acknowledged.

It is important to recall that in principle, there is one comprehensive safety case; that is, the evidence, arguments, reasoning and underlying basis are the same and what differs is simply the manner and degree of detail in the presentation (see also Section 11.4.3 of this paper).

To increase confidence in a safety case, independent technical or peer reviews can be conducted of the scientific basis, the safety assessment and safety case arguments. These reviews can examine the science underlying the assessment calculations as well as the conceptual and mathematical treatment of the data and key assumptions and descriptions of features, events, and processes (FEPs) in the models used. The types of information considered in such reviews range from general scientific knowledge to the fine details of tests and the representativeness of the testing conditions (NEA 2005b).

11.6 Conclusions

Since 1991, much experience has been gained in modelling and evaluating the performance of potential repository concepts. The experience gained in site characterisation and other research and development – which leads to a more defined repository concept – underscores the importance of modelling the performance of system components and evaluating the safety of a proposed system throughout the disposal programme, from siting to construction through operations and final closure.

Additionally, the need to iteratively re-evaluate and update the assumptions being made in the developing safety case has been discussed. This includes evaluating the practicality and feasibility of building underground openings, installing the engineered barrier system, and final repository closure, consistent with the safety case and safety-assessment assumptions. The pervasive need to identify, evaluate and manage uncertainties has also been emphasised.

Recent NEA symposia (NEA 2008) and related studies demonstrate that safety cases have evolved into tools with which to both build confidence in safety and to aid in decision-making. The safety assessment, which provides a tangible and quantifiable assessment of repository evolution and performance/safety is at the heart of the safety case. It affects, and is affected by, all other elements of the safety case.

Programmes, especially in earlier stages of development, are focused on developing specific aspects of the scientific or modelling basis of the safety assessment in anticipation of making part of a safety case. Even though national programmes are now assembling the essential elements of a safety case, national programmes also continue to refine the scientific basis and methods for assessing and documenting safety. Some of the more noteworthy of these refinements will be discussed in the other papers in this series.

The emergence of the safety case concept has usefully defined the context in which safety assessment is conducted. This new context has highlighted the role of safety assessment in building confidence in safety. The 1991 NEA brochure foreshadows this concept (p. 14), when it notes that "performance and safety assessment are to be understood as a broad activity aimed at the following major goals:

- "developing a sufficient understanding of the physical and chemical behaviour of the disposal system;
- quantifying this understanding in order to allow predictions of future system behaviour;
- assessing the uncertainties in the predictions; and
- convincing all relevant groups (project staff, regulators, and the public) of the adequacy of the analysis."

Yet the safety case concept does more than simply bring these ideas more clearly into focus. It also makes more evident the links between safety assessment and other aspects of repository planning and development. Indeed, the application of the safety case concept, and the greater awareness of these links and of how the results are applied, has had a profound effect on safety assessment, in terms of the overall assessment strategy as well as the methodologies that support it. Many of these changes are evidenced in MeSA Issue Paper No. 2 (Schneider *et al.* 2011), which shows clearly the evolution over time of how safety assessment is defined. For example, the much greater recognition of safety assessment as an iterative process can be tied to the safety case concept. MeSA Issue Paper No. 5 (Noseck *et al.* 2011) will also illustrate a new trend in the use of "safety functions" as a tool to integrate information and trace clearly the relevance to safety of key aspects of repositories.

This is the first in a series of papers giving the overall structure for the Methods for Safety Assessments, or MeSA, project of the Nuclear Energy Agency's Radioactive Waste Management Committee, Integration Group for the Safety Case. The second through sixth papers delve deeper into aspects of safety assessment. Topics addressed in MeSA Issue Papers No. 2 through No. 6 are:

(2) Safety assessment and safety case flowcharts (Schneider *et al.* 2011);

(3) System description and scenarios (Röhlig *et al.* 2011);

(4) Modelling strategy (Gierszewski *et al.* 2011);

(5) Indicators for safety assessment (Noseck *et al.* 2011); and

(6) Treatment of uncertainties (Mönig *et al.* 2011).

The seventh and last paper (Navarro *et al.* 2011) provides a regulatory perspective on the topics addressed in papers one through six. The purpose of this series of papers is to document the current state of the art with respect to the role of safety assessment in geological repository development programmes.

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12. Safety assessment and safety case flowcharts

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Abstract

This paper is the second in a series of papers produced in the NEA Methods for Safety Assessment (MeSA) project. It addresses the processes of safety assessment and safety case development, and their representation in flowcharts. A clear strategy for developing, updating and/or reviewing a safety case is essential to all waste management and regulatory organisations. Approaches to safety assessment and safety case development are continually evolving as experience is increasing. In 1991, the NEA published a Review of Safety Assessment Methods, containing a flowchart showing several key elements of the safety assessment and the safety case. Since then, flowcharts have been produced by the NEA, IAEA and various national programmes, which have tended to become more comprehensive and broader in scope. New concepts have emerged, including the assessment context and the definition and use of safety functions. Also, with progress in implementing disposal facilities more emphasis is put on the explicit management of uncertainty and quality assurance. Common elements of these flowcharts are identified in this paper, and a generic assessment strategy is illustrated in terms of two example flowcharts, one higher-level and broader in scope than the other, though both at a level of detail at which programme-specific differences are generally minor. An example of a more detailed, programme-specific flowchart is also presented. The importance of feedback from safety assessment to scientific and design studies is widely recognised and is reflected explicitly in the generic flowcharts and many recent programme-specific flowcharts. Comparison of flowcharts is complicated by some differences in the terminology used in flowcharts in the different programmes.

Keywords: Safety assessment, safety case, geological repository, radioactive waste, disposal.

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12.1 Introduction

As part of the NEA MeSA project, issue papers are being produced, each focussed on a specific topic related to safety assessment. The topics addressed are:

1. Safety assessment in the context of the safety case.
2. Safety assessment and safety case flowcharts.
3. System description and scenarios.
4. Modelling strategy.
5. Indicators for safety assessment.
6. Treatment of uncertainties.
7. Regulatory issues.

The present paper addresses Topic 2: Safety assessment and safety case flowcharts.

Terminology is a key issue for this and other topics. The present paper defines the terms relevant to the topic at hand. For the purposes of this paper, the definition of the term "assessment strategy" is taken directly from the NEA Safety Case Brochure (NEA 2004), where it is considered as being the strategy to:

> "… perform safety assessments and define the approach to evaluate evidence, analyse the evolution of the system and thus develop or update the safety case".

The assessment strategy is one of three elements of the broader safety strategy, the other elements being:

> " … the overall management strategy of the various activities required for repository planning, implementation and closure, …;
>
> the siting and design strategy to select a site and to develop practicable engineering solutions, … ".

A clear strategy to develop, update or review a safety case is essential to all waste management and regulatory organisations, given the critical role of the safety case in supporting major decisions in repository planning, implementation and operation, including decisions that require the granting of a licence. Assessment strategies are continually evolving as they are being applied in safety assessments and compiling safety cases. This paper considers the following aspects of the assessment strategies currently adopted in radioactive waste management programmes:

- the steps typically undertaken for different stages of a safety assessment and the development of a safety case;
- the linkages and feedback among components of safety assessment and to other parts of the safety case (e.g. siting and design).

These two aspects relate to questions originally posed by the NEA's Integration Group for the Safety Case (IGSC), and are addressed through a consideration of "assessment strategy flowcharts" produced by international organisations, including the NEA, and by national waste management programmes.

12.2 Methodology

12.2.1 Starting point: the 1991 NEA Review of Safety Assessment Methods

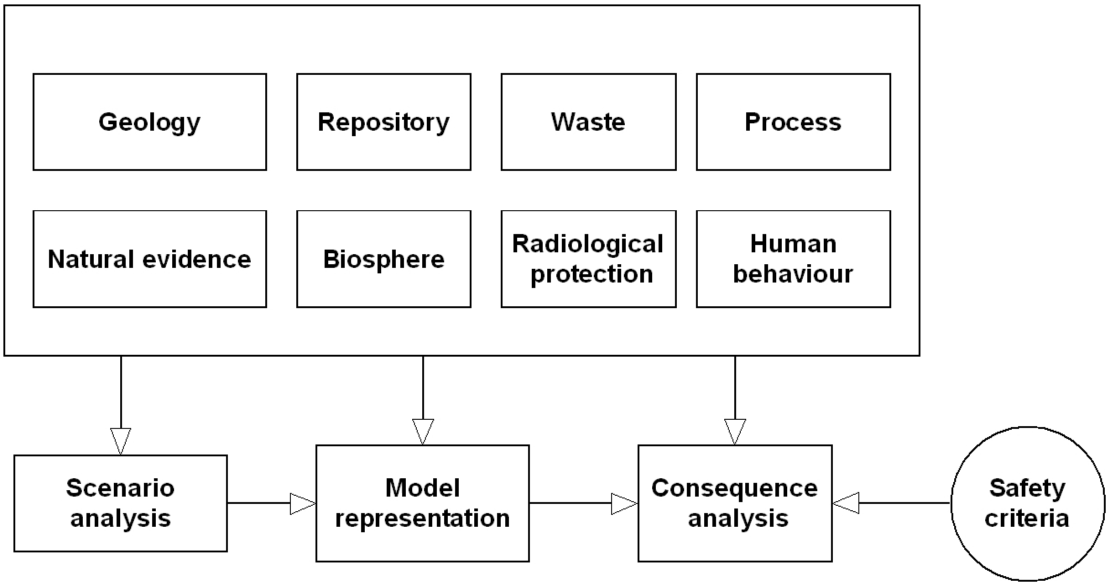
Assessment strategy flowcharts are presented in many safety reports, although not always referred to as such. An early example is the flowchart shown in Figure 12.1, which is taken from the NEA Review of Safety Assessment Methods, published in 1991 (NEA 1991).

The review provides a concise summary of the safety assessment methods as seen at that time. The flowchart shows the main tasks identified in these safety assessments as being:

- scenario analysis;[1]
- model representation; and
- consequence analysis, including comparison with safety criteria.

In addition to the main tasks in safety assessment, the flowchart also shows how these tasks are supported by extensive and systematic use of information from many scientific and technical areas. This information base roughly corresponds to what has more recently become known as the *assessment basis* (see, e.g. NEA 2004). The term *safety case*, now widely used, was not in widespread usage in the context of radioactive waste management in 1991, and does not appear in the flowchart.

Figure 12.1: The flowchart presented in the 1991 NEA Review of Safety Assessment Methods



Source: NEA, 1991, Figure 10.

12.2.2 Recent work on the topic

In 1999, the NEA published *Confidence in the Long-term Safety of Deep Geological Repositories: Its Development and Communication* (NEA 1999). It defined the basic steps for deriving a safety case at various stages of repository development as:

(i) "A safety assessment, which includes:

- the establishment of an assessment basis in which there is confidence, i.e. the strategy for the building of a safety case, the selection of a site and design, and the assembly of all relevant information, models and methods;

---

[1] Note that the 1991 review used the term "scenario analysis" in the sense of scenario *development* or scenario *derivation*. In other reports, the meaning of "scenario analysis" is rather analysis *of* scenarios which would, in the terminology of the 1991 brochure, fall under model representation and/or consequence analysis.

- the application of the assessment basis in a performance assessment, that explores the range of possible evolutions of the repository system and tests compliance of performance with acceptance guidelines; and
- the evaluation of confidence in the safety indicated by the assessment and modification, if necessary, of the assessment basis.

(ii) The documentation of the safety assessment, a statement of confidence in the safety indicated by the assessment, and the confirmation of the appropriateness of the safety strategy, either in anticipation of the next stages of repository development or in response to interaction with decision makers."

The document (NEA 1999) presents these broad steps as a high-level flowchart, which also showed, as a final step, interaction with decision makers and modification, if necessary, of the assessment basis. It emphasises that the development of the assessment basis benefits from the experience gained in previous development stages (including interaction with decision makers). It also notes that a temporary freeze of the assessment basis elements is necessary in order to carry out a traceable safety assessment of the repository and its component parts.

In 2004, the NEA published a Safety Case Brochure which, as noted above, provides a definition of the assessment strategy. It also defines the safety assessment and safety case as follows:

> "Safety assessment is the process of systematically analysing the hazards associated with the facility and the ability of the site and designs to provide the safety functions and meet technical requirements.
>
> The safety case is an integration of arguments and evidence that describe, quantify and substantiate the safety, and the level of confidence in the safety, of the geological disposal facility."

The place of safety assessment in the safety case is the subject of Topic 1 of the Review of Methods for Safety Assessments within the NEA MeSA project (Van Luik *et al.* 2011).

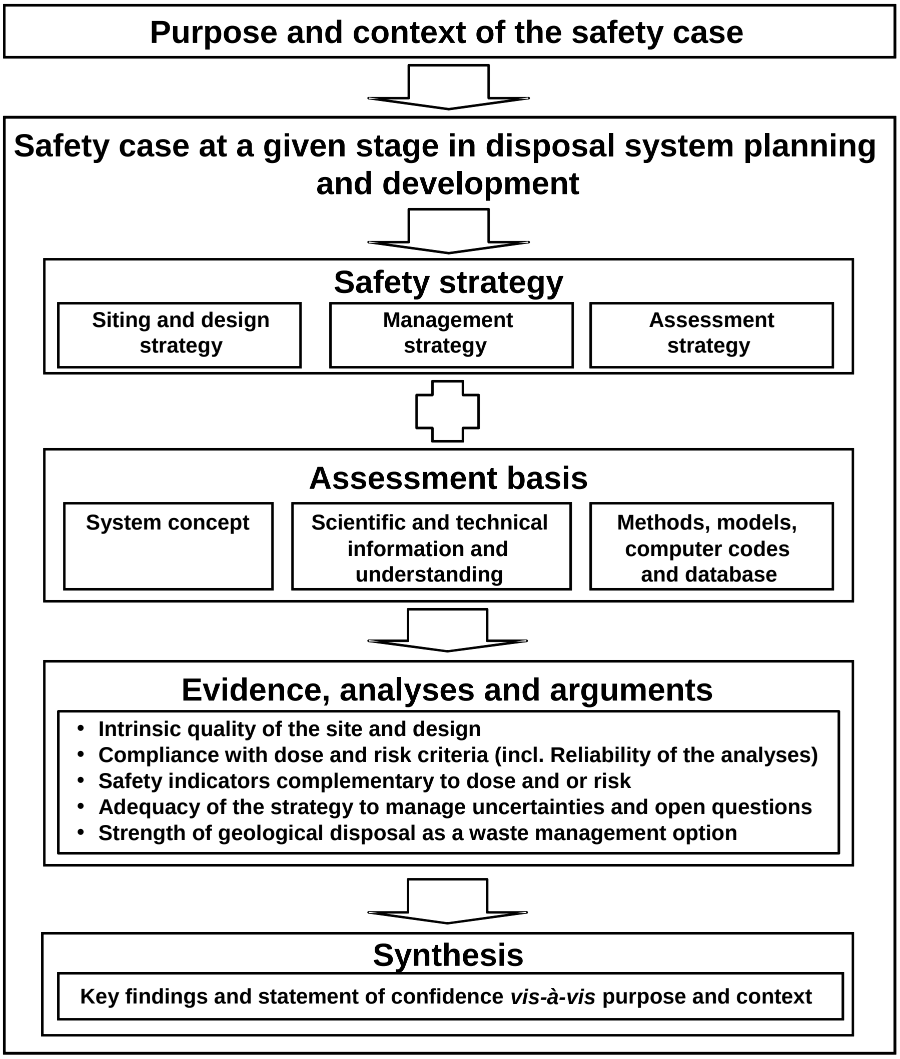
The Safety Case Brochure presented a flowchart for the development of the safety case (Figure 12.2), which emphasises the broad nature of the supporting argumentation, which extends beyond the modelling of scenarios.

The Safety Case Brochure notes in its text that the assessment strategy should provide:

> "… a range of arguments and analyses for the safety case that are well-founded, supported, where possible, by multiple lines of evidence, and adequate in their treatment of uncertainty …
>
> The assessment strategy must ensure that safety assessments capture, describe and analyse uncertainties that are relevant to safety, and investigate their effects."

Thus, a key element of the assessment strategy is the adequate treatment of uncertainty (this is discussed broadly in the paper on Topic 1 and is treated in more detail in the papers on Topics 3 and 6). Some general discussion of the treatment of uncertainties in safety assessment is given in the brochure. However, the Safety Case Brochure and the flowchart shown in Figure 12.2 give little description of the work process as defined by the assessment strategy, including the carrying out of a safety assessment.

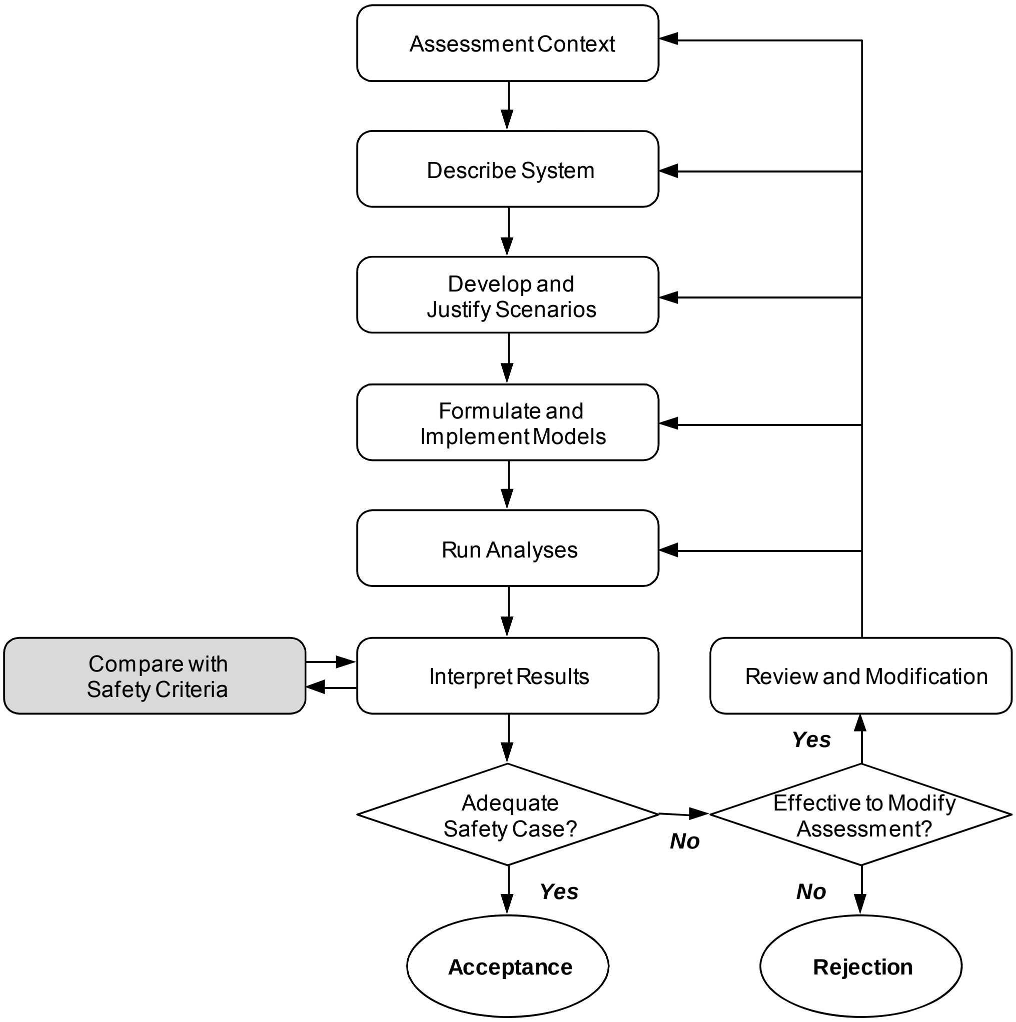
Figure 12.2: The flowchart presented in the 2004 NEA Safety Case Brochure (NEA 2004)



The IAEA has proposed a flowchart in the context of its ISAM methodology: "Improvement of Safety Assessment Methodologies for Near Surface Disposal Facilities" (IAEA 2004). The elements and linkages in the ISAM flowchart – shown in Figure 12.3 – are used to structure the IAEA draft safety guide DS355 (IAEA 2008). In an updated version, from March 2010 (IAEA 2010), DS355 presents a flowchart with a scope that is more general, but still broadly comparable with that shown in Figure 12.2.

The ISAM flowchart contains each of the main steps shown in the earlier 1991 NEA Review of Safety Assessment Methods (although the components of the assessment basis are not explicitly represented, but are rather lumped together in the box "describe system"). In addition, the ISAM flowchart highlights the importance of the assessment context in determining the scope of the safety assessment (as does the 2004 Safety Case Brochure flowchart), and, like NEA (1999), also shows by "feedback arrows", the iterative nature of the assessment process.

Figure 12.3: The ISAM safety assessment methodology (IAEA 2004)



The ISAM flowchart (IAEA 2004) is more limited in its scope than the Safety Case Brochure flowchart (NEA 2004), in the sense that it focuses on safety analyses and their results, rather than on the broader range of evidence, analyses and arguments that are synthesised in a safety case. Consequently, the iteration loops shown are limited to the assessment, while the idea that assessment results can serve as a basis for system optimisation (i.e. improving system performance and/or robustness by changes in siting and design) is missing. In addition, it should be noted that the scope of the ISAM flowchart is limited to an "acceptance versus rejection" situation, i.e. to the typical circumstances of a licensing application. In contrast, the Safety Case Brochure (NEA 2004) sees the safety case as "… key input to support the decision to move to the next stage in repository development." Such decisions may or may not involve the granting of a licence and are certainly more complex than a simple yes/no decision in that they might involve future R&D directions, the consideration of alternative options, etc. Another aspect neither accounted for in the ISAM flowchart nor in the 1991 NEA flowchart is that iterations take place *between* assessment activities such as scenario development, model formulation, numerical analyses, and result interpretation (termed "scenario analysis", "model representation", and "consequence analysis" in the 1991 NEA flowchart). Experience shows that such iterations occur during the whole assessment process and not only in an acceptance/rejection situation.

Thus, the NEA flowcharts and the ISAM flowchart also have limitations as a generic depiction of assessment strategies adopted by the different waste management programmes and internationally. Nonetheless, although they differ in scope, in their degree of detail and in the terminology adopted, many common elements and linkages may be identified between the NEA flowcharts, the ISAM flowchart and many other recent flowcharts.

In part (i) of the analysis below, a generic assessment strategy is illustrated in terms of two example flowcharts (one higher-level and less detailed, but including interaction with decision makers, and one more detailed, though still rather high level, focussing on the steps in developing the safety case itself). At the level of detail shown in these flowcharts, the assessment strategy is broadly common to all organisations responsible for the development of safety cases, and the flowcharts are, thus, described as "generic". At a still more detailed level, procedures can vary more significantly between organisations. In part (ii), an example of a more detailed, programme-specific flowchart is presented, based on the current Nagra assessment strategy. This detailed flowchart conforms with, but expands upon, the elements shown in the generic flowcharts.

12.2.3 Generic flowcharts

The proposed higher-level generic assessment strategy flowchart that illustrates the main common elements and linkages identified in recent assessment strategies is shown in Figure 12.4. The figure shows the main elements of the assessment context and the assessment basis (elements of safety assessment are shown in Figure 12.5). Key points to note about the figure are:

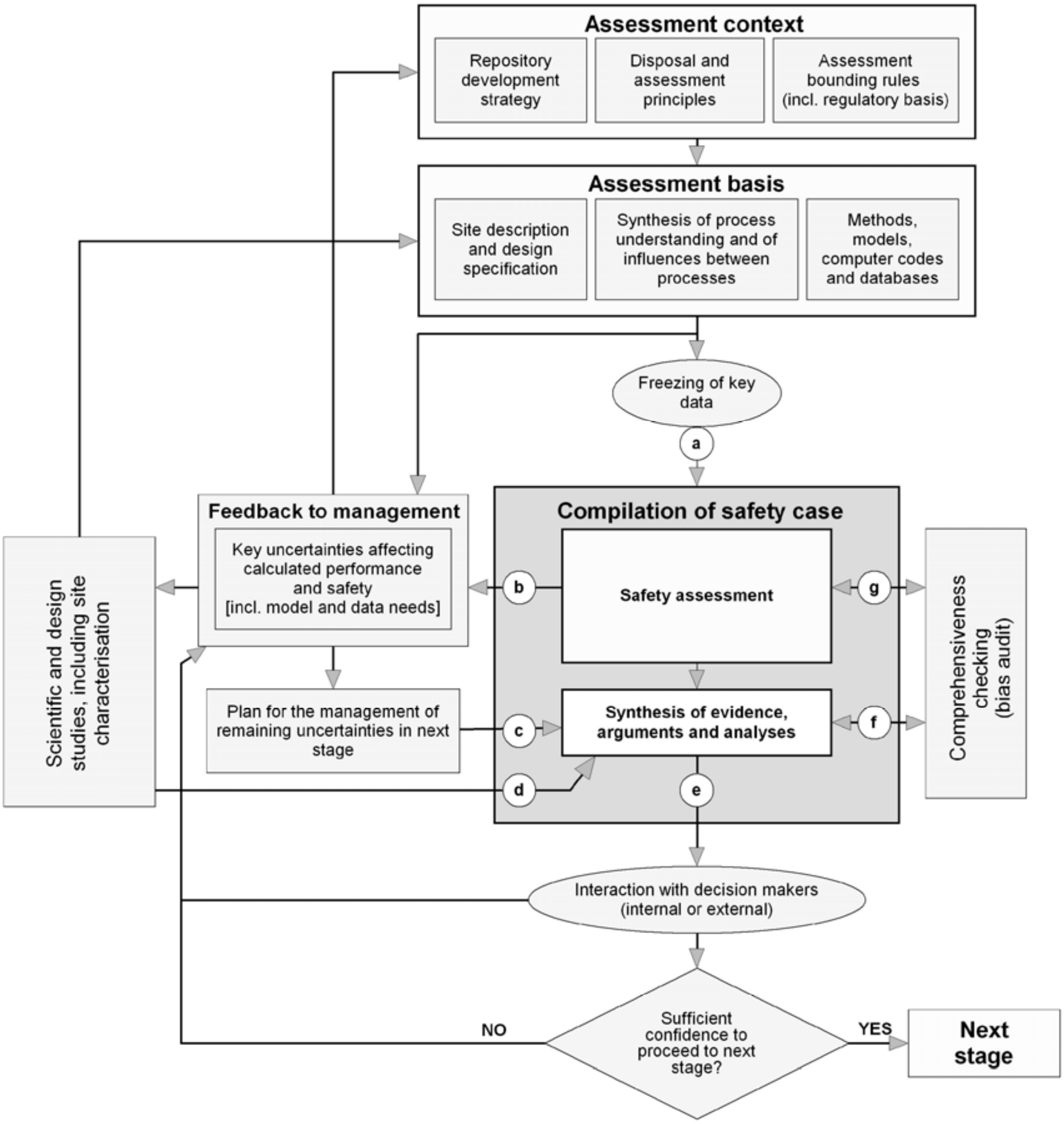
- The inclusion of a step "freezing of key data" (a key step, for example, in the NEA 1999 flowchart).
- Comprehensiveness checking (bias audit) as an activity that is independently performed from the main activities needed in compiling the safety case (see the discussion of an example detailed, programme-specific flowchart, below).
- The inclusion in the synthesis of evidence, arguments and analyses not only of the results of safety assessment (dose/risk calculations), but also of complementary evidence and lines of argument for safety, such as those based on geoscientific and technical arguments and on natural and anthropogenic analogues.
- Feedback (guidance) to programme management as a result of (i) an evaluation of remaining uncertainties identified in the course of safety assessment and (ii) interaction with decision makers, either internal (within an implementing organisation) or external (typically the regulator and/or licensing body) following the compilation of a safety case.

Guidance to programme management can support decisions regarding site selection and future scientific and design studies, including site characterisation, and also on the future steps needed for repository development/optimisation and implementation (feedback to assessment context).

The more detailed flowchart focussing on the steps in developing the safety case is shown in Figure 12.5. It shows, as labelled arrows, the main flows of information to and from safety assessment and to and from the synthesis of evidence, arguments and analyses (these labelled arrows are also shown in Figure 12.4). It also shows, as arrows, the main flows of information that take place during the course of safety assessment.

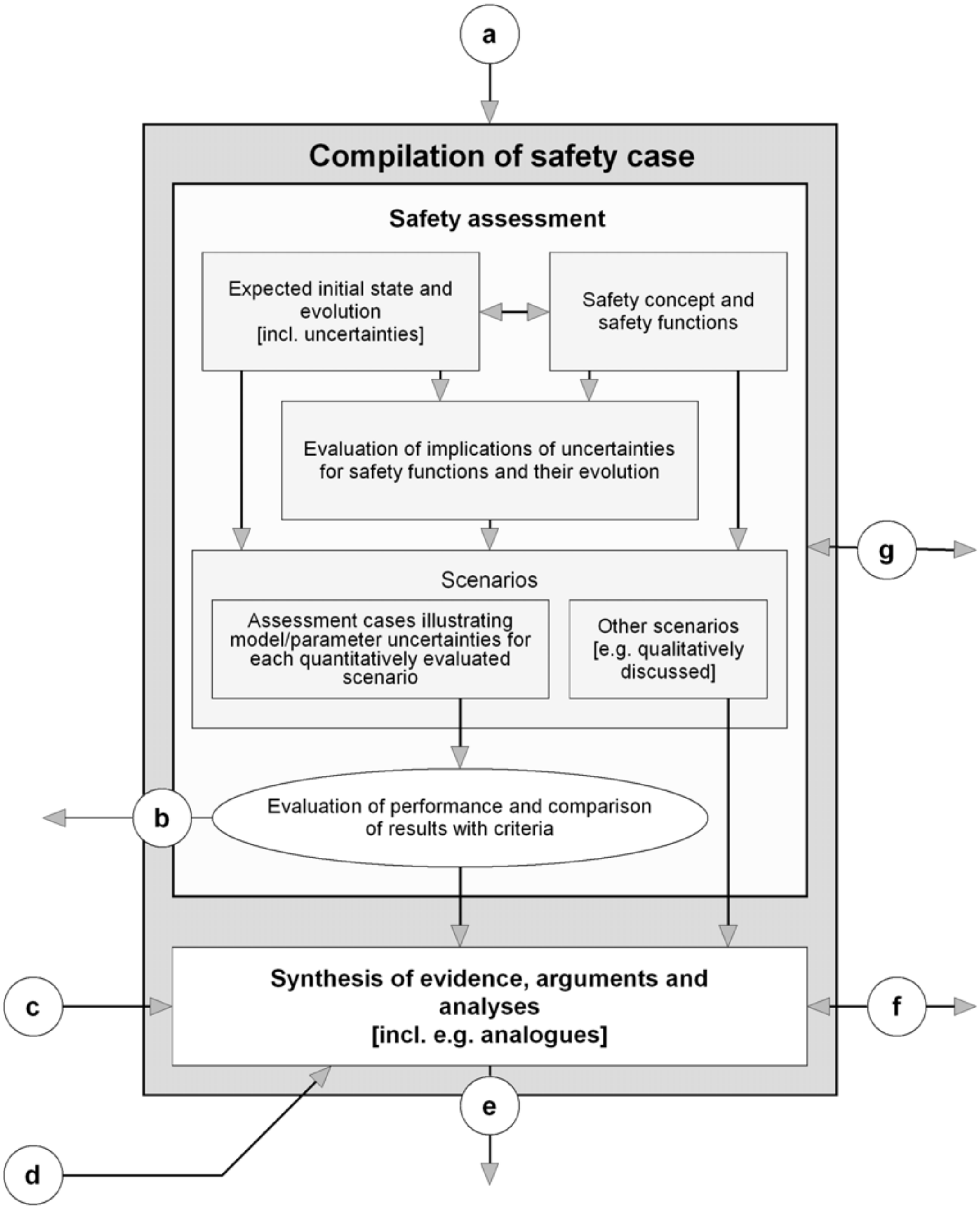
The flowcharts shown in Figures 12.4 and 12.5 are based on a review of common elements and differences of flowcharts presented by a range of national and international organisation, as well as trends in such flowcharts that are apparent over time. As noted above, the decision as to the level of detail to be included in these flowcharts was based on the desire to make the flowcharts generic.

Figure 12.4: A high-level generic flowchart, showing the common elements and linkages in safety assessment and safety cases



Note: The arrows labelled with a letter correspond to the arrows labelled with the same letter in Figure 12.5. The essential roles of quality assurance and other management systems in safety case development are recognised, but not explicitly illustrated.

Figure 12.5: A more detailed generic flowchart, showing the main elements of the compilation of a safety case



Note: The arrows labelled with a letter correspond to the arrows labelled with the same letter in Figure 12.4.

Annex 12.A gives a comparison of the assessment strategy flowchart with selected flowcharts presented elsewhere. The flowcharts with which comparisons are made are from:

- the NEA Review of Safety Assessment Methods (NEA 1991);
- the NEA Safety Case Brochure (NEA 2004);

- a figure from the NDA generic Environmental Safety Case (NDA 2010);
- Andra's Dossier 2005 Argile (Andra 2005); and
- Posiva's Safety Case Plan 2008 (Posiva 2008).

The comparison – especially with the 1991 NEA Review of Safety Assessment Methods – shows that flowcharts have tended to become more comprehensive and broader in scope in the intervening years, often including elements of the safety case over and above the quantitative analysis of (alternative) evolution scenarios. The importance of feedback from safety assessment via programme management to repository development and scientific and design studies is widely recognised, as is the iterative nature of safety case development, and these aspects appear explicitly in some of the more recent flowcharts. Furthermore, in spite of some differences in terminology and presentation, the present generic assessment strategy flowcharts are shown to be broadly consistent with flowcharts produced in recent safety assessments and with the NEA Safety Case Brochure of 2004.

The starting point of the generic flowcharts (as in the ISAM methodology) is the assessment context. According to the NEA Safety Case Brochure (NEA 2004): "A clear statement of purpose and context is an intrinsic part of the safety case …".

Examples of the elements that may fall within the scope of the assessment context are as follows:

- The repository development strategy: The repository development strategy defines the iterative process of planning and implementing the repository, including the various milestones and decision points that are foreseen. The purpose of the assessment at hand will be defined within the context of this strategy.
- The disposal and assessment principles: The disposal principles are principles related to long-term safety guiding the development of the disposal system and implementation procedures. Disposal principles include, for example, providing safety through well understood phenomena, and ensuring flexibility in implementation by keeping multiple options available. Some disposal principles may be given in regulation. The assessment principles are principles that guide the carrying out of the safety assessment. Assessment principles include, for example, principles related to the treatment of uncertainty (use of conservatism, use of stylised approaches, etc.), the role and treatment of the biosphere and the treatment of future human actions. Some assessment principles may be given in regulations (see Topic 7 of the Review of Methods for Safety Assessments) and, as such, form part of the assessment bounding rules (below).
- The assessment bounding rules: The assessment bounding rules define the assumptions on which the assessment is based (e.g. the wastes to be disposed of in the repository) and the regulatory context, which will typically determine the main assessment end points (e.g. safety indicators such as dose and risk). Regulations may, for example, define certain phenomena or scenarios that must be analysed, and others that need not (e.g. the impact on the repository of certain catastrophic events, such as meteorite impact). The assessment bounding rules may also include the definition of the time frames over which assessment cases are evaluated.

The assessment basis is the scientific and technological information and understanding on which the safety assessment is based. The components of the assessment basis are discussed in the NEA Safety Case Brochure. They include, for example:

- A site description and design specifications: This typically includes the main geological, hydrogeological, geochemical, mechanical and other features of the repository site, and the location and layout of the repository (or the procedures, criteria, etc. by which the location and layout will be determined), a description of the engineered barriers and how they will be constructed and emplaced, plans for any pre-closure open period and plans for repository closure. It may include a description of possible alternatives in the implementation of the system. Site description and design specification are usually presented as dedicated reports or sets of reports within the safety case, the site description sometimes being termed "geosynthesis" or "site-specific model" (NEA 2009).

- The synthesis of process understanding and influences between processes: This involves a consistent description of the various features, events and processes (and interactions between these) that may affect the evolution and performance of the repository, based on the multi-disciplinary information collected during scientific and technological studies. The scope and approaches for such syntheses have evolved considerably over the last decade. Approaches might include sophisticated tools and methods which address complex, often coupled thermo-hydro-mechanical-chemical (THMC) processes and their influence on safety functions (cf. MeSA Issue Paper No. 4 – Gierszewski *et al.* 2011).

The assessment methods, models, computer codes and databases for analysing system performance may also be included in the assessment basis.

From the assessment basis, safety assessment generally starts with the development of an integrated description of the expected initial state[2] of the disposal system and of its expected evolution, including uncertainties in both of these. The description will include the processes and events expected to influence repository evolution and performance in the course of time. It will also indicate how various features, events and process relate to the safety concept and safety functions of the repository (e.g. processes that contribute to, or may be detrimental to, the safety functions, see below). It should be noted that the Safety Case Brochure includes an element termed "system concept" among the components of the assessment basis (see Figure 12.2). In some programmes, such as that of Nagra, the system concept is taken to include a description of expected evolution (Nagra 2002). Ondraf/Niras considers the phenomenological description of system evolution as part of the assessment basis (see Annex 12.B, Figure 12.B-1), whereas, for example, Posiva does not (the description of the disposal system in Annex 12.A, Figure 12.A-5 refers to the initial state and not to system evolution). The position of expected evolution in the flowchart, thus, depends on how the boundary is defined between the activity of assessment basis development and the activity of safety assessment, and is an operational choice that varies between different programmes.

The safety concept is the understanding of why the disposal system is safe. It includes a description of the roles of the natural and engineered barriers and the safety functions that these are expected to provide in different time frames, and why the disposal system is expected to be safe, irrespective of identified uncertainties and detrimental phenomena; i.e. why it is expected to be *robust*.[3] As part of the safety concept, broad safety functions, such as isolation by the geological environment from the surface environment and containment by engineered and/or geological components, will be defined before the details of the system are described. However, more detailed safety functions, such as the function of a clay buffer in filtering colloids generated from the

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[2] The meaning assigned to the term "initial state" may vary between programmes, or even between system components (e.g. the state of the environment before repository construction, the state of a canister/overpack and its surroundings at the time of its emplacement, the state of repository at closure, the state of barriers at the time when radionuclide release starts).

[3] "Robustness" in this context refers to insensitivity of overall system performance to uncertainties regarding the future evolution of the disposal system and insensitivity to uncertainties concerning the scientific understanding.

waste, require the specification of clay as a buffer material, which may be regarded as part of the system description. The system description and safety concept are therefore developed to some extent in parallel. According to the summary report of the NEA INTESC project (NEA 2008) safety functions can serve:

- as high-level principles (containment, isolation, retention) guiding repository design and siting; and
- to identify key issues in a safety evaluation.

Safety functions are intrinsic to the safety concept. However, as noted in the NEA INTESC project (NEA 2008), a number of different meanings of the term safety functions can be observed in the different existing safety cases. In particular, there can be broad safety functions that relate to general properties of the entire repository system, as well as more specific functions related to properties of barriers or repository components. Annex 12.B shows examples from Ondraf/Niras and Posiva of how concepts closely related to safety functions, such as safety and feasibility statements (Ondraf/Niras) and performance targets (Posiva) have been represented in detailed flowcharts produced by these organisations. Whatever definition of safety functions is adopted, safety assessment generally involves an evaluation of the implication of uncertainties for the safety functions and their evolution, leading to the formulation of scenarios for the evolution of the repository system over time in terms of safety functions. Note that system description and scenarios, including the linkage between safety functions and scenarios, is the subject of Topic 3 of the Review of Methods for Safety Assessments. Modelling strategy is the subject of Topic 4.

Scenarios are analysed by means of conceptual models, mathematical models, their abstraction into assessment models (and corresponding computer codes) and data, uncertainties in which may lead to the definition of a range of calculation cases, also sometimes termed assessment cases (if, for example, considerations of alternative models are found to be consistent with current scientific understanding, then calculation cases may be defined that explore the effects of this model uncertainty). Conversely, model simplifications may mean that some calculation cases need not be evaluated (e.g. cases relating to uncertain phenomena that are conservatively omitted in models).

Assessment cases may be defined and evaluated with parameter values specified individually (*deterministically*). Alternatively, large numbers of calculations may be performed probabilistically using parameter values sampled from probability density functions (PDFs); see Topic 6 of the Review of Methods for Safety Assessments. Models, computer codes and data (individual parameter values or PDFs) are selected during safety assessment based on the synthesis of scientific understanding in the assessment basis and cover both variability and uncertainty.

The results of the analyses of scenarios are complemented with arguments, for example, for the quality of the site and design and for the validity of model assumptions and boundary conditions from the assessment basis. They are also combined with any independent supporting evidence for safety (e.g. the existence of relevant natural analogues for the repository) to construct the synthesis of evidence, analyses and arguments that quantify and substantiate the safety and constitute the safety case. Supporting evidence, such as that related to groundwater ages, can provide direct support for the quality of the system (in this case the geological barrier). This and other evidence can also support modelling assumptions made in carrying out a safety assessment.

A safety case compiled at a decision point will, at least in the early phases, typically identify open issues that must be dealt with by scientific and design studies at future programme stages.

Another important element in recent safety assessments and in recent and planned safety cases is the greater emphasis on quality assurance. For example, according to Posiva's Safety Case Plan 2008 (Posiva 2008):

> "The general quality objectives, requirements and instructions defined in Posiva's management system will also form the foundation for the quality management of safety case activities carried out in the future. However, special attention will be paid to the management of the processes that are applied to produce the safety case and its basis. The purpose of this enhanced process control is to offer full traceability and transparency of the data, assumptions, modelling and calculations."

A specific aspect of quality assurance is the use of compilations of features, events and processes (FEP databases) for checking the comprehensiveness of the phenomena analysed in the assessments and considered in safety cases. According to the summary report of the NEA INTESC project (NEA 2008):

> "'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 light of known long-term processes and international FEP lists …
>
> FEP lists or FEP databases (such as the international FEP database compiled by NEA) are essential tools, but they have evolved (at least in more advanced programmes) 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."

The use of FEP lists or databases in this manner is part of the "bias audit" in the Nagra flowchart described below (Figure 12.6 and accompanying text). It is pointed out that the bias audit has been placed outside the safety assessment in the flowchart, although in other programmes activities related to, or based on, FEP lists are considered typical *assessment* activities. The intention is that comprehensiveness checking should be at least partly an independent process, separate from the main line of safety assessment activities. However, perhaps this can also be seen as a manifestation of the changing role of FEP databases or lists.

Scientific and design studies include site characterisation, modelling and laboratory studies of key processes, natural analogue studies, design studies and demonstration of technologies. These contribute to the optimisation of the system and provide direct input to the assessment basis. They also provide supporting evidence for the safety case that complements that provided by the quantitative analyses of radiological consequences performed in safety assessment. According to the NEA Safety Case Brochure:

> "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."

The process of carrying out a safety assessment can reveal issues and uncertainties that need to be addressed by further scientific and design studies. Furthermore, an element of the safety case will be arguments that an adequate programme of scientific and design studies is in place to resolve remaining safety-relevant issues. These issues will typically be identified and discussed in the safety report. According to the Safety Case Brochure:

> "A safety case should acknowledge uncertainties, show how they have been identified and taken into account, discuss their implications and explain how any that are critical to safety are to be further addressed or otherwise managed in future project stages."

These types of feedback to scientific and design studies are illustrated by the arrows leading to the "scientific and design studies" in Figure 12.4.

12.2.4 Example of a detailed, programme-specific flowchart

Figure 12.6 is a more detailed flowchart showing the current Nagra concept for developing a safety case, with the key products developed (rectangles) and steps undertaken (ovals) as part of the activities directly related to the corresponding safety assessment. These products and steps are broadly consistent with the generic, higher-level flowcharts shown in Figures 12.4 and 12.5. Only aspects where Figure 12.6 shows more detail than Figure 12.5 are described below.

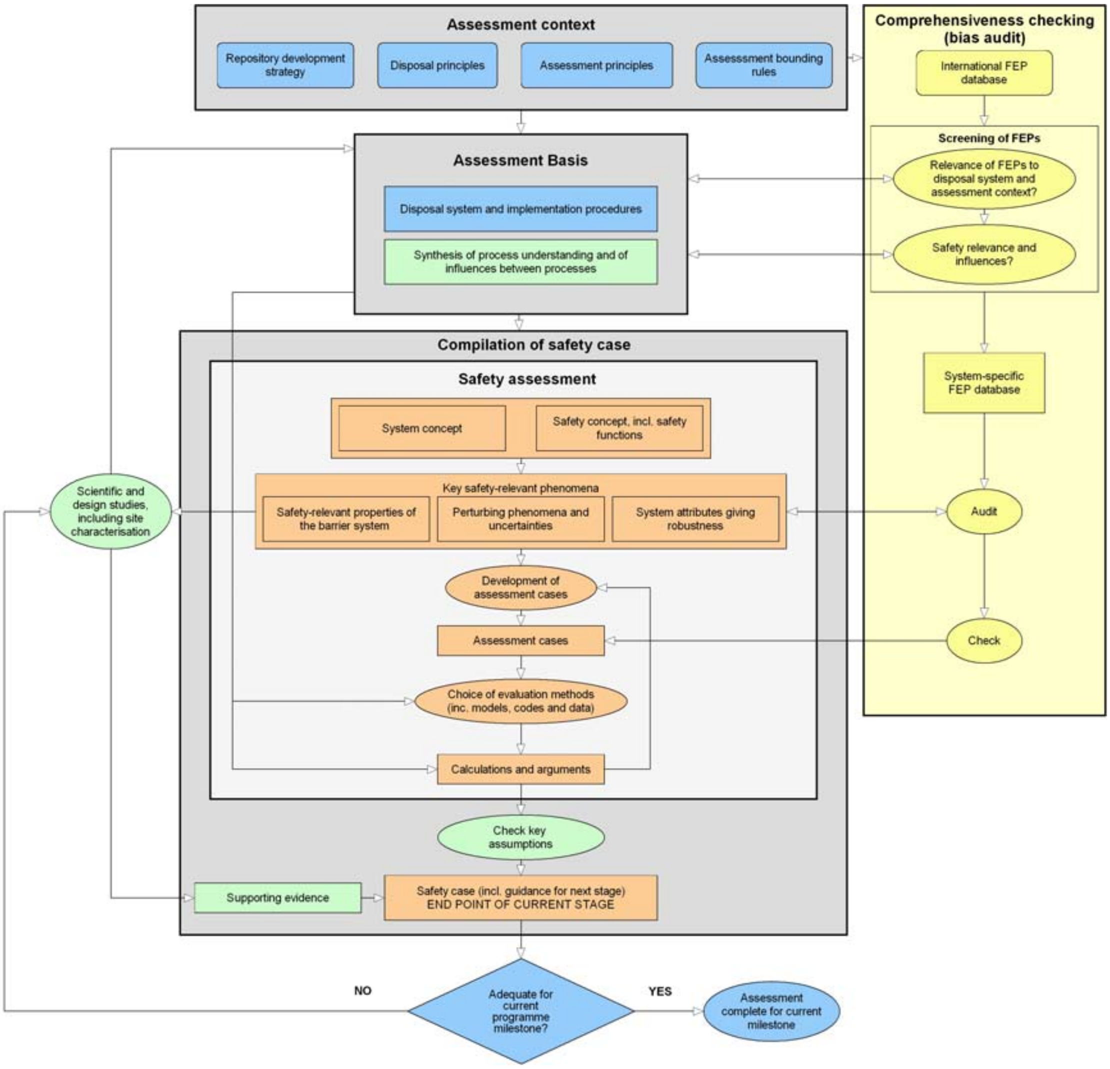
The detailed flowchart in Figure 12.6 includes elements of management strategy as well as assessment strategy (see the definitions in the introduction). In particular, colours indicate how the primary responsibility for the various steps is assigned to different groups (or individuals acting in different roles). The groups are:

- Project management (blue): The group responsible for the overall management of the project, which includes ensuring feedback from interim safety assessment results to science and repository design, thus using new insights to strengthen the safety case ("learning during the process of compiling the safety case"). Within the compilation of a specific safety case, however, such feedback will typically lead to small modifications only; i.e. the assessment basis will not change. The group is also responsible for defining the repository concept, though with input from the science and technology group.
- Science and technology (green): The group responsible for developing and evaluating the scientific basis for safety assessment (the assessment basis), including the engineering design.
- Safety assessment (orange): The group responsible for formulating and analysing assessment cases (see below), for assessing complementary supporting evidence, and for compiling the safety case.

Together, these groups are responsible for the main assessment activities leading to the safety case. It is important that the scientific basis for safety assessment is sufficiently complete, adequately documented and fully utilised in the safety assessment. For this purpose, a fourth group is established, the so-called "bias audit group":

- Bias audit (yellow): This is an independent activity for checking that the scientific basis for safety assessment is complete, adequately documented and fully utilised in the safety assessment. A key tool for this activity is the system-specific FEP database.

Figure 12.6: The Nagra concept for steps undertaken and products obtained in the course of a safety assessment and the production of a safety case (modified from Nagra 2002)



Main assessment activities

As in the generic flowcharts, the assessment context provides the starting point for the main assessment activities. From the assessment basis, the safety assessment group defines the system concept and the safety concept. From the system concept and safety concept, the safety assessment group identifies key safety-relevant phenomena. These include:

- Safety-relevant properties of the barrier system. These are the properties of the components specified in the system concept that provide the safety functions. For example, in current system concepts for the disposal of spent fuel and vitrified high-level waste, the waste forms are placed in metallic canisters, that have the safety function of providing a period of complete containment. Safety-relevant properties of these canisters include their mechanical strength and corrosion resistance.
- Perturbing phenomena and uncertainties. Again taking the example of canisters for spent fuel and vitrified high-level waste, important perturbing phenomena and uncertainties will include, for example, gas generation due to anaerobic metal corrosion which can perturb the performance of the system. These will be affected by a range of other uncertainties, such as uncertainties in the chemical composition of the water coming into contact with the canister, which will in turn be affected by uncertainties in the evolution of groundwater flow and composition. Scoping calculations and sensitivity analyses play an important role in determining which perturbing phenomena and uncertainties are safety relevant.
- System attributes giving robustness. In determining the safety relevance of perturbing phenomena and/or uncertainties (e.g. by scoping calculations), attributes of the disposal system that lessen the sensitivity of the safety functions to detrimental phenomena and/or uncertainties must be taken into account; i.e. attributes giving robustness. For example, the canisters may be surrounded by a material that buffers the chemical composition of the water coming into contact with the canister against changes in groundwater composition. The canisters themselves will also be designed for robustness, having ample mechanical strength for any foreseeable mechanical loads and a thickness that includes an allowance for corrosion.

The identification of key safety-relevant phenomena provides guidance from safety assessment to scientific and design studies. For example, these studies may aim (by improved understanding) to reduce or better quantify or (by design) to avoid or mitigate the impact of perturbing phenomena and uncertainties. The identification of key safety relevant phenomena and corresponding uncertainties also provides the basis for the development of calculation cases. In Nagra's terminology these are termed assessment cases. An assessment case is a specific conceptualisation of the evolution of the disposal system that is investigated in the assessment. Typically, a wide range of assessment cases will be defined with which to illustrate the impact of uncertainties regarding scenarios, models and parameters.

The development of calculation cases, the selection of conceptual models, codes and data and the carrying out of assessment calculations is an iterative process, as described in the discussion of the generic flowchart and depicted by feedback arrows in Figure 12.6.

As in the generic flowchart (Figure 12.4.), the results of the analyses of assessment cases are complemented with supporting evidence to construct the safety case. The adequate use of scientific evidence in the safety case is checked by the science and technology group to ensure that the scientific basis has been correctly integrated.

Bias audit

The starting point for the bias audit is typically a generic set of features, events and processes (FEPs) taking advantage of previously compiled databases of FEP databases have been compiled by international organisations (the OECD/NEA) and by national organisations in the course of earlier safety assessments.

FEPs from relevant databases are screened for relevance to the assessment at hand. Screening takes account of:

- The assessment bounding rules. For example, as noted above, regulations may define certain phenomena or scenarios that need not be analysed (e.g. the impact on the repository of certain catastrophic events, such as meteorite impact). FEPs associated with these phenomena or scenarios can therefore be screened out.
- The disposal system and implementation procedures. FEPs associated with, for example, rock types not present at the site or engineered materials that are not planned to be used are irrelevant.
- The synthesis of scientific understanding. FEPs that are known (or can be shown by simple arguments or scoping calculations) to have no significant impact on the disposal system at hand can also be screened out. An example could be certain off-diagonal Onsager processes, or colloid facilitated radionuclide transport in systems where colloids are known to be unstable.

The FEPs that survive this screening process are compiled as a system-specific FEP database. The set of key safety-relevant phenomena is then audited against this FEP database and influence diagrams:

- If the audit reveals that key contributors to the safety functions, perturbing phenomena and uncertainties or system attributes giving robustness that are not included in the original set of key safety relevant phenomena, then these additional phenomena are added to the original set.
- If the audit reveals that potentially safety-relevant, system-specific FEPs or influences that are not included in the original system-specific FEP database or influence diagrams, then these are added to the system-specific FEP database or influence diagrams.

Finally, the set of assessment cases, identified during safety assessment, is checked against the system-specific FEP database and influence diagrams; i.e. for each FEP (and each influence in influence diagrams) it is checked whether it is reflected in at least one assessment case. The set of assessment cases is derived from a consideration of the key safety relevant phenomena, and this set of phenomena has already been audited against the system-specific FEP database. Thus, the specifications of the assessment cases should contain no FEPs that are not already present in the system-specific FEP database (this is why the term “check” is used here, rather than “audit”). The check ensures that no potentially safety-relevant FEPs have been inadvertently overlooked in the specification of assessment cases.

12.3 Conclusions

The questions originally posed by the NEA’s Integration Group for the Safety Case (IGSC) regarding Topic 2 (Safety assessment and safety case flowcharts) were:

- Which steps are undertaken at which stage of the assessment?
- What are the linkages and feedback among components of safety assessment?

These questions have been addressed by proposing generic assessment strategy flowcharts, which are shown in Figures 12.4 and 12.5. The first is at a higher-level and is less detailed, but includes interaction with decision makers. The second is more detailed, though still rather high level, and focuses on the steps in developing the safety case itself.

Comparing these generic flowcharts with that presented in the 1991 NEA Review of Safety Assessment Methods, it is concluded that flowcharts have tended to become more comprehensive and broader in scope in intervening years, often including elements of the safety case over and above the quantitative analysis of evolution scenarios that was the focus of the earlier flowchart. A comparison of the new generic assessment strategy flowchart with flowcharts produced by the NEA and by a number of waste management organisations indicates that it reflects current thinking regarding the broad elements of the safety case development process (Annex 12.A). New issues are given more importance in performing safety assessments and in developing the safety case, including the assessment context and the definition and use of safety functions. Today, there is wide recoginition of the importance of the explicit management of uncertainty and quality assurance, including the use of FEP lists for completeness checking. Programme-specific differences are, however, apparent, especially in more detailed flowcharts.

There remain some differences in the terminology used in flowcharts. Furthermore, the scope and the level of detail of flowcharts presented will always depend on the stage and purpose of the project that they support and the message that is intended to be conveyed by the flowchart within that project (which will, for example, influence whether feedback loops are important to show). The present generic assessment strategy flowcharts are, however, broadly consistent with flowcharts produced in recent safety assessments.

The importance of feedback from safety assessment to scientific and design studies is widely recognised and is reflected explicitly in the generic assessment strategy flowcharts and many recent programme-specific flowcharts, as is the iterative nature of safety case development. Some flowcharts depict not only the assessment strategy, but also aspects of the overall management strategy of the various activities required for repository planning, implementation and closure, including strategies for site selection and engineering design. Such flowcharts depict the broader safety strategy (which includes management and siting and design aspects), as well as the assessment strategy. In many programmes, safety functions serve as a key tool for organising these activities and for communication between those involved in the activities.

12.4 References

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Annex 12.A

Comparison of the assessment strategy flowcharts with selected flowcharts presented elsewhere

In this annex, similarities and differences are noted between the present assessment strategy flowchart and selected flowcharts presented in NEA documents and documents produced by radioactive waste management organisations.

The flowcharts with which comparisons are made are:

- Figure 10 of the NEA Review of Safety Assessment Methods (NEA 1991);
- Figure 1 of the NEA Safety Case Brochure (NEA 2004);
- a figure from the NDA generic Environmental Safety Case (NDA 2010);
- a figure provided by Andra based on Block Diagram 1-1 of the Safety Report of Andra's Dossier 2005 Argile (Andra 2005); and
- Figure 1-6 of Posiva's Safety Case Plan 2008 (Posiva 2008).

The flowcharts are presented in Figures 12.A-1 to 12.A-5. It should be noted that flowcharts with similar elements have been produced by other radioactive waste management organisations. The flowcharts are broadly similar in scope, covering the process leading to the production of a safety report or safety case. The selection of these specific flowcharts is, however, somewhat arbitrary and other comparable flowcharts could also have been selected.

In each case, the present assessment strategy flowchart (the higher-level version – Figure 12.4) is shown on the left hand side of the figure, and one from each of the above flowcharts is shown on the right hand side. Similar elements identified in the flowcharts being compared are highlighted using shaded boxes linked by dashed lines.

Figure 12.A-1 shows the present assessment strategy flowchart (Figure 12.4) compared with the flowchart presented in the NEA Review of Safety Assessment Methods (NEA 1991). It can be seen that some concepts considered central in many recent safety assessments are not explicitly shown in the 1991 figure, including the importance of the assessment context. Furthermore, the notion of a safety case as a synthesis of the results of the analysis of scenarios together with other, complementary evidence and arguments is not explicitly shown in the 1991 figure. The process of safety assessment is depicted as linear, with no explicit feedback to scientific and design studies (although the importance of feedback was certainly recognised in the Review of Safety Assessment Methods; see Section 3.3 of NEA 1991). It should also be noted that "scenario analysis" in the 1991 figure refers to the development of scenarios. "Model representation" together with "consequence analysis" in the 1991 figure is broadly equivalent to "evaluation of performance and comparison of results with criteria" in the present more detailed assessment strategy flowchart (Figure 12.5).

Figure 12.A-2 presents a comparison of the present assessment strategy flowchart with the flowchart presented in the NEA Safety Case Brochure (NEA 2004). The main elements of the production of the safety case are included in both flowcharts, with the exception of the safety assessment process (especially the development and analysis of scenarios), which is not explicitly shown in the flowchart in the NEA Safety Case Brochure. The present more detailed assessment strategy flowchart (Figure 12.5) elaborates the safety assessment process, while the flowchart in the NEA Safety Case Brochure elaborates more the types of evidence, analyses and arguments that contribute to the safety case. This difference reflects the focus of the Safety Case Brochure, which was on the broad nature of safety case argumentation. Other points of difference include:

- in the present assessment flowcharts, a synthesis of process understanding and of influences between processes (e.g. a geosynthesis or a site descriptive model) is shown as a fundamental element of the assessment basis; the importance of the synthesis of understanding from scientific and design studies is not explicitly shown in the flowchart in the NEA Safety Case Brochure;
- the present assessment flowchart includes feedback via management to scientific and design studies; and
- the present assessment flowchart includes an assessment of adequacy of the safety case with respect to the current programme milestone.

Figure 12.A-3 presents a comparison of the present assessment strategy flowchart with a figure from the NDA generic Environmental Safety Case (NDA 2010). The figure is similar to that presented in the NEA Safety Case Brochure (NEA 2004), with many of the same similarities and differences compared with the present assessment strategy flowchart. However, like the present assessment strategy flowchart (and unlike the NEA Safety Case Brochure flowchart), the NDA flowchart indicates:

- qualitative safety arguments (part of safety analysis in the NDA flowchart, and indicated by the arrow labelled "d" in the present flowchart);
- modelling results (also part of safety analysis in the NDA flowchart, and part of safety assessment in the present flowchart); and
- the importance of a plan for the management of remaining uncertainties as a part of the safety case.

Figure 12.A-4 presents a comparison of the present assessment strategy flowchart with a flowchart presented in Andra's Dossier 2005 Argile. The main point to note is that the Andra flowchart is wider in scope, in that it includes operational safety and risk analysis, as well as long-term safety assessment. In contrast to the earlier NEA flowcharts, both flowcharts in Figure 12.A-3 indicate the feedback from the findings of safety assessment to scientific and design studies. The flowcharts differ, however, in a number of detailed respects, including that the Andra flowchart makes the distinction between the normal evolution scenario and altered evolution scenarios.

Figure 12.A-5 presents a comparison of the present assessment strategy flowchart with a flowchart presented in Posiva's Safety Case Plan 2008 (Posiva 2008). Some points of similarity and difference are as follows.

- as in the case of the Andra flowchart, the Posiva flowchart distinguishes expected scenarios and other (unlikely) scenarios;
- the Posiva flowchart explicitly depicts external events, such as climate change, as important to consider in the process of safety assessment; and
- the feedback to scientific and design studies is not explicitly shown in the Posiva flowchart (although Posiva has presented another figure that shows this: see Figure 12.B-2 of Annex 12.B).

Overall, it can be concluded that flowcharts have tended to become more comprehensive and broader in scope in the years since the 1991 NEA Review of Safety Assessment Methods, often including elements of the safety case over and above the quantitative analysis of evolution scenarios. The importance of feedback from safety assessment to scientific and design studies is widely recognised, as is the iterative nature of safety case development. There remain some differences in terminology. Furthermore, the scope and level of detail of flowcharts presented will always depend on the purpose of the document that they support and the message to be conveyed by the flowchart within that document (which will, for example, influence whether feedback loops are important to show). The present assessment strategy flowchart is, however, broadly consistent with flowcharts produced in recent safety assessments, including those described in this annex and the current Nagra flowchart described in detail in the main text.

Figure12.A-1: The present assessment strategy flowchart compared with the flowchart presented in the NEA Review of Safety Assessment Methods (NEA 1991)

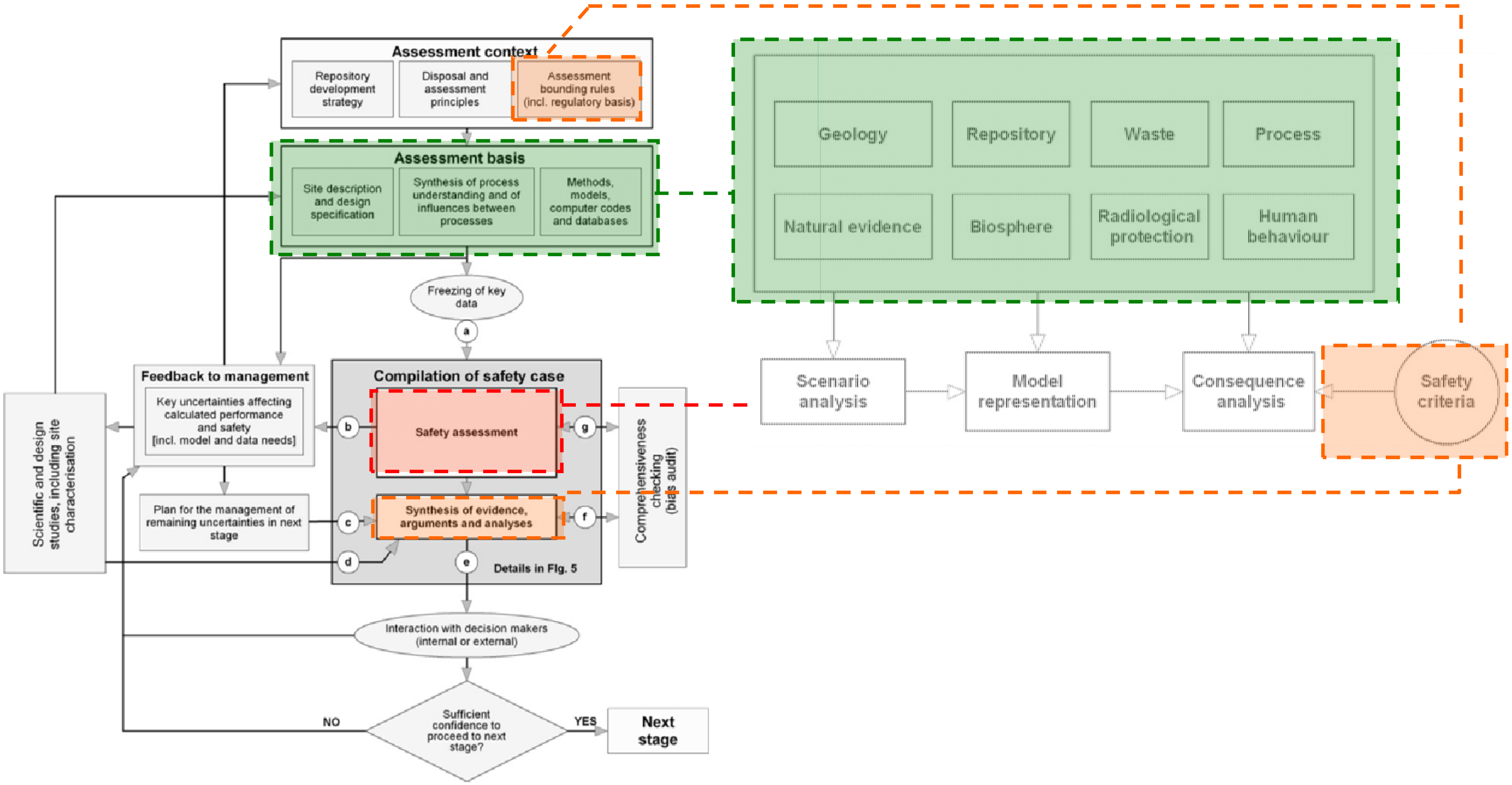


Figure 12.A-2: The present assessment strategy flowchart compared with the flowchart presented in the NEA Safety Case Brochure (NEA 2004)

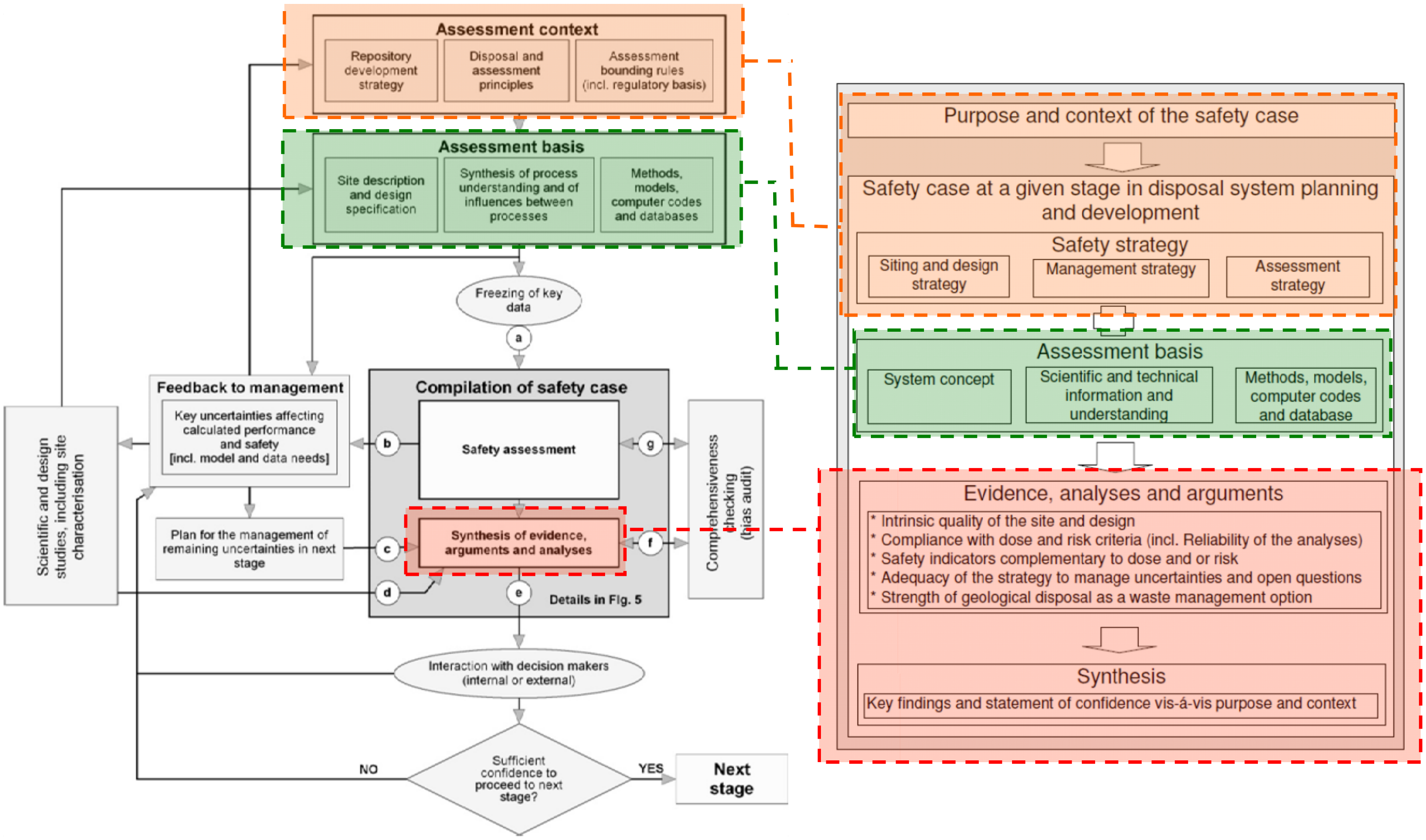


Figure 12.A-3: The present assessment strategy flowchart compared with a figure from work in progress for the NDA generic Environmental Safety Case

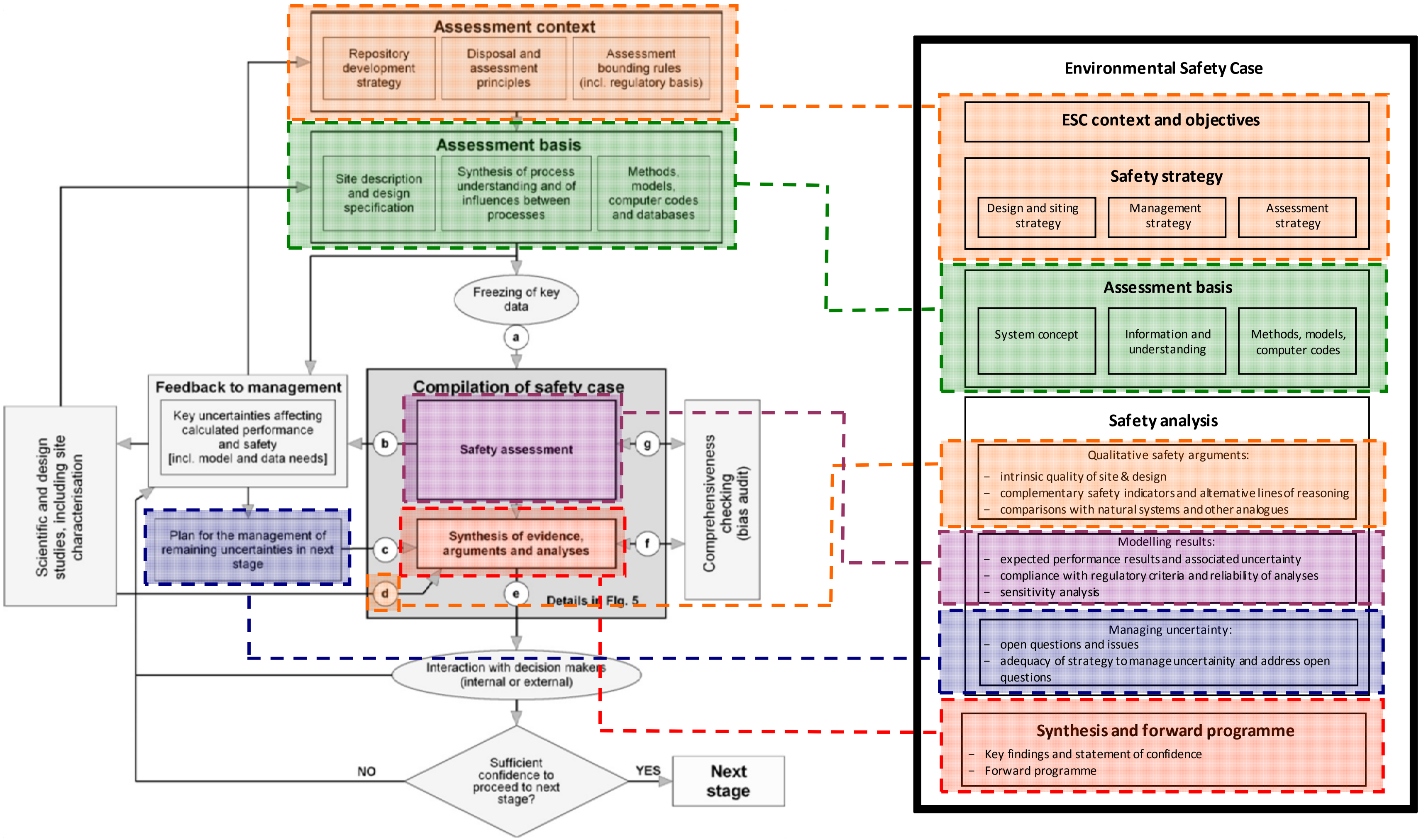


Figure 12.A-4: The present assessment strategy flowchart compared with Andra's flowchart based on that presented in Andra (2005)

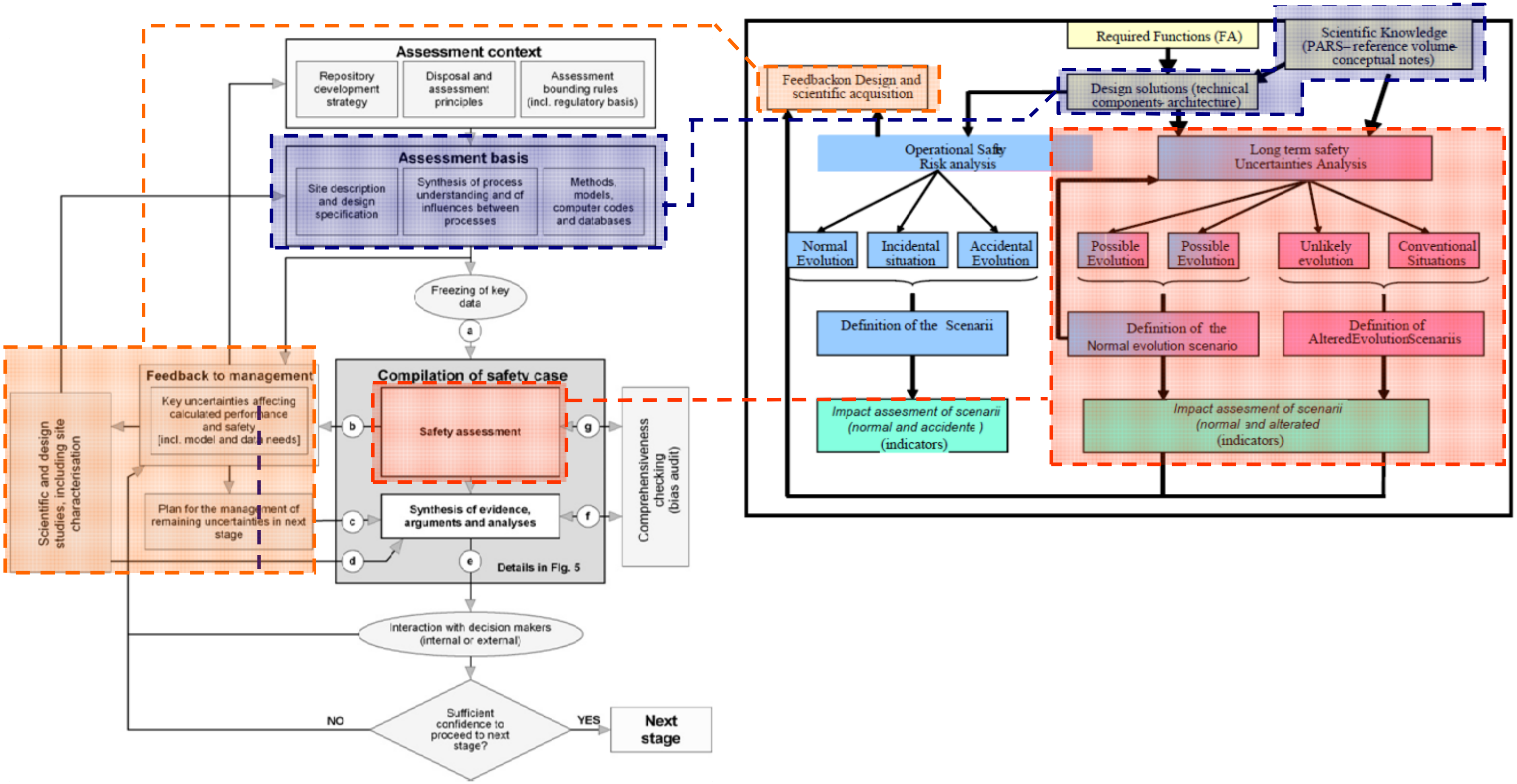
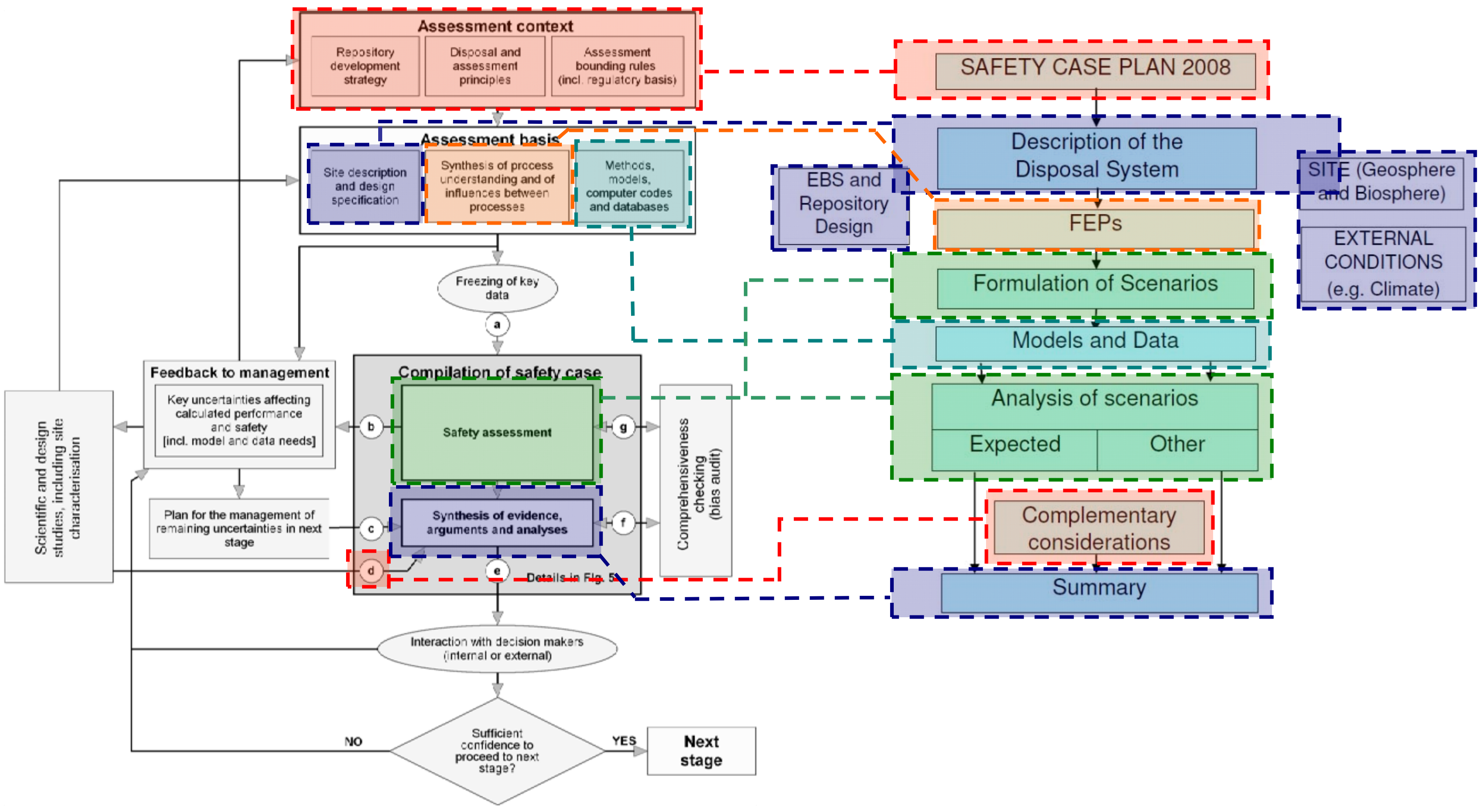


Figure 12.A5: The present assessment strategy flowchart compared with the flowchart presented in Posiva (2008)



Annex 12.B

Safety functions and related concepts in assessment strategy flowcharts

This annex shows some examples of the representation of safety functions and related concepts (safety and feasibility statements, performance targets) in safety strategy flowcharts from the Belgian and Finnish programmes.

Ondraf/Niras has developed a set of "safety and feasibility statements", which include safety statements concerning the safety functions of the disposal system. The statements are organised in a hierarchy, and are developed and structured in a "top-down" manner, based on *a priori* knowledge and experience, starting with the most general, highest-level statements, and progressing to increasingly specific, lower-level statements. High-level statements include statements regarding the specific safety functions of the disposal system and the time frames over which they are expected to be provided. Lower-level statements are used to substantiate these high-level statements.

Statements generally begin as hypotheses and develop into increasingly well-substantiated claims as the design and implementation procedures are developed and optimised, and the evidence, arguments and analyses that underpin each statement are acquired or developed. The assessment of support for statements, which is periodic, tends to be carried out from the bottom-up in a process termed "preparatory assessment". Preparatory assessments may identify the needs for further R&D, or even changes to the strategic choices underlying the safety concept and design. For a formal assessment of safety and feasibility to be carried out, it is important that a review of the safety and feasibility statements indicates that there is sufficient support for such statements. The role of safety and feasibility statements and of preparatory and formal assessments within the broader scheme leading to a safety and feasibility case (SFC) is shown in Figure 12.B-1.

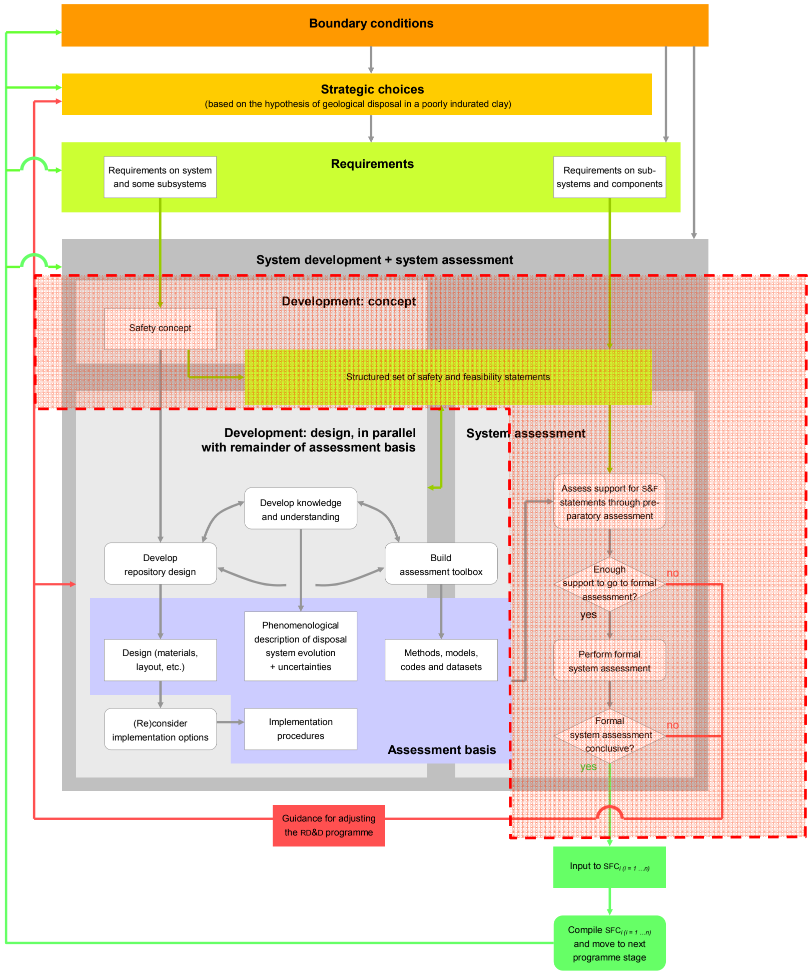
The safety statements also play a fundamental role in scenario development within the formal safety assessment methodology. The Ondraf/Niras approach involves systematically examining perturbing phenomena and associated uncertainties potentially affecting the validity of each safety statement, and the propagation of the consequences of these uncertainties from lower-level statement to higher-level statements. Any uncertainty propagating upwards to a safety statement representative of a safety function of the disposal system gives rise, potentially, to alternative-evolution scenarios and is thus categorised as a scenario uncertainty. Other uncertainties that do not propagate to the highest-level statements concerning the safety functions may nevertheless affect how specific processes are modelled in a given scenario, and the values assigned to model parameters. These are, respectively, the model and parameter uncertainties.

As a key part of their assessment strategies, SKB and Posiva have developed safety function indicator criteria (SKB) and performance targets (Posiva) that, if upheld, indicate that specific safety functions can be assumed to operate in safety assessment (in Ondraf/Niras terminology, the related safety and feasibility statements can be assumed to hold). If, on the other hand, events or processes are identified that affect the ability of the components to uphold their safety function indicator criteria or performance targets, then the consequences of these events and processes must be evaluated by safety assessment in terms of their acceptability from the viewpoint of long-term safety by means of the formulation and evaluation of scenarios. R&D must support this evaluation, reducing uncertainties where necessary. If the consequences cannot be shown to be acceptable, then;

- the events and processes (and associated uncertainties) must be avoided by change in design; or
- their likelihood and consequences are reduced by modifications to the design solution.

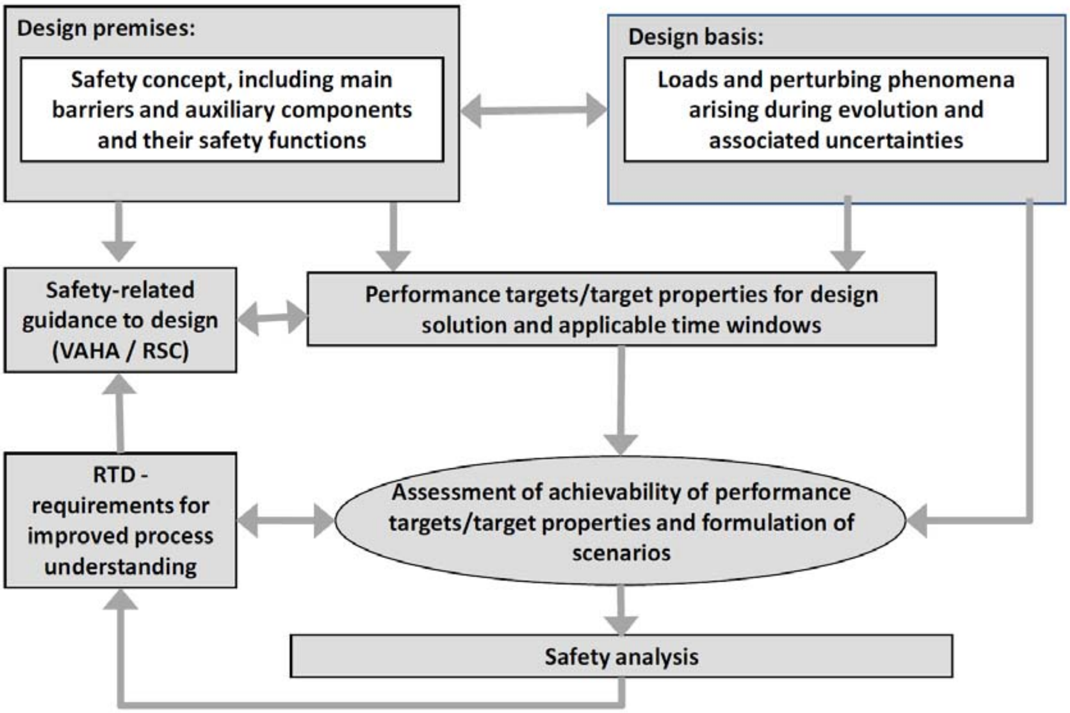
Thus, as indicated in Figure 12.B-2, for these programmes, the assessment of the achievability and applicability of safety function indicator criteria or performance targets in different time windows is a key activity leading to R&D requirements for improved process understanding and also to the further development of safety-related guidance to design.

Figure 12.B-1: The role of safety and feasibility statements and of preparatory and formal assessments (red dashed box) within the broader scheme leading to a safety and feasibility case (SFC) according to Ondraf/Niras (2009)



Note that boundary conditions, strategic choices and requirements guide system development and assessment, and can be seen as providing the assessment context.

Figure 12.B-2: Overview of key activities according to Posiva leading to R&D requirements for improved process understanding, to the further development of safety-related guidance to design and to the development of scenarios for analysis in safety assessment (corresponds to Figure 6-1 in Posiva 2009)



13. System description and scenarios

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Abstract

As part of the NEA Project on the "Review of Methods for Safety Assessments" (MeSA), issue papers, each focussed on a specific topic related to post-closure safety assessment for deep radioactive waste disposal, were produced. This paper, the third in this series, addresses system description and scenario development. After a brief review of the evolution of the subject, it sets it into the context of repository development, the safety case, and safety assessment. Methods being used in national programmes for structuring scientific knowledge and describing the initial state and the evolution of the system as well as for deriving scenarios for further assessment are described and reviewed. Part of the information presented is based on a survey of scenario development methods and tools undertaken within the MeSA project.

Keywords: Safety assessment, safety case, geological repository, radioactive waste, disposal.

13.1 Introduction

In this paper, the role of system description and scenario development in safety assessment for deep radioactive waste disposal is reviewed. The paper is the third in a series in an overall structure called the Methods for Safety Assessment (MeSA) project. In 1991, NEA issued a brochure on safety assessment methodology. The aim of the MeSA project is to review the evolution of safety assessment methodology since then, to describe the current state of the art, and, where possible, to identify common views, differences, and issues deserving further attention and work.

It is worth noting that the contents and the role of this issue may vary in different organisations depending not only on the stage of the programme but also on national regulations. Section 13.2 presents a summary of the history and recent development of the

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topic and identifies major sources of information for the ensuing sections. Section 13.3 places the issue in the overall context of the safety strategy and the safety case. Section 13.4 deals with system description and evolution, while Section 13.5 addresses scenario derivation and its connection to uncertainty treatment. Section 13.5 also summarises approaches for developing scenarios and introduces the concept of safety functions and their link to features, events and processes (FEPs). Regulatory issues are briefly addressed in Section 13.6. Section 13.7 presents the conclusions and synthesis of this paper identifying areas of international consensus and further development needs.

The question of human intrusion has not been addressed in this paper due to the necessarily illustrative nature of human intrusion scenarios and because of different regulatory attitudes and requirements concerning this issue.

13.2 History and recent developments

13.2.1 The NEA safety assessment brochure (1991)

The 1991 brochure (NEA 1991) describes scenario development as "the starting point for safety assessments … concerned with defining the broad range of possible futures to be considered in the subsequent modelling and consequence calculations". The statements made in the brochure mainly rely on the work of the PAAG Working Group on the Selection and Identification of Scenarios for Performance Assessment of Nuclear Waste Disposal (NEA 1992) which, in turn, was based on scenario development works carried out in the national programmes of Canada (AECL), France (IRSN), Sweden (SKI/SKB), Switzerland (NAGRA), the United Kingdom (HMIP, INTERA), and the United States (NRC, SNL).

First attempts to carry out scenario development in a systematic way rather than on an ad hoc basis are reported in the brochure. The brochure identifies a number of basic requirements scenario development has to fulfil, including logic, consistency, understandable and traceable documentation of decisions, comprehensiveness, flexibility within an iterative assessment, and involvement of multiple disciplines. It emphasises the importance of human judgement and acknowledges that there is no absolutely rigorous and objective procedure to assure scenario completeness.

In the brochure, scenario development methods are categorised under the "four main classes: (1) judgemental, (2) fault/event-tree analysis, (3) simulation, and (4) systematic". While "judgemental" refers to an informal interaction of experts, the term "simulation" addresses attempts undertaken in the United States and the United Kingdom under the heading "probabilistic system assessment (PSA) approach". The methods reported as "systematic" are apparently the first FEP-based approaches. Although the term FEP itself is used in the brochure in a way different from today's understanding[1] it refers to "factors that could influence repository safety" and provides an exemplified set of such factors the relationship of which to FEP lists derived later is clearly visible. The generic systematic scenario development method described in the brochure comprises the elements of FEP ("factor") collection, classification, and screening, followed by scenario construction and screening, and results in a base-case scenario and several disturbed-case scenarios.

The brochure emphasises that human activity that may interfere with the barrier system of a repository form a special category of scenarios.

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[1] "Scenario development is the procedure to identify the features, events, and processes that require treatment by modelling and consequence calculations" (NEA 1991).

13.2.2 Further developments and recent work

In the ensuing years, different scenario development methods were developed and applied in several national programmes. At an NEA workshop on scenario development held in 1999 (NEA 2001), requirements on scenario development were formulated which were similar to the ones described above. However, the evolving role of scenarios became evident: it was acknowledged that their importance goes beyond the boundaries of safety assessment ("to guide decisions concerning research priorities, the collection of data, and allocation of funds") and – at least implicitly – the fact that repositories are designed with a view to future developments and, thus, to scenarios ("… define cases to study the function of individual barriers or the robustness of the multi-barrier system") was referred to. Although scenario development was still seen as an early step of safety assessment, the iterative nature of the assessment process was now better recognised.

It became evident at the 1999 workshop that a majority of national programmes now used "systematic" FEP-based approaches, although the details of these approaches showed considerable variation. This development went along with the construction of an NEA FEP database [(NEA 2000), second version (NEA 2006b)] which comprised a number of national FEP databases. The database was considered an "important contribution" to "achieving completeness, comprehensiveness or sufficiency", although the workshop acknowledged that completeness in the literal sense of the word is "neither achievable nor necessary". Perhaps, the requirement that "sufficiency" can be checked, amongst other things, by asking "whether the scenario list adequately explores uncertainties in the performance of all the barriers" can be seen as an early hint for the later evolving role of safety functions in scenario development. The papers presented at the workshop make it evident that the idea of such functions, although not explicitly acknowledged, was a major driver for scenario development in most if not all of the cases.

FEP processing was a major theme of the workshop, and a number of formalised methods and tools for handling FEPs and their interactions were presented (event trees, logic diagrams, Latin squares, fault and/or dependency diagrams, influence diagrams, interaction matrices, audit tables). However, it became also clear that the methods by which scenarios finally are being constructed using the FEPs were much less formalised.

Apart from re-emphasising a number of messages from the NEA Safety Assessment Brochure the 1991 workshop stated that scenario-based approaches, as opposed to "integrated simulation", "seem to be the most common method for dealing with future uncertainties". It raised the question of the advantages and disadvantages of formalised methods for scenario development, of the use of expert judgement, and of the treatment of FEP sequences. Emphasis was put on the importance of regulatory guidance with regard to the scenarios to be investigated in general, but in particular to human intrusion and biosphere issues.

It was concluded that scenario development methods used in national programmes, although considerably varying, were generally adequate and sufficient. The identified open issues included the quantification (or otherwise) of likelihoods for uncertain events which might initiate scenarios, time dependence, and communication and traceability issues.

Scenario development methodology and its application evolved, often divergent, in national programmes. An attempt to identify a "common approach for scenario selection" was undertaken in the frame of the EC project EVEREST (1990-1994) (EC 1997). Three methods, all categorised as "systematic" (cf. previous section) (Independent Initiating Events I.I.E. by Andra and IPSN/France, the PROSA methodology by ECN/The Netherlands and SCK•CEN/Belgium, and the transport mechanism methodology T.M.M. by GRS/Germany) were compared and tested for different host rocks and sites. As a result, three "common lists of scenarios", one for clay, one for granite, and one for salt, were developed. In the conclusions of the exercise, it was claimed that the organisations involved "have harmonised their methodology for scenario selection" and that "irrespective of the approach, the selection ends up in the same final list of scenarios for a specific rock formation". From the description of the methodologies, again the role of barrier states or safety functions becomes evident (although the term "safety functions" was not explicitly used).

The further evolving assessment methodologies in national programmes and, in particular, methodological aspects related to system description and scenario development are reflected in several NEA documents (NEA 2002, 2003a, 2004a, 2006a, b, 2008b, 2009c). Most recent developments are documented in the frame of the NEA INTernational Experiences in Safety Cases (INTESC Initiative) (NEA 2009c) as well as within the European Project PAMINA (Performance Assessment Methodologies in Application to Guide the Development of the Safety Case) (PAMINA 2006-2009), both being major references for this document.

INTESC, which took place shortly after the 2007 international "Safety Case Symposium" (NEA 2008b), provided a state-of-the-art report on the practical experiences of safety cases for geological repositories and on the lessons learnt from current practices, taking into account the outcomes of the symposium.

In a dedicated component "Comprehensive Overview of Methodologies, Tools and Experiences", the European Project PAMINA collected contributions from the participating organisations on 11 topics (PAMINA 2006-2009), several of which are of special interest for this report ("Safety Functions", "Definition and Assessment of Scenarios", "Analysis of the Evolution of the Repository System"). These contributions were then summarised in a PAMINA task report which outlines both common and divergent features.

The perhaps most striking development of this time is the one "of new conceptual tools such as safety functions, which embody key aspects of performance of the geological disposal system from which can be developed internal requirements that relate the ability of the disposal system to fulfil these functions, thus making more transparent the role of the various components (and their synergies in the disposal concept)" (NEA 2009c). At least in some programmes, the role of safety functions goes beyond their use in safety assessments. Rather, they provide a link between activities important for repository development and safety case building (MeSA Issue Paper No. 1 – Van Luik *et al.* 2011; MeSA Issue Paper No. 2 – Schneider *et al.* 2011). Naturally, the role of safety functions in safety assessment is strongly linked to the question of system description and scenario development. Often, contemporary scenario development is referred to as mostly relying on safety functions ("top-down" approaches as opposed to the FEP-based "bottom-up" approaches):

> "In some assessments, scenarios are identified using a bottom-up approach that begins by assessing a range of external events or conditions (i.e. climate change scenario, intrusion scenario, initial defect scenarios) that may trigger changes in the disposal system or affect its performance.
>
> 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.
>
> 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 Argile 2005 … in which analyses of safety functions were used to derive alternative 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)." (NEA 2009c)

These issues will be discussed later in this document, but this section about earlier and recent developments would not be complete without mentioning that the NEA FEP database has been updated (NEA 2006b) and a FEP catalogue for argillaceous formations

("FEPCAT") (NEA 2003a) has been developed within NEA activities. The update of the NEA FEP database was mainly devoted to the integration of more project databases and to a few changes in format but did not result in any major change in approach or format. FEPCAT took a broader view on the FEPs under consideration by providing much more extensive descriptions of processes and phenomena. This goes along with a tendency in national programmes to support safety analyses by so-called "process reports" (Andra 2005b, SKB 2006b-d, Posiva 2007) the scope of which goes far beyond simple FEP descriptions. Another tendency in national programmes is to link FEP records with statements about safety functions, e.g. by specific tools such as FEP charts (SKB 2006a) or directly in the database (DBE 2008).

13.2.3 Major information sources for this document

The following projects, activities and documents were identified as major information sources for the following sections:

- Recent safety assessments carried out in national programmes (e.g. Andra 2005a-c, DBE 2008, Nagra 2002, Ondraf/Niras 2009a, b, Posiva 2007, 2009, 2010, SKB 2006 a-d).
- Outcomes of the OECD/NEA INTESC initiative (NEA 2009c).
- Development and review work undertaken in the frame of the European Project PAMINA (PAMINA 2006-2009).
- An information survey carried out by the authors of this document in order to identify major issues and developments in national programmes and to compile them systematically.

The survey was based on the questionnaire presented in the annex of this document. The answers received relate to assessments carried out in the following national projects and activities (cf. also the list of references at the end of this document):

- Feasibility and safety case development in Belgium (Ondraf/Niras).
- Work carried out in the Czech Deep Geological Disposal Programme (NRI).
- Finnish work based on the relevant STUK guidelines (Posiva, SROY).
- *Dossier 2005 Argile*, France (Andra).
- Safety assessment in the frame of the German ISIBEL project (DBE Technology, BGR, GRS).
- Work on safety functions and scenarios in the frame of the German VerSi project (GRS).
- Safety assessment for the ERAM LILW repository in Germany (BfS).
- Work carried out in the Japanese Deep Geological Disposal Programme (NUMO, JAEA).
- SR-CAN assessment in Sweden (SKB).
- NDA work based on earlier developments by UK Nirex Limited.

The authors of this paper would like to acknowledge the contributions of these organisations and to thank them for the efficient, straightforward and timely co-operation.

13.3 Place and purpose of system description and scenario development in the safety strategy and safety case

As discussed in Section 13.2, the place and purpose of scenarios in safety assessment and the safety case has been discussed in several international *fora*. According to their outcomes, scenarios aim at defining:

> "the broad range of possible futures to be considered in the subsequent modelling and consequence calculations"…"Scenario development is concerned with the identification, broad description, and selection of potential futures relevant to safety assessment of radioactive waste repositories." (NEA 1991)

Scenarios are needed because:

> "… it is virtually impossible to predict exactly what will be the evolution of the disposal system through time. A scenario describes one possible future of the disposal system, corresponding to a combination of events and processes together with their characteristics and their chronological sequence" (PAMINA 2006-2009).[2]

Scenario development is, thus, an essential part of the assessment strategy, which defines the approach taken to:

> "… perform safety assessments and define the approach to evaluate evidence, analyse the evolution of the system and thus develop or update the safety case" (NEA 2004a).

The details of the assessment strategy can differ significantly between repository programmes. However, at a higher level, common (generic) aspects, including the formulation and analysis of scenarios, can be identified. As part of the NEA MeSA project, generic flowcharts for developing the safety case (Figure 13.1) and carrying out safety assessments (Figure 13.2) have been developed (MeSA Issue Paper No. 2 – Schneider *et al.* 2011), illustrating:

- the steps typically undertaken for different stages of a safety assessment and the development of a safety case; and
- the linkages and feedback among components of safety assessment and to other parts of the safety case.

The flowchart shows the formulation and analysis of scenarios as elements of safety assessment, which is based on the description of the expected initial state and evolution of the system as well as on the safety concept. Scenario development and analysis can be seen as a means to take into account a range of safety-relevant phenomena and uncertainties.

> "The safety concept: The safety concept is the understanding of why the disposal system is safe. It includes a description of the roles of the natural and engineered barriers and the safety functions that these are expected to provide in different time frames, and why the disposal system is expected to be safe, irrespective of identified uncertainties and detrimental phenomena; i.e. why it is expected to be robust.[3]" (Schneider *et al.* 2011)

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[2] Note that terminology is varying: Some understand by one scenario and one possible future "one possible set of events and processes and … a broad brush description of their characteristics and sequencing" (NEA 1992). Consequently, variation (e.g. of parameters) within this scenario is considered possible. Others, however, see a scenario as "what is usually referred to as an elementary event in the standard terminology of probability theory" (DOE 2009). Consequently, even the slightest parameter deviation would form a new scenario. "Similar" scenarios would under this latter terminology form scenario classes. In other words, a scenario class would be what in the terminology of (NEA 1992) is considered a single scenario.

[3] "Robustness" in this context refers to insensitivity to uncertainties regarding the future evolution of the disposal system and insensitivity to uncertainties concerning the scientific understanding.

Obviously, the description of the expected initial state and evolution of the system provides the most important link between the assessment basis and the quantitative safety assessment in that it ensures that the assessment is consistent with the knowledge about the disposal system, in particular about the features and phenomena relevant for safety as well as the elements of the repository design. Scenarios are important since they are means to test whether the disposal system will be able to perform appropriately assuming a range of possible conditions and evolutions. One could also argue the other way round: The rationale behind designing a disposal system is enabling it to respond appropriately to possible future evolutions, i.e. to scenarios.

Figure 13.1: Generic flowchart, showing the common elements and linkages when developing the safety case (Schneider *et al.* 2011)

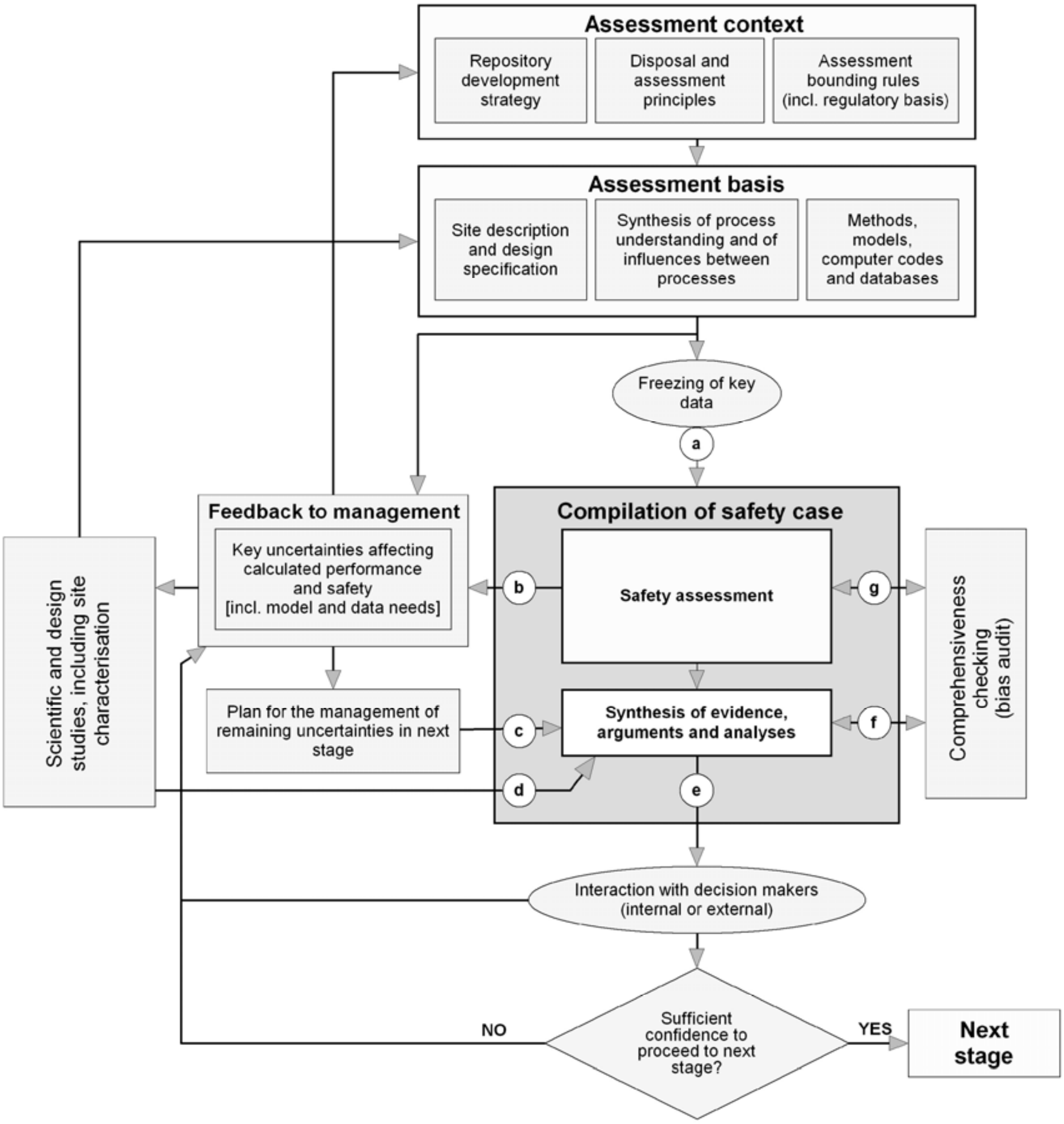
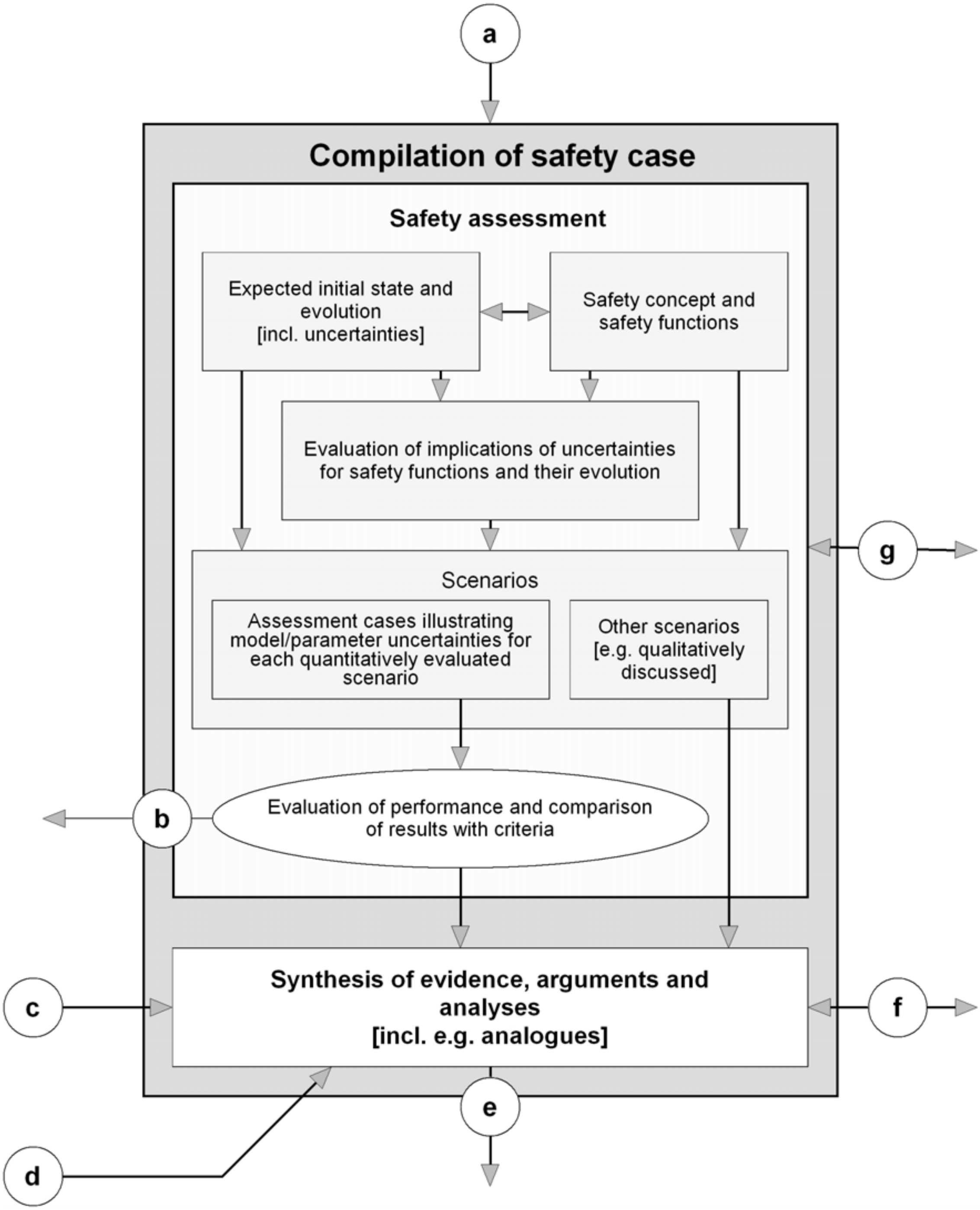


Figure 13.2: Generic flowchart, showing the common elements and linkages when carrying out safety assessments (Schneider *et al.* 2011)



The system description (initial state and evolution) and safety concept are discussed further in Section 13.4. The derivation of scenarios is addressed in Section 13.5.

13.4 System description: Initial state and evolution

The term "scenario" represents (and is understood as) a simplified description of a potential evolution of the repository system from a given initial state. Scenarios describe the compilation and arrangement of safety relevant features, events and processes as a fundamental basis for the assessment of post closure safety which includes assessing the potential consequences on human and its environment.

The background required for the development of scenarios has been identified in the 1991 NEA brochure: "Data must be gathered on the repository layout, the waste composition, the material used in to construct the engineered barriers, and site characteristics…."

Over the last two decades, several organisations developed large acquisition programmes that allowed production of extensive lists and descriptions of data and phenomena concerning the characteristics of the repository and its constituent parts:

- the identification and characterisation of the waste to be disposed of;
- the characterisation of the site;
- the characterisation of the concept, including the roles of the natural and engineered barriers and the safety functions that these are expected to provide in different time frames.

Identification and characterisation of the waste: Besides the inventory of radionuclides and chemotoxic components, the physico-chemical characteristics of the waste, as well as their long term evolution in disposal condition, are input data to design and dimensioning the disposal system. Due to the potential variety of waste, some organisations have collected the main characteristics of the waste in specific documents which present the typology, radiological contents and radionuclides release processes from the waste. It should also be noted that waste characterisation is not a completely descriptive activity – on the contrary, it becomes prescriptive when formulating waste acceptance criteria. Safety assessment is one of several bases for the derivation of such criteria.

Characterisation of the site: The characterisation of the host rock and its surroundings concerns the collection and integration of the geoscientific information. The acquisition of knowledge is a progressive process which is strongly linked with the maturity of the project and the availability of a designated host formation. Its objectives are:

- obtaining a sufficiently detailed understanding of the geological host medium and its surroundings, which includes characterising the geological configuration, its properties and evolution;
- characterising its potential long-term behaviour under the effect of the disturbances, including those caused by the repository.

For various reasons that may be linked with geoscience (e.g. glaciation cycles) but also with regulations, the interest of the waste management/disposal organisations may focus on different time frames, e.g. the present, the system evolution up to 10 000 years, up to 100 000 years, and up to 1 million years. However, it should be noted that in some national programmes the term "system description" covers only the present situation while potential future evolutions are covered elsewhere, e.g. as part of scenario development. Regulations may recommend or require considering the effects of certain external events or features (natural phenomena or human induced phenomena) (see MeSA Issue Paper No. 7 – Navarro *et al.* 2011). The landscape evolution model (SKB 2006a, Posiva 2007, Posiva 2010) and the geodynamic evolution model (Andra 2005b) are examples of recent modelling activities and tools addressing potential evolutions of the site.

Characterisation of the concept: The characterisation of the concept addresses the design and layout of the facility, the features and properties of the engineered components and the functions assigned to the engineered and geological components of the system. Based on material and engineering sciences, the features and processes relevant for safety and their interaction are identified and described and the data relevant for the assessment are compiled.

The description and analysis of the initial state and the potential evolution of the repository system is an important part of gaining understanding of how the entire system is characterised and may behave under certain circumstances, and of which factors, effects, FEPs and uncertainties influence the evolution of the disposal system and the safety functions. It requires:

- a systematic identification and study of thermal (T), hydraulic (H), mechanical (M), chemical (C), gas formation (G), radiation (R), and biological (B) processes, effects and influences of waste and repository induced phenomena, and their interactions (at present and in the future);
- the modelling of potential evolutions of the site and the disposal system, including influences of any disturbances (natural or human induced).

The NEA AMIGO project was concerned with the collection and integration of all types of geological information in repository siting and design, performance assessment models and the overall safety case for deep disposal of radioactive waste (NEA 2009a). The AMIGO workshops (NEA 2004b, 2007a, 2009b) show that considerable progress has been made since 1991 in defining the roles of geoscientific information in safety cases, and how such information is integrated and applied: "Concepts such as safety functions and the geosynthesis have provided useful mechanisms in prioritising and synthesising relevant information, and in conveying their significance to the overall safety of a disposal system."

The AMIGO project (NEA 2009a) outlined some important aspects when defining and ensuring safety functions related to the geosphere: "the geological and mechanical predictability of the host formation, the predictability of groundwater flow, the retention properties with regard to any released radionuclides, the predictability of the composition of the groundwater and the absence of resources in the host rock (and its vicinity)". The concept of a geosynthesis evolved and allows "best use to be made of geoscientific information in a safety case in encouraging, and indeed requiring, that a proper integration of such information takes place…".

Other outcomes were:

- "There are increasing links and iterative feedbacks between site characterisation, engineering design and safety assessment. There is an increasing emphasis in safety cases on specifying the repository layout and ensuring engineering feasibility – developments which have implications for the types of data required from geoscientific investigations and for the manner in which such data are integrated and made use of ..."
- "New tools and methods have emerged in recent safety cases to aid in the prioritisation of geoscientific investigations and in the integration of geoscientific information. Some of the most important in this regard are safety functions and the development of a geosynthesis or a Site Descriptive Model (SDM)…."
- "In recognition of the importance of such integration, some national programmes, including those of Andra, Nagra, Posiva and SKB, have even adapted their organisational structures and used other management tools to improve communication and foster mutual understanding among different disciplines and teams..."

The EC/NEA EBS (Engineered Barrier System) Project was concerned with the role of the EBS in the context of the entire safety case (NEA 2003b, 2004c, d, 2007b, c; EC/NEA 2003, 2010). The project examined how to design, characterise, model and assess the performance of engineered barrier systems, and how to integrate these aspects within the safety case for geological disposal of long-lived radioactive wastes. Key messages from the EBS project included:

- "The development and optimisation of repository and EBS design requires a continual process of iteration between detailed research and process modelling studies, performance and safety assessment studies, and engineering design studies. This process involves the simultaneous transfer downwards of high-level system requirements, and upwards of detailed materials and process understanding and performance assessment results, coupled with the periodic conduct of safety assessments, which integrate the various different types of information. The process is necessarily multi-disciplinary and involves communication between different teams of staff and wider stakeholder groups over considerable periods of time. The development and maintenance of expertise in safety and performance assessment is, therefore, key to establishing detailed designs for a repository and an EBS that meet the various requirements."
- "The EBS is best regarded as a system of components that functions in conjunction with the surrounding rock and thus provides acceptable levels of safety. The EBS should be tailored to the wastes that need to be disposed of and to the host rock in which it is required to function."
- "The EBS has a central role in the safety case for disposal. Even where the host rock offers the potential of significant performance, a well-designed EBS that will fulfil multiple safety functions is essential. First, operational issues dictate that reliable engineering solutions must be found for waste transport, handling and disposal, and these solutions must ensure adequate worker protection and radiological shielding. Second, the safety case for disposal cannot rely on a single barrier; confidence in the safety of disposal derives from the provision and fulfilment of multiple safety functions and defence in depth. Third, the EBS plays an important role in other key safety case arguments, such as those relating to feasibility, to monitoring, to the reversibility of waste disposal operations, and to waste retrievability. A well designed EBS is even more important in cases where, on its own, the host rock offers relatively less performance in terms of long-term containment and retardation."

It can be seen that since 1991, several methods to analyse and integrate data and illustrate process understanding have emerged. Several approaches relying on "story boards" or similar tools have been used, notably because they provide a first step for the system understanding by giving an overview of the dominant processes over time.

Such approaches consider the identification of FEPs, their analyses and their conceptualisation by dividing the disposal system into time and space sequences or situations. Each space-time sequence corresponds to a space and time interval within which a few major phenomena dominate the evolution of the component.

These situations or key-time sequences represent the basis for identification of uncertainties and their analyses (qualitative and quantitative analyses), and the background for definition and assessment of scenarios (reference or altered evolutions).

The overall time frame for analyses and integration may be defined/recommended by regulation, notably to account for some specific FEPs such as climatic and geological evolution. More specific time windows are then usually defined based upon the major THMCGRB processes and their coupling.

Two examples, hereafter, illustrate such an approach: the phenomenological analysis of repository situations (PARS) methodology (Andra 2005b) and the so-called “story boards” in (Ondraf/Niras 2008) by Ondraf/Niras.

The system description also includes a description of possible deviations in the implementation of the system (e.g. engineering mishaps), and uncertainties and detrimental phenomena that could potentially affect system evolution. It requires the identification of FEPs that may adversely affect the safety functions of the different components as well as addressing questions about how, where and when this might happen (see the following section).

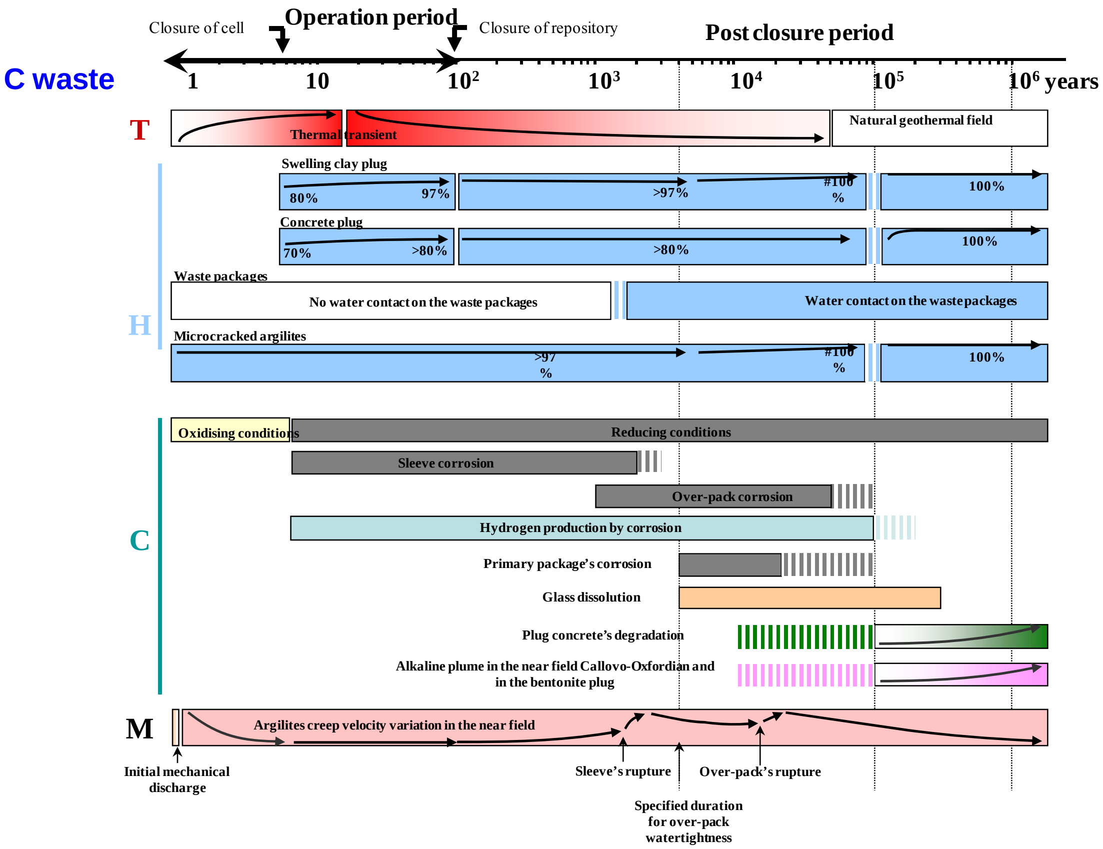
Several categories of scenarios are defined, usually one normal evolution or reference scenario and one or several altered scenarios. The latter will correspond to the main categories of FEPs potentially initiating or causing significant deviations or disturbances from the reference scenario. This might be the case e.g. due to uncertainties concerning the assumptions on safety functions, or due to effects such as climate change, repository issues (such as canister or seal defects), or future human actions. These scenarios will be evaluated by a systematic analysis of initiating features, events and processes affecting the safety functions of a selected disposal system, its subsystems and individual components. Such scenario development usually involves close interaction with scientists in various disciplines to understand the different evolutionary pathways. The uncertainties considered for a geological repository, such as those caused by the randomness or unpredictability of certain events, the natural variability of geological media and the biosphere, the lack of characterisation of processes and the limited possibility to forecast human habits imply a phase space of the possible evolutions of the system, the range of which increases, or broadens, over the very long timescales considered in safety assessment. However, the robustness of the safety concept makes is reasonable to address and to cover the broad range of possible evolutions of the system using typically just a handful of typical scenarios in the safety case (e.g. climate evolution, human intrusion, early canister failure).

13.4.1 Examples of approaches

To analyse the evolution of the disposal system, Andra divides the evolution of the repository into “situations”. The methodology used is the “phenomenological analysis of the repository system” (PARS) (Andra 2005a-c). PARS structures the THMCGRB processes from the initial state up to 1 million years in a way very similar to a “story board”. Such an approach relies upon spatial and temporal discretisation of the main disposal system components with regard to the safety functions they must fulfil. This discretisation is based on a detailed description of the aforementioned components, by identifying their major characteristics and processes and identifies the associated uncertainties. THMCGRB phenomena are recorded in this context. These different phenomena have their own time characteristics (constants), which determine the successive, distinctive states of the disposal system. It is therefore possible to define a “typical sequence” of situations, with each of these situations corresponding to a space and time interval within which a few major phenomena dominate the evolution of the components. In this evolution, each state of the disposal system depends on the former state (Figure 13.3).

These situations, organised into time-space sequences, provide the basis for the derivation of uncertainties and their analyses (qualitative and quantitative), and provide a baseline for the definition and assessment of scenarios (normal or altered evolutions). The behaviour of the repository’s various components and its environment is represented by models. This is the conceptualisation of the repository. The models are concatenated to form a model that can be used to assess the safety of the entire disposal system. The system representation within the safety assessment model thus developed is based on a “normal evolution scenario” (SEN). The safety assessment model represents the likely timing and rate of radionuclide release from the waste packages, the radionuclide transfer pathways and behaviour (retention, diffusion) in the engineered system, in the host rock, and in the surrounding host rock and overlying layers up to the biosphere.

Figure 13.3: High-level long-lived vitrified waste modules – Chronological evolution of the THMCGRB processes during the post-closure period (Andra 2005b)

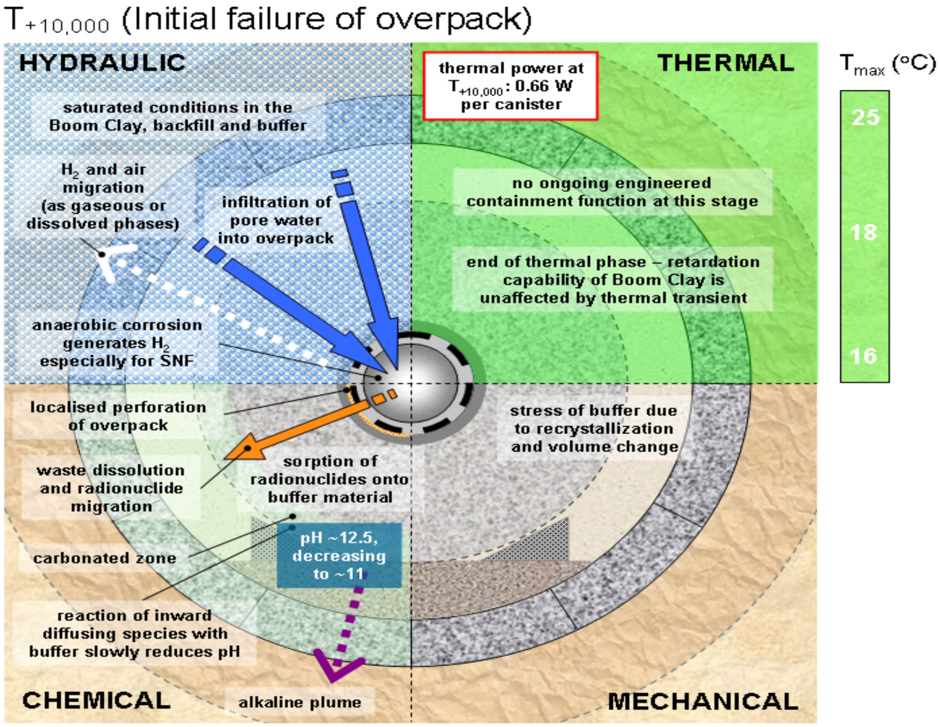


Andra's qualitative safety analysis (QSA) studies each uncertainty that may either (i) affect its ability to perform a safety function, (ii) or have an influence on another component's ability to perform a safety function, or (iii) modify the component's environment in a way that could affect the way the component fulfils its functions. This analysis checks if the uncertainty is taken into account either by design or by the way the normal evolution scenario is represented.

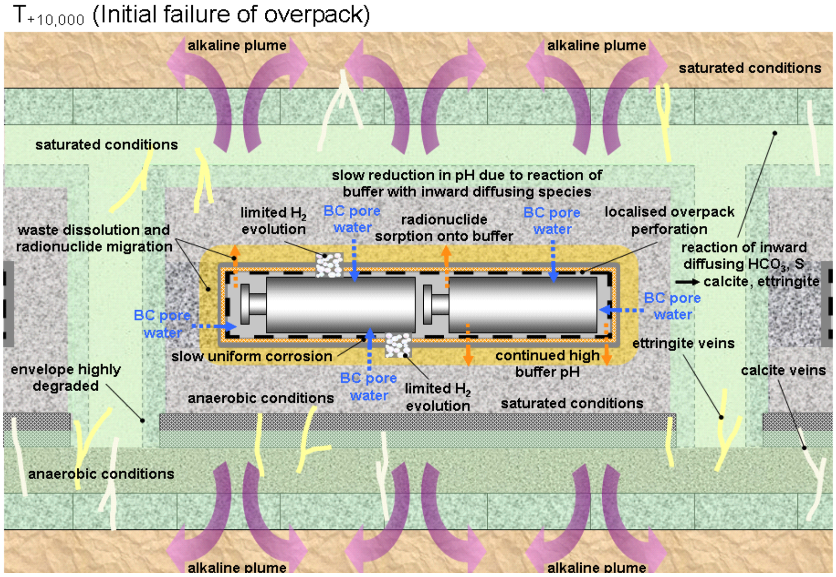
The QSA offers an integrated vision of all uncertainties. A set of four "altered evolution scenarios" (SEA) were developed to provide an understanding of the potential impact of unlikely future evolutions related to specific system failures: (i) partial or overall deterioration of seal performance, (ii) waste disposal packages failure, (iii) human intrusion, and (iv) strongly degraded safety functions.

Calculation results (radionuclides flows through barriers and end-of pipe impact) based on these SEAs, and sensitivity cases within the SEN and SEAs make it possible to evaluate overall repository performance and robustness, and provide information on the contribution of each component/barrier to safety.

Figure 13.4: Story boards representing the transverse and longitudinal cross-section of a disposal tunnel (Ondraf/Niras 2008)



Transverse cross-section through the disposal tunnel showing key processes occurring approximately 10 000 years after emplacement.



Longitudinal cross-section through the disposal tunnel showing key processes occurring approximately 10 000 years after emplacement.

The safety assessment methodology presented to the Belgian regulator in 2009 (Ondraf/Niras 2009a, b) in support of the forthcoming Safety and Feasibility Case, SFC-1, in 2013, included use of a "story board". In order to structure analysis of the multitude of processes taking place, the expected evolution of the EBS has been divided into key time sequences and classes of processes (thermal, mechanical, hydraulic and chemical). Each time sequence corresponds to a state of the repository characterised by key processes and events. The successive stages in the evolution are illustrated by a series of diagrams, which form "story boards" and which represent the transverse and longitudinal cross-section of a disposal tunnel (Figure 13.4). These story boards aim at illustrating the processes taking place concurrently (Ondraf/Niras 2008, 2009a, b).

13.5 Derivation of scenarios

13.5.1 Top-down and bottom-up approaches to develop scenarios

Figure 13.2 illustrates that the approach to develop scenarios takes into account the system description, which is linked to the safety concept. The safety concept may include top level safety functions (isolation, containment, retardation) and more detailed safety functions that are specific to system components. Methods to derive low-level functions from the high-level ones vary, but are often not very formalised.

In Figure 13.2, system description seems to include the present (initial state of the system) and the future (evolution of the system), but it should be acknowledged that in some national programmes the system description covers only the present (cf. previous section). In these programmes, the future or evolution of the system is dealt with in the frame of scenario development, posing a difference in the methodology and links between the elements of the safety assessment.

Figure 13.2 also illustrates that scenarios are being derived based on the safety concept including the safety functions and taking into account safety-relevant phenomena and uncertainties. Both safety concept and phenomenology, in turn, depend on the system description and vice versa. Here the role of FEPs is most pronounced: on one hand, it is necessary to perform a thorough examination of what FEPs could "endanger" the safety functions. This might either concern the initial state of the system or its evolution, and uncertainties about when and where the phenomena may disturb the system have to be taken into account. On the other hand, an examination of which FEPs contribute to maintain the safety functions can give support to the safety concept and be used to add to confidence.

The connection between "expected initial state and evolution" and "scenarios" in Figure 13.2 can be seen as an illustration of a bottom-up phenomena-based (in some programmes FEP-based) approach to derive scenarios, while the connection from "safety concept and safety functions" to "scenarios" refers to top-down thinking and working (cf. Section 13.2). Both are sometimes seen as alternatives, but in reality it is hard to imagine either of them without the other.

The components of the bottom-up approach are summarised in the 4-point methodology identified in the EU PAMINA project (PAMINA 2006-2009):

- collection of FEPs;
- screening of FEPs;
- combination of FEPs to form scenarios;
- grouping of scenarios to identify representative scenarios.

It is, however, acknowledged in the PAMINA documentation that:

> "Although this seems a logical sequence of steps to develop scenarios, in practice the process of developing scenarios is iterative – e.g. screening of the FEPs requires from knowledge of the central evolution scenario…."

Indeed, it is questionable whether an exclusively bottom-up approach has ever been successfully implemented – i.e. has a set of scenarios (or even an individual scenario) ever really been developed by piecing together individual features, events and processes (FEPs), as was sometimes claimed in the descriptions, particularly of older safety assessments, or does one actually always begin from an integrated understanding of system evolution and associated uncertainties, and use FEPs (together with interaction matrices, influence diagrams, etc.) to ensure that nothing is overlooked? Moreover, even the earliest, formally perhaps purely FEP-based, approaches to develop scenarios were driven by the necessity to investigate repository performance (and, by that, safety functions) and its potential disturbance, which was particularly visible in the FEP and scenario screening criteria applied in these approaches.

Safety assessments that claim to combine FEPs into scenarios sometimes lack any description of how exactly this is done. A combination of FEPs to derive scenarios certainly requires a first-cut description of the system and its evolution. It could be contended that the "top-down" approach described in recent safety assessments is in fact a more accurate representation of the approach that was in reality adopted (though not documented) in earlier safety assessments.

It could further be contended that "top-down" approaches to scenario development are, in fact, better described – at least in some cases and perhaps more generally – as "top-down/bottom-up". This is because, while the description of the initial state of the system and its expected evolution begins from an integrated "top-down" understanding of FEPs and their interactions, the identification of safety-relevant uncertainties starts from a "bottom-up" consideration of the impact of uncertainties in individual processes, system features, and a subsequent evaluation of whether the potential perturbations resulting from these uncertainties could significantly impact the safety functions. While the phenomena or FEP-based aspect of scenario development is less visible, it does, however, still exist in the wealth of phenomenological knowledge accumulated and documented in the safety cases. This seems to reflect at least the approaches adopted by Nagra (key safety-relevant phenomena), Ondraf/Niras (propagation of uncertainties upwards through the hierarchy of safety statements), Andra (qualitative safety analysis QSA), DBE Technology/GRS/BGR, and also by SKB and Posiva, as described further in the following sections.

This co-existence of both approaches is further evidenced by the outcomes of the survey on scenario development methodologies carried out in the frame of the MeSA project. In summary, each approach, if seen in isolation, has advantages and limitations as explained in the following, and the limitations of each may be compensated by the advantages of the other:

- FEP processing is an effective basis to understand and describe individual safety-relevant features and processes in a system, and also to identify factors that may trigger changes in the disposal system or affect its performance. Furthermore, FEP catalogues and the related process-describing documentation are an important base for modelling. However purely FEP-based or phenomena-based scenario development has difficulties concerning establishing an objective and formalised methodology (particularly for forming scenarios as sequences or combinations of FEPs) and also of ensuring the comprehensiveness of the combinations of FEPs to be considered.

- Safety functions are useful to describe the initial state and evolution of a system in relation to the safety concept. Scenario sets derived from studying (scientific and technological) uncertainties potentially affecting the safety functions (e.g. barrier performance) are perhaps not necessarily "complete", but may be better targeted to, and comprehensive with regard to, safety-relevant issues. However, for providing a sufficient scientific basis concerning the phenomenological knowledge needed to establish scenarios with confidence, it will also be necessary to take advantage from systematic and comprehensive databases of the underlying THMCGRB features and processes.

The survey also showed a tendency to formally link the two approaches in hybrid approaches, sometimes using formal tools linking FEPs to safety functions [e.g. the FEP chart for investigating the impacts of FEPs on safety functions which are studied by means of safety function indicators (SKB 2006a)].

The authors, thus, agree with the conclusion of the INTESC project (NEA 2009c):

> "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" (cf. Section 13.2), but would like to go a step further by saying that pure bottom-up or a top-down approaches hardly ever existed and that in reality most organisations use a mix of both.

13.5.2 Structuring scientific knowledge and identifying safety-relevant phenomena and uncertainties

As noted in Section 13.3, safety assessment includes the formulation and analysis of scenarios for the evolution of the safety functions over time, taking into account all safety-relevant phenomena and uncertainties. The main steps involved in the structuring of scientific knowledge and, from this, identifying safety-relevant phenomena and uncertainties can be extracted from the generic strategy flowcharts (Figures 13.1 and 13.2) and described as in Figure 13.5.

Table 13.1, parts of which are based on the MeSA survey on scenario development, identifies some of the tools that have been used by organisations to support these steps. It should be noted that many of these tools and methods reach beyond the issues of system description and scenario development in that they e.g. contribute to consistent and thorough modelling in safety assessment.

In all programmes, the starting point for the identification of safety-relevant phenomena and uncertainties is the development of a detailed description of the initial state of the system and its subsequent evolution. Tools are available to support the development of this description – e.g. the SKB FEP interaction matrices. Programme-specific tools are also available to structure the description in terms of spatial domains and time windows, including PARS (Andra) and story boards (Ondraf/Niras and NUMO). Both essentially describe spatially and temporally segmented situations (see Section 13).

The description of the initial state of the system and its subsequent evolution provides the basis for a main scenario, also termed normal-evolution, base or reference scenario. It also provides a platform for discussion between specialists in certain disciplines (e.g. hydrogeologists, chemists, engineers) and safety assessors on what are the safety-relevant uncertainties that could significantly affect evolution and lead to deviations from this main scenario.

Further tools are used to focus this discussion. These tools generally make use of the concept of safety functions. They include:

- the approach of Andra (QSA) to identify which uncertainties in components can affect safety functions (Andra 2005c); and
- the identification and classification of phenomena by Nagra according to:

  - (i) key contributors to the safety functions;
  - (ii) perturbing phenomena and uncertainties; and
  - (iii) system attributes providing robustness against these phenomena and uncertainties;

- the safety statements regarding what system/subsystem properties support safety functions (Ondraf/Niras); and
- safety function indicators/performance targets and associated criteria, and FEP charts summarising how the most important FEPs are related to the safety functions (SKB and Posiva).

Short descriptions explaining the use some of these tools are used are given in the following paragraphs.

Figure 13.5: The main steps involved in the identification of safety-relevant phenomena and uncertainties in safety assessment

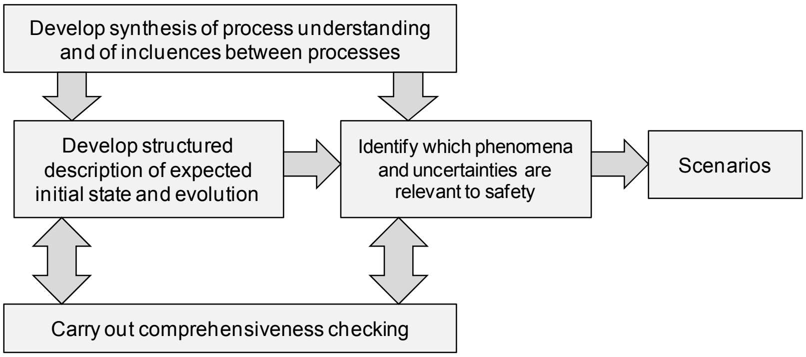


Table 13.1: Examples of the tools used to support the main steps or objectives involved in the identification of safety-relevant phenomena and uncertainties

Step/objective	Tool	Organisation
Developing system-specific understanding of processes and the interactions or influences between processes, including uncertainties	System-specific FEP databases	All
	FEP interaction matrices	SKB, DBE Tec/GRS/BGR, BfS, NUMO, JAEA
	Influence diagrams	Nagra, NUMO, JAEA
	Process diagrams, Influence tables	SKB
	Master directed diagram (MDD) (tree structure)	UK Nirex Limited/NDA
	Assessment Model Flowcharts (AMF)	SKB
Structuring description of initial state and subsequent evolution, including uncertainties	Phenomenological Analysis of the Repository System (PARS)/“situations”	Andra
	Storyboards	Ondraf/Niras, NUMO
	Timelines/subdivision of time frame	GRS, BfS, NDA, POSIVA, BGR, NRI
	Process reports	SKB
	Subdivision in space	BGR, NDA, POSIVA

Table 13.1: Examples of the tools used to support the main steps or objectives involved in the identification of safety-relevant phenomena and uncertainties *(continued)*

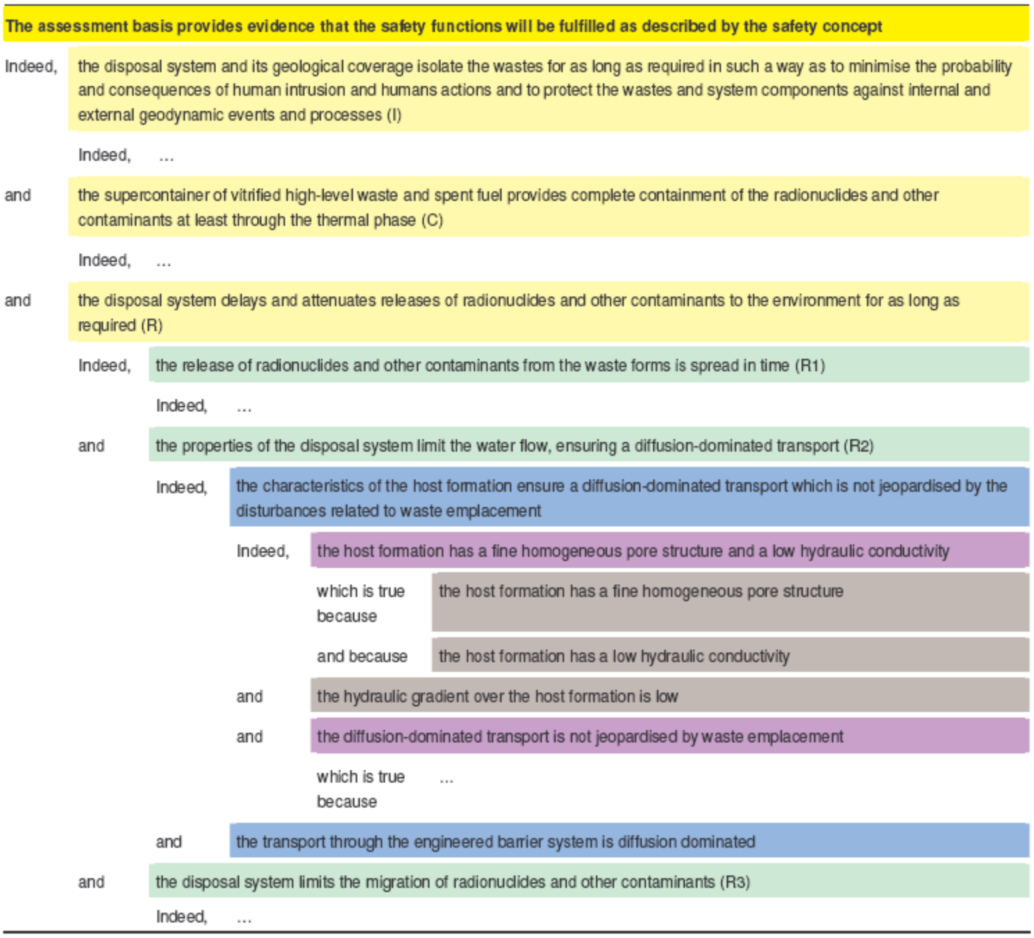
Step/objective	Tool	Organisation
Identifying which uncertainties in the initial state and subsequent evolution are safety relevant	Procedures to address (i) key contributors to the safety functions, (ii) perturbing phenomena and uncertainties, and (iii) system attributes giving robustness to these perturbing phenomena and uncertainties. In the case of Andra, this is termed "qualitative safety analysis (QSA)"	Andra Nagra
	Phenomenological description of disposal system	BfS
	Safety concept / safety statements	Ondraf/Niras
	Safety functions,safety function indicators and criteria, performance targets and associated criteria, FEP charts	SKB, Posiva
	Sensitivity analysis	All
	Function analysis	GRS
	Table and graphics (safety function *vs*. time and component)	NUMO
Ensuring all potentially relevant FEPs taken into account in the above steps	International FEP databases	All

Andra's QSA determines and assesses, component by component and with respect to the safety functions assigned to each, whether or not each identified uncertainty is taken into account either by design or is considered in the normal evolution scenario. If the analyses reveal residual uncertainties that are not taken into account, then it is determined (e.g. by sensitivity analyses) whether their effects are minimal. If not, the analysis may lead to the definition of altered or disturbed evolution scenarios (Andra 2005c).

Examples of the Ondraf/Niras safety statements are shown in Figure 13.6. The statements form a hierarchy, with lower-level statements underpinning those at higher levels. The highest level statements concern the overall safety and feasibility of the proposed system. At the next level down, the safety statements address the safety functions that the system is intended to provide as a function of time. At still lower levels, the statements relate to the safety-relevant properties of the system components, as well as the results of safety analyses. Many statements are, in effect, translations of the requirements that the overall system and its components should fulfil according to the safety concept. The lowest level statements are directly underpinned by phenomenological understanding from the assessment basis.

In the above mentioned methodology presented to the Belgian regulator in 2009, which will be developed further for the planned Safety and Feasibility Case SFC-1 in 2013, the validity of each statement is examined in a systematic uncertainty analysis, whereby the effects of perturbing phenomena and associated uncertainties identified within the assessment basis are considered. Effects on the lowest-level statements are considered first. Any uncertainty that calls into question the validity of low-level statements may also call into question the higher-level statements that the low-level statements underpin. In this way, uncertainties may propagate through the hierarchy of statements, from the bottom up. Any uncertainty propagating as far as safety statements representative of the safety functions of the disposal system gives rise to altered or disturbed evolution scenarios and is, thus, categorised as a scenario uncertainty. Other uncertainties that do not propagate to the highest-level statements concerning the safety functions may nevertheless affect how specific processes are modelled in a given scenario, and how the values are assigned to model parameters. These are, respectively, the model and parameter uncertainties. This methodology is discussed in detail in Ondraf/Niras (2009a, b) and is a clear example of "top-down/bottom-up" approach. The statements themselves are developed from the top down, starting with high-level statements about the system as a whole and the safety functions it provides, and progressing to increasingly detailed lower-level statements. The assessment of the impact of uncertainties on the statements is, however, carried out from the bottom up, beginning with detailed statements underpinned by the assessment basis, and considering if the impact propagates through the hierarchy to higher-level statements.

Figure 13.6: Examples of the hierarchical structure of Ondraf/Niras safety statements (after Ondraf/Niras 2009a)



The assessment basis provides evidence that the safety functions will be fulfilled as described by the safety concept

Indeed, the disposal system and its geological coverage isolate the wastes for as long as required in such a way as to minimise the probability and consequences of human intrusion and humans actions and to protect the wastes and system components against internal and external geodynamic events and processes (I)

Indeed, …

and the supercontainer of vitrified high-level waste and spent fuel provides complete containment of the radionuclides and other contaminants at least through the thermal phase (C)

Indeed, …

and the disposal system delays and attenuates releases of radionuclides and other contaminants to the environment for as long as required (R)

Indeed, the release of radionuclides and other contaminants from the waste forms is spread in time (R1)

Indeed, …

and the properties of the disposal system limit the water flow, ensuring a diffusion-dominated transport (R2)

Indeed, the characteristics of the host formation ensure a diffusion-dominated transport which is not jeopardised by the disturbances related to waste emplacement

Indeed, the host formation has a fine homogeneous pore structure and a low hydraulic conductivity

which is true because the host formation has a fine homogeneous pore structure

and because the host formation has a low hydraulic conductivity

and the hydraulic gradient over the host formation is low

and the diffusion-dominated transport is not jeopardised by waste emplacement

which is true because …

and the transport through the engineered barrier system is diffusion dominated

and the disposal system limits the migration of radionuclides and other contaminants (R3)

Indeed, …

Note: Statements at the same level are given the same colour. Statements directly supported by phenomenological evidence from the assessment basis are shown in grey.

The safety function indicator criteria defined by SKB, and the performance targets and target properties of Posiva, are an important development in that they give, for some safety functions at least, a quantitative test whereby it may determined whether a particular uncertainty needs to be taken into account when analysing performance and safety. As an example, Figure 13.7 shows, as a grey band, the range of buffer densities identified by Posiva as consistent with buffer satisfying its safety functions. Any (uncertain) process or event that could lead to the establishment of buffer densities outside this range needs to be considered further in scenario development and analysis.

In the future, it would be interesting to consider whether criteria related to the performance of key barriers can be defined for disposal systems other than KBS-3, such as the systems and concepts developed by Andra, Ondraf/Niras and Nagra for argillaceous host rocks and those developed in Germany for disposal of HLW and spent fuel in salt (DBE 2008). This might lead to a general approach for developing safety statements that take account of specific uncertainties, which might be regarded as an extension of the approach developed within the Belgian programme for scenario development.

13.5.3 Classification of uncertainties

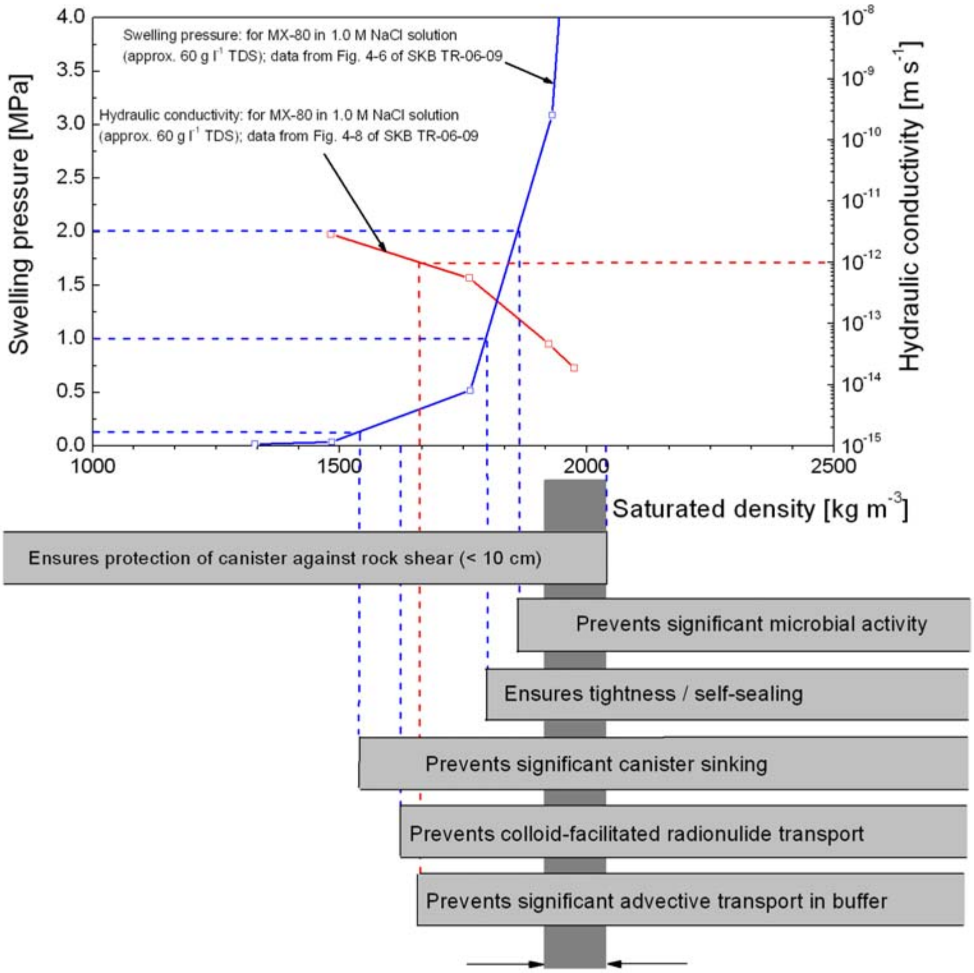
Uncertainties can be classified in a number of different ways. Classification may relate to the impact of uncertainties on the understanding and modelling of the evolution and performance of a disposal system. The division of uncertainties into those that are or are not safety relevant is an example of this type of classification, as is the division of safety-relevant uncertainties into scenario, model and parameter uncertainties (MeSA Issue Paper No. 6 – Mönig *et al.* 2011). This division reflects the typical way of treating uncertainties in safety assessment. In this respect, an usual distinction is made between epistemic and aleatory uncertainties. Epistemic uncertainties are knowledge-based and, therefore, reducible with further effort. Aleatory uncertainties, on the other hand, are random in nature and irreducible. It is generally considered that “scenario” uncertainties contain a larger element of aleatory uncertainty than the two other groups (Crawford and Galson 2009).

The recent development of the tools presented here for analysing system evolution from a phenomenological perspective has made it possible to go further than these restrictive classifications and to consider the uncertainties in the perspective of their causal relationships with the features, processes and events to which they are bound. For example, as well as considering scenario/model/data uncertainties, Ondraf/Niras also categorises uncertainties on the basis of whether they relate to (i) upscaling, which refers to the applicability of the phenomenological data obtained from observations or laboratory experiments over relatively short intervals of space (or time) over the larger scales of interest in safety assessment, (ii) transferability, which refers to the applicability of the phenomenological data representative of the host formation in one location to another location or a larger zone and (iii) evolving conditions, which refer to the impact on the phenomenological data obtained today of phenomena occurring over time that may affect the disposal system, such as phenomena triggered from within the disposal system (for example, the effect of the thermal phase on clay properties) or external events (for example, human intrusion or climate changes).

Similarly, in applying QSA, Andra considered uncertainties related to (a) the input data to the project (waste inventory), (b) the inherent characteristics of the components, (c) processes affecting evolution (including the applicability of models), (d) technological uncertainties, and (e) external events.

This type of classification of uncertainties according to their origin or cause can help, for example, to focus discussions amongst phenomenological experts on how uncertainties might arise and reduce the chance of any significant uncertainties being overlooked. However, uncertainties themselves are often identified and quantified by means of expert judgment, depending to some extent of the amount and the quality of evidence supporting the associated scientific hypothesis. The use of expert judgement in the identification and quantification of uncertainties is discussed at length in MeSA Issue Paper No. 6 (Mönig *et al.* 2011).

Figure 13.7: Schematic illustration of the balance between competing requirements on buffer density. A saturated density in the target range of about 1900 to 2050 kg m-3 should ensure that the buffer fulfills all of the six safety functions identified in the grey bars below the graph (after Figure 6-8 of Posiva 2009)



Range of saturated buffer densities ensuring all density-related performance targets are met (lower bound conservatively rounded up to 1900 kg m^{-3})

13.5.4 Scenario probabilities

Since one of the purposes of scenario development is to explore the space of potential system evolutions, it is sensible to assign qualitative or quantitative statements about their probability or likelihood of occurrence to the scenarios developed. The first and most basic of such assignments is the qualitative categorisation of scenarios or evolutions as "main", "base", "normal", "expected", or "likely" (as opposed to "altered", "disturbed", or "less likely".[4] As discussed in Section 13.6, some regulations require such

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[4] Some safety assessments describe and assess a "reference" scenario. In some instances this is similar in concept to an *expected* or *likely* scenario, but in other cases the *reference* scenario may simply be a convenient scenario or base case (with a near-zero probability of occurrence) from which other (more realistic/likely) scenarios can be derived.

a categorisation. The rationale behind this categorisation is the attempt to identify the way the system should perform (its design basis – "expected evolution") as an important basis for further modelling, but also as a basis for communication to target groups of the safety assessment or safety case. The challenge is the necessity to demonstrate that this evolution is indeed the most likely one, or, correspondingly, that altered evolutions connected with less efficient safety functions are (much) less likely.

Risk-based regulations which allow "compensating" higher calculated consequences for some scenarios by lower probabilities or likelihoods associated to these scenarios might give rise to a more sophisticated, quantitative derivation of scenario probabilities, mostly based on probabilities of initiating or scenario-defining FEPs. Several conceptual questions have to be clarified if such an approach is chosen:

1. Do the probabilities refer to the occurrence of a disruptive event (e.g. a seismic event), or to the existence (or otherwise) of a feature potentially jeopardising safety functions (e.g. an undetected fault or an unidentified mishap related to canister fabrication or to the construction of a geotechnical barrier)?
2. Do they represent a probability per annum (often associated with an event) or one for the whole assessment time frame (e.g. presence or absence of a feature)?
3. If events are considered: can the event occur once (e.g. shaft seal failure) or repeatedly (e.g. seismic events)? In the latter case: what is the impact of such an event occurring more than once?
4. What is the factual basis for assigning probabilities to FEPs?
5. How can it be ensured that an exhaustive set of mutually exclusive scenarios will be addressed in the risk summation?

The answers to the first three of these questions have an impact on how safety indicators such as annual risk or mean dose per annum have to be calculated: as discussed e.g. in DOE (2009) for scenarios initiated by events, the calculation requires integration of the consequence for each event multiplied by the probability density function for the event occurrence over the space of events. If a probability per annum can be quantified for "reasonably similar" events (e.g. for seismic events of a certain magnitude), the integral can be simplified to a sum of the (usually time-dependent) consequences resulting from the event occurring in each year, weighed with the annual probability. More generally, Monte Carlo simulations can be performed by sampling the time (and perhaps other characteristics such as magnitude) of the initiating event according to the distribution law assumed for this time and then calculating the consequence resulting from this event. The "simulation" approach referred to in Section 13.2.1 and discussed in (Röhlig and Plischke 2009) is based on this idea.

If noteworthy consequences only occur for a time frame which is relatively small compared to the assessment time frame, this might result in so-called "risk dilution". This effect is caused by the fact that the dose per annum to a hypothetical individual living at a certain time in the future is strongly dependent on the point in time assumed for the initiating event. Averaging over these points in time (i.e. calculating the mean, its peak over time then being the "peak of the mean") then results in a relatively low mean dose calculated for that individual although all conceivable pathways to this individual (the "victim's perspective" according to Baltes and Röhlig 2004) have been considered. The low mean dose is calculated due to the fact that doses for a large number of potentially exposed individuals living at different times were averaged, many of which being low or perhaps zero, but some possibly being rather high. Taking, however, the "culprit's perspective" (i.e. "taking the position that an implementer wants to avoid any harm no matter when it might occur", Baltes and Röhlig 2004) leads to considering total (instead of annual) scenario probabilities or to calculating the peak consequence over time for each simulation run and to average over these peak values ("mean of the peaks"). However, some argue that this value "is more difficult to interpret" than the "peak of the means" (SKB 2006a). Risk dilution might, more generally, occur for several reasons when averaging over uncertain quantities. Wilmot and Robinson (2004) mention, besides of event timing (as described above), also spatial effects, ignoring parameter correlation, and inappropriately biased parameter distributions. Paradoxically, these causes might lead to situations in which calculated risk is decreased when the assumed input uncertainty increases. Risk dilution can be addressed by e.g. comparing "peak of the mean" with "mean of the peaks" values and by a disaggregated presentation of calculation results (presentation of dose curves, empirical distributions, percentiles, etc.).

The fourth of the above questions is fundamental: factual bases for estimating scenario probabilities are rather rare. Conceivable possibilities include earthquake statistics (transferability to different time frames to be taken into account), detection accuracies for scenario-initiating features or statistics based on manufacturing practises. For example, destructive testing of sample canisters might indicate how many defective canisters will remain undetected by non-destructive testing which will later take place as part of the QA to be undertaken during canister production. Another example is that known resolutions of geophysical methods can give rise to estimating probabilities of undetected faults.

An interesting example of combining more than one of these methods can be found in the Swedish assessment SR-Can (SKB 2006a). The probabilities for canister failure initiated by a shear movement along a fracture intersecting the emplacement borehole and initiated by an earthquake are derived based on earthquake probabilities, fracture detection probabilities and probabilities for fractures intersecting canisters.

In many cases, however, scenario probabilities are derived on the basis of expert judgement, the probabilities then representing a degree of belief that the scenario might occur. Further information on such use of expert judgement is given in MeSA Paper No. 6 (Mönig *et al.* 2011).

In summary Galson *et al.* 2009 identify the following possibilities for deriving FEP or scenario probabilities:

- "derivation from observations of past events and existing conditions;
- sampling a model of the physical system using Monte Carlo simulations;
- use of a probability model (e.g. Poisson);
- use of expert judgement …ideally through a well-developed expert elicitation process, particularly where data are scarce or where safety case results depend strongly on probability."

Faced with difficulties connected with these options, organisations sometimes simply chose to overestimate the probabilities by applying a value of one [e.g. SKB (2006a) for scenarios other than the canister shear failure scenario]. As long as consequences are sufficiently low, numerical compliance can still be ensured without taking advantage of weighing high consequences against low probabilities. It should be acknowledged, though, that in such cases the decomposition of the calculated overall risk into its components coming from different scenarios and their comparison has little or no meaning since only the consequences are addressed but not their likelihoods.

13.5.5 Use of FEPs and FEP databases

Project-specific FEP databases as well as the NEA FEP database have proved to be valuable tools, especially for programmes that are in the early stages of repository planning. In particular, they can support the development of a first description of the system. When a programme matures and THMCGRB understanding evolves, the knowledge to be managed and documented will go far beyond the capacity of simple FEP records (cf. Section 13.4). It will then become necessary to supplement FEP databases with other tools and means for documentation. Often, THMCGRB understanding and knowledge is compiled in extensive process reports (cf. the SKB example below). Interactions of FEPs and their influence on safety functions are examined using a number of tools (cf. Table 13.1), some of which (as well as content of process reports) might be electronically linked to the FEP databases.

The role of FEP databases for more advanced programmes has been discussed in the course of the INTESC project. It was concluded that:

> "FEP lists or FEP databases (such as the international FEP database compiled by NEA) 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." (NEA 2009c)

Nonetheless, some advanced programmes attach more significance to FEPs than simply completeness checking. In this context, it is important to distinguish between FEP catalogues or key safety-relevant phenomena derived from an integrated understanding of the system under consideration, which can have a central role in scenario development, and the more general NEA FEP database, which is increasingly used for completeness of comprehensiveness checking (see e.g. Figure 13.7).

The handling of FEPs in the methodology applied in SKB's SR-Can safety assessment is shown in Figure 13.8. The FEPs in the yellow boxes constitute the SR-Can FEP catalogue. The starting points are FEPs in i) the SKB interaction matrices, ii) the SR 97 Process Report, and iii) the NEA international FEP database with a number of national data bases linked to it. FEPs were sorted into three main categories: i) initial state, ii) process FEPs, and iii) external FEPs. FEPs were also categorised as irrelevant or as being related to methodology at a general level. Process FEPs are used to support the documentation of processes in the SR-Can process reports, including a description of uncertainties, some of which could affect the safety functions and, thus, also need to be handled in scenario selection. The reference initial state, the identified long-term processes and a reference external evolution is used to define a reference evolution for the repository system. This evolution is an important basis for defining a comprehensive main scenario. A set of additional scenarios addresses deviations from the reference initial state and from the reference external evolution, as well as situations related to future human actions. Thus, although the NEA FEP database is used to ensure that the system-specific SR-Can FEP catalogue is complete, the SR-Can FEP catalogue itself, is rather fundamental to the identification of the main scenario and of important uncertainties and deviations leading to additional scenarios.

As another example, the Nagra approach, which is shown in Figure 13.9, is somewhat different to that of SKB. Here, the system description is decomposed into a set of "key safety-relevant phenomena", which includes perturbing phenomena and uncertainties. These are then considered in terms of their potential impacts on the safety functions in order to derive scenarios and assessment cases. The system-specific FEP database – which is checked for completeness against the NEA FEP database – is used in turn to check that the set of key safety-relevant phenomena is complete. Thus, in this case, although both the NEA FEP database and the system-specific FEP database are used for completeness checking, the system-specific FEP database maps onto the set of key safety-relevant phenomena, and these have a central role in scenario development.

In spite of its proven usefulness, some significant shortcomings in the NEA FEP database have been identified. These include its content (e.g. lack of FEPs related to the presence of concrete in the repository – cf. NEA 2011), structure (lack of balance in the level of detail of the descriptions of FEPs, lack of flexibility concerning FEP characterisations going beyond the rather simplistic IFEP records) and context (lack of explanation of possible uses). Developing the NEA database further and addressing its shortcomings would require a commitment of resources from the more advanced programmes and from the NEA, e.g. to feed information from programme-specific databases into the NEA FEP database. Nevertheless, an enhanced NEA FEP database would be valuable to all programmes, especially those at early stages, and would represent a knowledge transfer from more advanced programmes to less advanced ones.

In addition to considering improvements to the NEA FEP database, it is further recommended that the role of FEP databases is further elaborated in future methodological developments. As evidenced in the MeSA survey on scenario development, some programmes establish explicit (ISIBEL, NRI, Posiva) or implicit (Nirex-NDA) links between FEP databases and safety functions. Some waste management organisations are using or developing requirements management systems for this purpose (e.g. NEA 2004c). Other options for FEP databases include entries for recording expert judgements or for addressing FEP interactions, sometimes by establishing linkages to other software tools.

Figure 13.8: The handling of FEPs in SR-Can, after Figure 3-2 of SKB 2006a

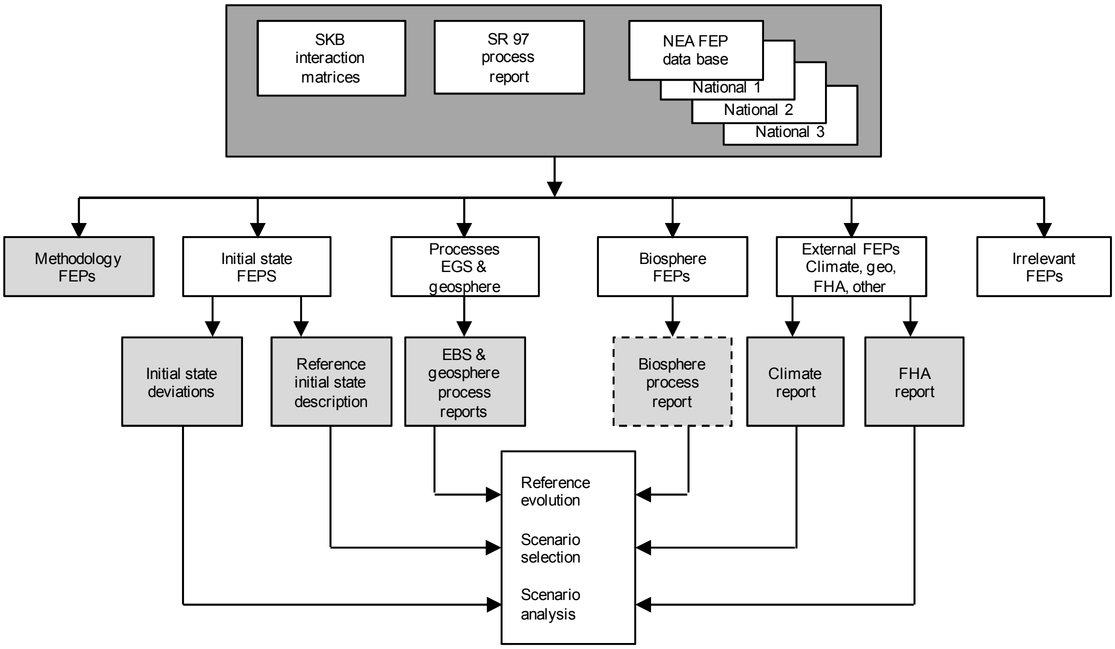
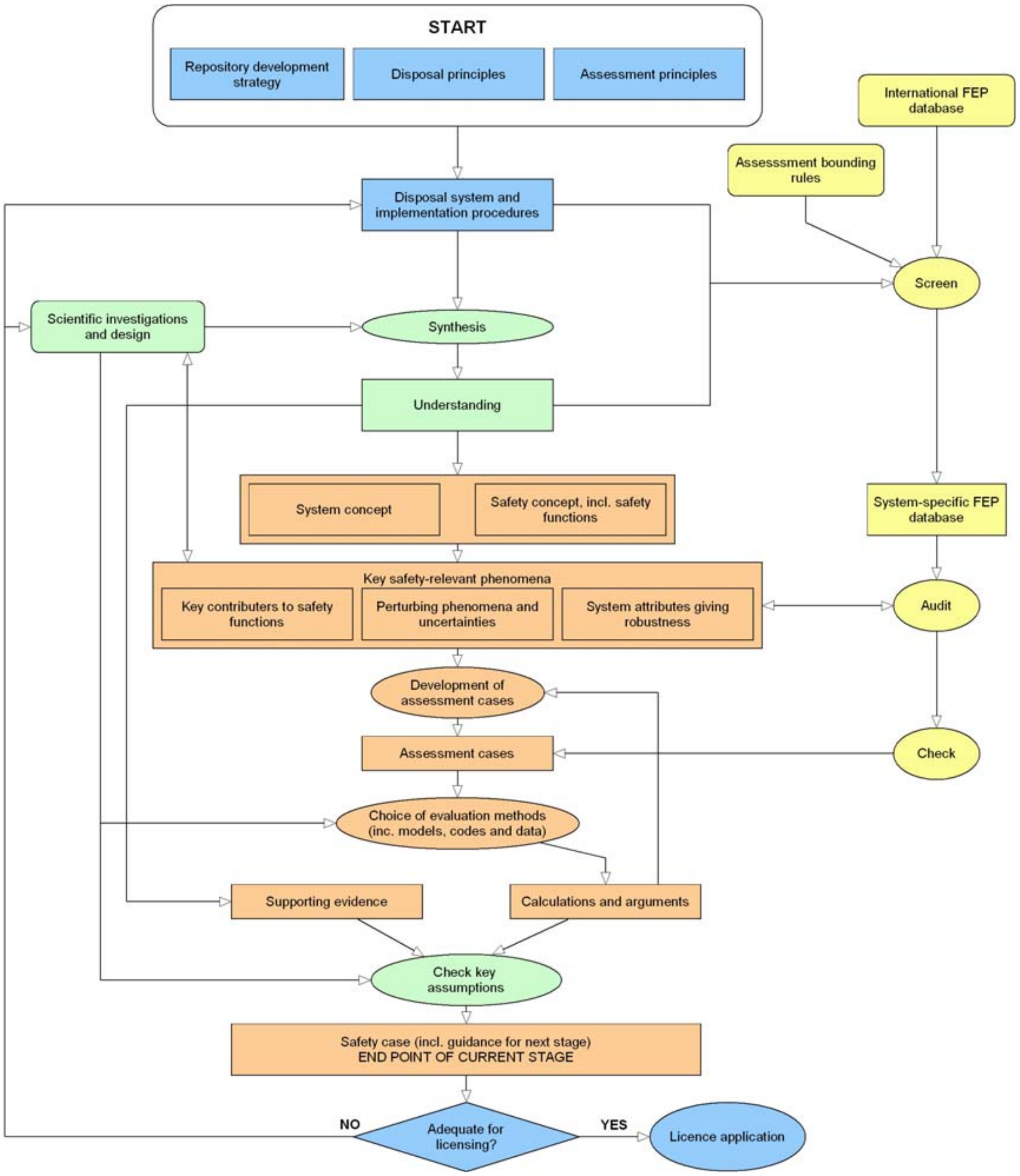


Figure 13.9: The current Nagra concept for steps undertaken and products obtained in the course of a safety assessment and the production of a safety case



13.6 The regulator's perspective

As emphasised at several places in the previous sections, regulations, regulatory guidance, and expectations of the regulator with regard to safety assessments have a significant impact on the issues dealt with in this paper. Regulatory issues in connection with safety assessments in general are the subject of MeSA Issue Paper No. 7 (Navarro *et al.* 2011). This section makes a number of points on regulatory aspects relevant to system description and scenarios, often by summarising, reiterating and discussing points made in (MeSA Issue Paper No. 7 – Navarro *et al.* 2011):

- A comprehensive system description is (explicitly or implicitly) required in most if not all regulations. One focus of a regulatory review will be scrutiny of this description and its elements, including checking the factual basis of data, assumptions and models used in safety assessments. Details about this issue, including regulatory expectations concerning the systematics, clarity, and traceability of the system description, can be found in (Navarro *et al.* 2011).
- Detailed requirements concerning the role of system components and/or the means and approaches to characterise them are not often found in regulations. "Most national regulations require that the repository system implements defence-in-depth by using multiple, diverse, and reasonably robust barriers or functions. A proponent may choose any way of implementing such a concept, and this should be part of the system description" (MeSA Issue Paper No. 7 – Navarro *et al.* 2011). It should, however, be noted, that some regulations go a step further by specifying requirements concerning the performance of subsystems, e.g. with respect to container lifetimes or the performance of the geological barrier (BMU 2009, ASN 2008). Such requirements have, of course, an impact on the safety assessment methodology in general and on the system description in particular.
- Concerning the use of safety functions and function indicators, MeSA Issue Paper No. 7 (Navarro *et al.* 2010) states that regulations do not "specify any target values for the safety indicators. The main reason for this is that such specification on the part of the regulator can hinder the development of an optimal system which a proponent should be free to develop based on available technology."
- In many cases, regulation or regulatory guidance addresses scenario classification. For example, Swedish guidance distinguishes a "main scenario, less probable scenarios, other scenarios or residual scenarios" (SKI 2002). BMU 2010 requires the assessment of "likely evolutions", "less likely evolutions", "unlikely evolutions", and "unintentional intrusion", for each of which advice concerning their role with regard to system optimisation and assessment is given. Similar approaches related to likelihood or plausibility but varying in detail and terminology can be found in other regulations.
- It has to be noted that the scenarios called "central", "main", "likely", or "expected" are the ones defining the design basis for the repository. This implies that an implementer has to demonstrate that the "expected" scenario (i.e. the way the system should perform) is also the most "likely" one.
- The examples of the SKI and BMU guidance show that regulatory expectations on scenario classification are often linked to numerical criteria for safety indicators: the SKI guidance (SKI 2002) specifies that residual scenarios are not to be included in the risk calculation,[5] while the BMU requirements specify different numerical criteria for the likely and the less likely evolutions. As pointed out in MeSA Issue Paper No. 7 – (Navarro *et al.* 2011), requirements or guidance on scenario classification is also dependent on the guidance (or otherwise) concerning the use of deterministic or probabilistic methods. Human intrusion scenarios are (with the exception of the WIPP regulation) to be treated separately.
- Regulators commonly expect that "scenarios are described, developed and treated in a systematic way" which is "traceable, structured and transparent" (Navarro *et al.* 2011). According to Navarro *et al.* 2011, regulators "may provide

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[5] On 1 July 2008 the Swedish Nuclear Power Inspectorate (SKI) and the Swedish Radiation Protection Authority (SSI) were merged within the Swedish Radiation Safety Authority *(Strålsäkerhetsmyndigheten)* (SSM), which is now the body in Sweden that issues and uses guidance on radioactive waste disposal.

guidance on the steps to be followed to develop scenarios or require reporting on how one or several methods have been used to identify and describe relevant scenarios for sequences of events and conditions that can affect the future evolution of the repository." In practice, however, the former ("guidance on the steps") is not often the case, while the latter ("require reporting …") is usual regulatory practice. A regulation which indeed specifies steps of scenario development is the French one (ASN 2008) which names:

  - the identification of events;
  - their classification with regard to their probability and origin;
  - the identification of "situations" resulting from events or their combination;
  - their grouping into families;
  - the selection of a reference situation, representative of "likely" events, or "altered situations" representative of less likely events.

- In addition, the French regulation provides guidance on the subdivision into time frames to be considered in the assessment.
- Some regulations specify FEPs which should at least be accounted for when developing scenarios. For example, SSI regulation (SSI 1998) requires that climate variants are addressed. French regulation (ASN 2008) is rather specific when considering this issue by naming the FEPs to be addressed, i.e. climatic changes, subsidence, uplift, diapirism, magmatic activity, meteorite impact, and, as human-induced events, drilling, mining, cavern solution, surface or subsurface constructions as well as deficiencies concerning the engineered components.
- Navarro *et al.* (2011) note that further differences in regulatory approaches exist with respect to the estimation of scenario probabilities and to the issue of stylisation.
- Navarro *et al.* (2011) hint to a deficiency which is apparently common to a number of assessments: "several regulators have underlined in their reviews the insufficient depth of scenario and uncertainty analysis (OECD 2000). This was motivated by the opinion that certain selected scenarios were often addressed in great depth and rigour but that insufficient attention was given to fully exploring the range of scenarios that might occur."

13.7 Conclusions

While the 1991 brochure (NEA 1991) describes scenario development as "the starting point for safety assessments … concerned with defining the broad range of possible futures to be considered in the subsequent modelling and consequence calculations", its present role in safety assessments is somewhat more complex. Scenario development requires a thorough system description which, in turn, establishes the links to safety case elements, such as site investigation and R&D results, engineering issues, and waste characterisation. Scenarios are important since they are the means to test whether the disposal system will be able to perform appropriately, assuming a range of possible conditions and evolutions. Put the other way round, the rationale behind designing a disposal system is enabling it to respond appropriately to possible future evolutions, i.e. to scenarios. System description and scenario development are, thus, not simple sequential activities but, in contrast, require iteration in the frame of safety assessment and the safety case. Modelling, especially at the process level, is no longer just an activity that follows scenario identification and description, but is rather a part of such iteration.

Basic requirements on scenario development (and system description) mentioned in the 1991 brochure such as logic, consistency, clarity, traceable documentation of decisions, comprehensiveness, flexibility within an iterative assessment, and involvement of multiple disciplines are still valid. Approaches to achieve these goals, however, have evolved considerably since 1991. Up to now, national organisations have developed a variety of approaches and tools to serve these purposes. Due to differences in safety concepts, regulations, traditions, and perhaps personal attitudes, the approaches used show, at least at a first glance, considerable variation. Only after a closer examination are the commonalities visible.

As already concluded at an NEA workshop on scenario development held in 1999 (NEA 2001), completeness of the scenarios considered in the literal sense of the word is "neither achievable nor necessary". It is, however, possible and necessary to achieve comprehensiveness in the sense that uncertainties concerning the performance of barriers and the fulfilment of safety functions are identified and appropriately addressed in the safety assessment.

Over the last decade or more, organisations have developed large acquisition programmes that have allowed the production of extensive lists and descriptions of data and phenomena concerning the characteristics of the repository and its constituent parts. Tools for system description include means to address geoscientific issues (geosynthesis, site descriptive models), but also more general tools describing THMCGRB phenomena based on discretisation in space and time (story boards, PARS). Other, sometimes computer-based tools and methods are in place to address the interaction of phenomena and to identify safety-relevant uncertainties (matrices, diagrams, tree structures).

The perhaps most striking recent development is the one "of new conceptual tools such as safety functions, which embody key aspects of performance of the geological disposal system from which can be developed internal requirements that relate the ability of the disposal system to fulfil these functions, thus making more transparent the role of the various components (and their synergies in the disposal concept)" (NEA 2009c). At least in some programmes, the role of safety functions goes beyond their use in safety assessments. Rather, they provide a link between activities important for repository development and safety case building (NEA 2004c; MeSA Paper No. 1 – Van Luik *et al.* 2011; MeSA Paper No. 2 – Schneider *et al.* 2011). Naturally, the role of safety functions in safety assessment is strongly linked to the question of system description and scenario development. Often, contemporary scenario development is referred to as mostly relying on safety functions ("top-down" approaches as opposed to the FEP-based "bottom-up" approaches), thus implying a decreasing role of FEPs, at least in advanced programmes. Both are sometimes seen as alternatives, but actually either of them is hard to imagine without the other. The authors of this paper believe that contemporary "top-down" approaches to scenario development are, in fact, better described as "top-down/bottom-up". A survey undertaken within the MeSA project also showed a tendency to formally link the two in hybrid approaches.

The authors further believe that – despite of some deficiencies – FEP databases, including the NEA FEP database, still have a value in repository development programmes. Especially in mature programmes such databases will tend to be supplemented with, and perhaps coupled to, the tools and methods mentioned above which address complex, often coupled THMCGRB processes and their influence on safety functions.

A relatively recent development is the one of safety function indicators which are being used as a tool to consider the relevance of phenomena and uncertainties for safety. Such indicators might have the potential for use in the context of host rocks and concepts other than granite and the KBS-3 concept for which they were developed.

Undoubtedly, expert judgement plays a central role when describing the system and deriving scenarios. In the future, it could also be interesting to examine guidelines for expert involvement further, and also to determine whether a more formal approach to expert judgement is warranted for safety assessment and in particular for system description and scenario derivation.

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Annex 13.A

NEA MeSA project: Template for describing formal methods addressing system and process description, FEP processing and scenario development methodologies in national programmes/projects

When filling in the template, please strive for completeness but do not artificially populate all entries if information is already available elsewhere in the document. If appropriate work with cross-references ("information provided under entry x.y") or state "obsolete because …".

General

Project/report(s) name, date:
Purpose(s) of project (in particular w.r.t. programme stage and disposal concept):
Relevant features of regulatory background:

System and process description, including FEP processing

Regulatory background (if any):
Origin of FEP database:
Structure of FEP records
Handling of FEP interactions:
Handling of evolution in time and system subdivision in space:

(Andra's PARS/APSS, although also serving other purposes, as typical example of what is meant by this entry)

Other formal tools/ ethods:
Role of FEPs when deriving scenarios:

Handling of safety functions, statements, or related concepts

Regulatory background (if any):
"Top-level" safety functions:
Methods and tools for deriving "lower-level" safety functions:
Role of safety functions when deriving scenarios:

Scenario development

Regulatory background (if any):
Types, groups, or classes of scenarios derived (e.g. reference/main/likely/expected scenario vs. residual/less likely scenarios, what-if scenarios etc.)
Steps when deriving scenarios
Formal tools for scenario development (if any)
Handling of scenario probabilities (likelihoods of occurrence).

14. Modelling strategy

P. Gierszewski,[A] L. Bailey,[B] U. Noseck[C] and J. Wollrath[D]

Abstract

The safety assessment modelling strategy is the approach to developing and applying models to assess quantitatively the potential performance and safety of a given repository system. The strategy must provide models that can address the key features events and processes relevant to safety over spatial scales up to kilometres and over a timescale of several hundred thousand years.

Over the past 20 years, there have been significant advances in scientific understanding. Along with increased computer power, this knowledge has resulted in a trend towards a more detailed description of processes on a mechanistic level and greater inclusion of coupled processes. System-level models still continue to require simplifications in processes or geometry, although not as much as before. The corresponding increase in model complexity and model input data has not been a limiting factor in their use. There is greater emphasis on accompanying these more complex models with simple models to help interpret the results.

Overall, there is wide consensus on the overall approach to modelling, and no major areas of disagreement have been identified. Certain topics continue to need attention within a specific site modelling strategy, such as the balance between process models and system-level models, and model validation. However these are well-understood topics and the solutions are generally site- and programme-specific.

Keywords: Safety assessment, safety case, geological repository, radioactive waste, disposal.

14.1 Introduction

To assess the influence of a deep geological repository on humans and the environment, a spatial domain up to several kilometres and a timescale over several hundred thousand years usually have to be considered. A wide range of features, events and processes (FEPs) are potentially relevant over this wide range of space and timescales. Therefore, an assessment of the performance of a repository can only be undertaken by

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simulation of the potential evolution of the repository system using mathematical or numerical models.

The safety assessment (SA) modelling strategy is the approach to developing and applying models to assess quantitatively the potential performance and safety of a given repository system. The purpose of this paper is to review current trends and issues in modelling strategy. It is part of the NEA Methods for Safety Assessment (MeSA) project.

14.2 Methodology

14.2.1 Previous reviews

In the 1991 NEA Review of Safety Assessment Methods (NEA 1991), it was concluded that there was wide consensus on the general approach to safety assessment. This has been reflected, for example, in the IAEA Safety Requirements for Geological Disposal of Radioactive Waste (IAEA 2006).

The 1991 NEA review also noted that modelling is an essential part of the safety assessment process, and noted the following issues related to modelling strategy:

- interdependence between model development and the corresponding effort to gather data;
- coupling of models for specific processes into larger integrated models, and their simplification into practical tools for safety assessments;
- the importance of treating transient phenomena;
- the linkage between field measurements and model parameters;
- our limited ability to validate models for processes that occur slowly over long time frames;
- balancing the increased capacity to conduct complex assessments and the capability to maintain perspective and understand the results.

The EC PAMINA project included a review of modelling strategies. The main conclusions of this review were (PAMINA 2009):

- Two types of models are used: integrated models used to perform consequence analyses for selected scenarios and detailed models used to characterise the evolution of sub-systems or to generate input data for the integrated models. In this paper the integrated models are also referred to as system-level models and the detailed models are also referred to as process-level models.
- Deterministic and probabilistic calculations are seen as complementary by most organisations.
- Simplifications are always made when modelling a complex system, such as a geological repository for radioactive wastes.
- Validation and verification of the models used in the safety assessment are considered very important topics. In this paper these topics are discussed under the term model qualification.
- The whole process of model generation must be undertaken following appropriate QA procedures and be properly documented, including the decisions taken during the generation of the model and the simplifications done.

14.2.2 Paper outline

This paper is organised into the following topics:

- summary of the types of models;
- description of process-level models;
- description of system-level models;
- advances in tools;
- data selection;
- model qualification;
- conclusions.

14.3 Types of models and modelling strategy

The purpose of modelling is to provide an understanding or demonstration of the behaviour of some or all of the repository system.

14.3.1 Model development stages

The development of a model involves four main stages:

- derivation of a conceptual model;
- formulation of the accompanying mathematical model;
- transfer of the mathematical model into a numerical model; and
- qualification of the model.

Conceptual models consist of qualitative statements that define the key processes and inter-relationships to be considered. They are derived from an understanding of how the repository system or parts of it might function and evolve, and may include important simplifications. Conceptual models are typically described in words, or block diagrams, or interaction matrices.

Mathematical models are comprised of mathematical equations that define the processes and relationships outlined in a conceptual model. The formation of the mathematical models identifies the specific parameters in the models, and therefore the data needs.

Numerical models are the representation of the mathematical equations in computer codes. Numerical models can range from simple codes such as Excel spreadsheets, to custom-designed sophisticated codes, such as finite-element codes.

Model qualification is the demonstration that the model is fit for the given purpose and generates reliable results.

In practice, these stages are iterative. The models usually become more detailed over time as more data and understanding become available and additional needs are identified.

14.3.2 Model types

In repository safety assessments, modelling is used for a variety of purposes. The models used in safety assessment can generally be classified due to their level of detail of representation of processes, and their overall level of integration. Although nomenclature is not harmonised internationally, in many safety assessments at least two levels of models are distinguished:

- process-level models,
- integrated or system-level models.

Process-level models tend to include more explicit and detailed treatments of a few specific physical and chemical processes. They are often used for research purposes and to derive input for system-level modelling. In the latter case, the process-level model may either produce input parameters for the system-level model, or it may lead to the development of simplified conceptual models that are incorporated into the system-level model. Within this group of models, a distinction is sometimes made between process models, which focus on a particular single process of interest, and component or subsystem-level models, which consider several (coupled) processes in a specific part of the repository system. The application of process-level models may be limited to a certain time window, e.g. the thermal phase in which coupled thermo-hydro-mechanical effects play the major role.

Integrated or system-level models are used to describe the entire repository system and – in comparison to process-level models – tend to include simplified representations of the effects of a wider range of features, events and processes. These typically include models for the near-field (e.g. water intrusion/saturation of the repository, degradation of the waste, radionuclide mobilisation), the far-field or geosphere [e.g. radionuclide transport through the geological formation(s)], and the biosphere (e.g. exposure pathways), leading to a quantitative estimate of potential impact on humans and the environment. System-level models usually cover the entire assessment time frame.

In addition, a third class of models is used in many assessments, namely simple models that can be summarised in a few fairly transparent mathematical equations. Simple models include only the main processes and give rough estimates of the results in question. Simple models can be used to show that particular processes are not important and need not be included in a system-level model, or conversely may be used to provide confidence in complex models by showing that the results can be largely explained as due to a few relatively simple processes. This has led to some programmes using the term “insight models” for these simple models. For example, “insight” models were used in the Swiss Entsorgungsnachweis (NAGRA 2002a); and in the UK (Nirex 1997) assessment to explain expected peak risks from the repository system. Simple models may also be used to provide conservative bounding results.

14.3.3 *Approach*

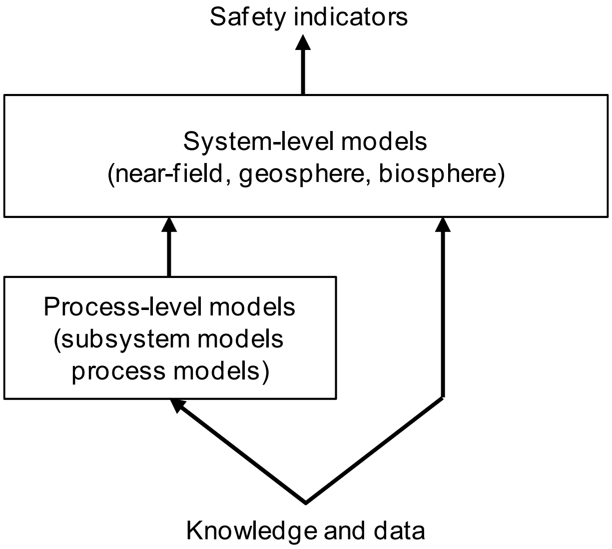
A generalised approach for the use of the different kinds of models in a safety assessment, which of course does not cover all details nor all repository programmes, is illustrated in Figure 14.1. At the bottom of the figure all the necessary data for the safety assessment are depicted. Most of the data are not directly used in the system-level models but are interpreted by process-level models. The lowest hierarchy of models deals with single processes. Above these process models are the group of component or subsystem models. Both belong to the group of process-level models, which generate input data and aid the development of conceptual models incorporated in integrated or system-level models. They may also be used to calculate indicators demonstrating the performance of the respective component or subsystem or how efficiently it contributes to fulfilling a specific safety function (performance or safety function indicators; cf. MeSA Issue Paper No. 5 – Noseck *et al.* 2011).

At the highest level are the integrated or system-level models, which simulate the entire repository system and quantify consequences by calculating indicators for safety, such as radiological risk, dose or another kind of safety indicator (cf. MeSA Issue Paper No. 5 –

Noseck *et al.* 2011). In addition, simple analytical models might be used at each modelling level.

The development of a safe repository and the demonstration of its safety is a stepwise process that can take several decades from the initial stages to final closure of the repository. The development of appropriate models is a fundamental part of the safety assessment and it is also undertaken following a stepwise approach. At the early stages of repository development, simplified and general models and generic data are commonly used, but at later stages, in particular when a site becomes available, site-specific information and data and correspondingly more sophisticated models will be used to describe the repository performance more accurately. At every stage there is the need to balance the complexity of the model with the available data and understanding.

Figure 14.1: Hierarchy of models used in a safety assessment



14.4 Process-level modelling

Process-level models are developed in order to gain a solid understanding of some aspect of the repository system. This includes identifying the parameters and processes governing the performance of specific repository components, to evaluate the performance of these components, or to identify critical uncertainties. These models are very important to the safety assessment since they represent our best understanding of the processes. In many cases these process-level models form the basis for conceptual models incorporated into, and parameters used in, system-level models.

Process-level models may also help provide justification for simplifications, notably reduction in dimensionality of processes incorporated in system-level models. A typical example is the application of a 3-D finite-element groundwater flow and transport model to develop or justify the use of 1-D or compartment models to describe the geosphere contaminant transport in system-level models.

Over the past 20 years, an increasingly important role of process-level models has arisen in the treatment of process couplings and in transient phenomena. Typically, in their early stages waste disposal programmes developed models for individual processes; more recently models that include couplings have been developed. This reflects both increased knowledge as well as increased computer capabilities. Within this context, today THMC models are increasingly being applied to consider temperature, hydraulic, mechanical, and chemical processes and their interactions (e.g. NEA 2007). Due to the complexity of the investigated processes and their limitation of relevance in time, process-level models are often applied for a certain time window of the overall assessment time frame.

One important example is the process of bentonite re-saturation, where the hydration leads to changes in pore water chemistry that in turn affect the mechanical and hydraulic properties of the buffer and the heat transfer. During the last decade a number of commercial codes such as "FLAC" (Itasca 2006) or "Code Bright" (UPC 2008) as well as custom codes have been developed or adapted to these problems.

The application of process-level models increases the understanding of such processes; and often enables the derivation or better justification of simpler models for integrated and system-level models. This kind of abstraction might, for example, take advantage of the reduction in thermal gradients after the early post-closure period such that models for the far future need not consider all the THMC interactions.

In summary, process-level models are essential and widely used as part of a modelling strategy. The major developments in the past 20 years have been in the increasing sophistication of some of these models, and a trend towards greater inclusion of coupled processes. These trends are likely to continue.

14.5 Integrated or system-level modelling

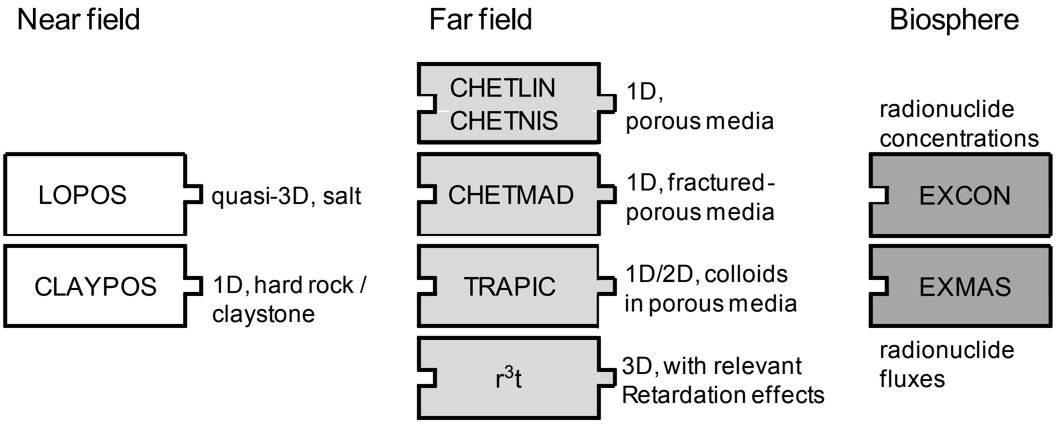
The central part of the safety assessment is the integrated or system-level model, which is used to assess the performance of the disposal system as a whole and to evaluate its potential environmental impact through performance measures such as dose for the whole assessment time frame. Another important role of safety assessment is to provide information and feedback on the design of the repository and the engineered barrier system (e.g. EC/NEA 2010).

The system-level model describes the evolution of, and the radionuclide transport through, the entire repository system. For modelling, the repository system is usually divided into three different components: the near field, the far field and the biosphere.

This classification has been used for several decades and is still valid for many safety assessments. Usually each institution performing safety assessments has developed and applied its own tool for system-level modelling, which has been further developed with each step in the disposal programme. A safety assessment typically uses one main system-level safety assessment code, while there are likely to be several process-level codes. However, for example, for the safety assessment for the closure of the Morsleben repository in Germany (Wollrath *et al.* 2008), two system-level codes were applied independently to enhance the confidence in the calculated results.

An example of a system-level model is given in Figure 14.2 showing the structure of the program EMOS that is used for integrated performance assessment calculations in Germany (Buhmann *et al.* 2000). It consists of optional modules for the three components (near-field, far-field and biosphere) that can be joined together for an overall system analysis.

Figure 14.2: Programme EMOS with modules for the different components



The safety assessment is usually performed for a set of scenarios, which have been defined by a systematic scenario development and selection (See MeSA Issue Paper No. 2 – Schneider *et al.* 2011). For each selected scenario, a suitable system-level model has to be applied – this could be the main system model if sufficiently flexible, or additional scenario-specific system models.

When modelling a complex system such as a deep geological repository, simplifications are unavoidable. This simplification of process models into a system model has important consequences in terms of the level of conservatism and representativeness of the modelling results. Consequently it was noted in the 1991 SA review as a key element of the modelling strategy (NEA 1991). It continues to be so today.

A first type of simplification is introduced when the results of process-level models are converted into system-level model inputs. At this stage, the modeller needs to address which are the essential processes that dominate the system evolution or the transport mechanisms, and on the other hand, which processes can be neglected because they have a negligible (or a limited positive) influence on the performance of the repository system. For example, in some cases advective transport in a clay formation could be neglected in comparison to diffusive transport. Or, for example, solubility limits in the geosphere are often neglected.

A second type of simplification can be introduced at the stage of developing numerical models. For example, the existence of symmetry planes allows a reduction of the modelled domain.

A third type of simplification is often needed to overcome limitations in the features presently available in computer codes or in the calculation capacity of the computers. As three-dimensional computer codes often require excessive calculation times, the real problem is frequently approximated by 2-D or 1-D models. The availability of more powerful computers in recent years has to some extent reduced the need to use such simplifications in deterministic calculations. However, the desire to include more processes, as well as to conduct probabilistic calculations, means that there is still a need for simplifications.

Integrated assessment calculations can be carried out in two principally different ways. A deterministic analysis is a calculation performed with a single set of parameters, and may provide a best estimate, conservative or extreme estimate (e.g. what-if cases) of system performance. In a stochastic or probabilistic analysis, some or all relevant parameters are varied to quantify the potential impacts associated with uncertainties in their values.

Since the 1991 review, there has been an emerging consensus on the use of deterministic and probabilistic approaches. In most safety analyses, deterministic and probabilistic calculations are now seen as complementary and both approaches are applied. Deterministic calculations are more appropriate for detailed calculations and communication purposes. Probabilistic calculations are especially appropriate to deal with parameter uncertainty. Stochastic sensitivity analyses can provide much information on the key parameters controlling the repository system behaviour. A more detailed discussion on the role of deterministic and probabilistic calculations can be found in MeSA Issue Paper No. 6 (Mönig *et al.* 2011).

Significant differences exist between countries regarding the extent to which regulations allow simplified handling of the biosphere in the safety assessment. Some regulations provide specific guidance, for example, by prescribing stylised approaches for converting geosphere releases into dose, defining how to handle future climate changes, and how to address potential changes in future human behaviour. Therefore biosphere modelling varies to a large extent. In many system-level models, dose conversion factors are used, which have been derived from biosphere process-level models and provide a simple way to convert radionuclide fluxes or concentrations into dose. Other system-level models implement a full biosphere model, describing radionuclide transfer between different compartments. The use of evolving landscape models is relatively recent, at least with respect to system-level models, and its utility remains to be fully explored.

There is a clear trend that models are getting more complex, due to both more powerful computers and our improved understanding of the processes. During the 1991 review, one issue identified was the balance between more complete but also complex models, and our ability to understand the results. This issue remains. However, in general the use of more complex models does not seem to have hurt our ability to understand the results. Possibly this is in part because the greater complexity is balanced by the greater completeness of the model, which in itself eliminated some uncertainty over the results. This is probably most noticeable with the better representation of geometry in more complete models.

This greater complexity also can be balanced by the use of simple models, as noted earlier, that provide a demonstration that the salient processes and features of the complex model are understood. Stakeholders increasingly want to understand the modelling approach (including the model concepts, the assumptions and the justification of simplifications) and have confidence in the modelling results (rather than just take it all on trust). A trend may be towards a strategy of using a more complex model to be as realistic as possible and using simple models to bound the results and enhance the confidence in the results of the more complex models.

14.6 Advances in tools

The move to more complex models is in part supported by the advances in computing power and software that allows these complex conceptual models to be included in the numerical models. It is an efficient interaction between the development of more sophisticated models, the increase in computer power and the improvement of numerical methods.

In the 1980s, computer capabilities were limited and there was a necessary emphasis on simpler models or more extensive use of analytic or semi-analytic mathematical models. Key advances during the 1990s that affect the modelling strategy are increasing computer power, and advances in software and numerical methods.

14.6.1 Computer power

The increase in computer power is in both processor speed and memory (RAM), as well as in the general availability of multi-processor cores and clusters of multiple machines.

The improvement in processor speed and memory directly allows more complex calculations to be performed, involving more variables and more time steps. This can allow treatment of larger models (more grid nodes) as well as the handling of numerically stiffer problems by using smaller time steps. The improvement in RAM in part supports the increase in processor speed, but equally significant is that it allows much larger grids to be modelled, with 1 million or more node finite-element or finite-difference models being practical on standard desktops. Future improvements in speed or RAM are readily applied in existing tools and will be quickly adopted.

The increase in parallel processing capability is not yet widely exploited in repository safety assessments. In part, the historic or legacy codes developed in many programmes were designed as single-threaded applications, and are not readily divided by humans or current compilers into multi-threaded applications. Presently, parallel processing is more likely to be used in process-level modelling or to support multiple independent analyses, such as part of a suite of calculation cases or as part of a probabilistic assessment. The use of parallel processors is an area not fully utilised at present, and a possible area where improvements in numerical simulation outside the radwaste community will be of benefit.

With respect to process-level models, the increased computer power generally allows better modelling of coupled and transient processes. With respect to system models, the main impacts are the more detailed description of several processes, reduction of computation costs, and an increase in probabilistic calculations.

14.6.2 Software and numerical methods

Over the past 20 years, developments in numerical methods have been more subtle. In many respects, the increased computer power noted above has simply allowed current numerical techniques to be extended to tougher problems by brute force – i.e. allowing the model to be represented with much smaller grid spacing or time steps, and thereby avoiding numerical instability issues.

However, there have been notable improvements in the numerical techniques used for discretisation and solvers. The use of implicit discretisation in time allows larger time steps and, thus, simulations over longer model times. Current finite element and finite volume discretisations permit a precise approximation of the model geometries, and unstructured, adaptive meshing allows finer resolution where needed. Sophisticated upwind strategies are able to stabilise the solution. Other important advances are algorithms for solving large sparse linear equation systems, such as classic and algebraic multigrid methods, such as BiCGStab (van der Vorst 1992).

Computer codes taking advantage of parallel processing include r3t (Fein 2004) and TOUGH2-MP (LBNL 2008). The code r3t, for example, was developed to describe flow and contaminant transport in large model areas over long time periods, and is parallelised by domain decomposition, i.e. the computation grid can be distributed to hundreds of processors of a cluster or a massively parallel computer.

Another important aspect for safety assessment has been the large improvements in software visualisation methods. This provides benefit in the preparation of input files, preparation of models and presentation of calculation results.

With respect to preparation of input files, the large multi-dimensional input files with thousands or even millions of nodes are only practical to create because tools allow the user to define complex geometries, and to rely on the software to generate acceptable grids and populate all the model elements with appropriate properties. These technologies are relatively mature, although they require a degree of expertise and familiarity to apply appropriately.

With respect to preparation of models, the main development has been software platforms in which the user defines the model more directly in terms of connected blocks or icons or mathematical formulae, rather than in a source code such as Fortran or C++. Examples include AMBER, GOLDSIM, COMSOL and MathCAD. These software tools are able to interpret this user information into suitable source code. This has three advantages. First, it simplifies the task of creating a numerical model by eliminating or automating a step. Secondly, it reduces the risk of human error in the source code step, and makes the verification of the model simpler by presenting the model in a more visual manner. Thirdly, it separates the physical model task from the numerical solver task; allowing experts to focus on each separately. The main disadvantage of such software is that the automatically generated source code may not be as efficient in solving specific problems as when coded directly by knowledgeable programmers who can take advantage of prior knowledge of the problem and expected solution.

14.7 Data selection

The broad areas in which data are required are concept-specific data, site-specific data, and research data. When identifying data for use in safety assessment models it is important to consider the quality of the data, its relevance to the spatial and temporal scale of the model (for example whether upscaling or extrapolation is required), the level of uncertainty associated with the data, and the purpose of the model.

14.7.1 Concept-specific data

The concept-specific data includes waste-related data such as waste inventory, conditioning and packaging, and repository design data, such as layout of the repository, and design and properties of buffer and backfill. Some of these data will be influenced by the nature of the site since the repository design should be tailored to the properties of the host rock (e.g. EC/NEA 2010).

Each waste disposal programme will generally have different concept-specific data. For example, the types of waste for disposal are highly dependent on national policy. There is more commonality with respect to data on containers, and even more on properties of seals, at least for countries with similar host rocks.

There may be a trend for the development of national reference waste inventories. In part, this may also reflect that some programmes are approaching licensing decisions and this information is needed.

14.7.2 Site-specific data

The safety assessment, and ultimately the safety case, requires a wide range of different types of information from the site characterisation programme (e.g. geology, hydrogeology, geochemistry, geotechnics). The safety case also provides feedback and guidance to site characterisation studies as to which parameters and processes require investigation and the level of detail or precision required. Generally, a safety case will require the following site-specific data:

- information to demonstrate a good understanding of the present-day system and how the system might change in the future;
- information to support the scenarios that are developed for assessing the future evolution of the system;
- detailed information on transport parameters to support the safety assessment models, for example information along the potential transport pathways;
- information on the biosphere and human activities near the site.

Site characterisation generates large amounts of data. Management of this data is critical to ensure it is accurately recorded and traceable since this data will be used in the near-term for licensing, and in the future during facility closure. Electronic storage systems are essential for this task. Owing to the long time periods between data collection and repository closure such systems and data will need to be actively managed and updated.

There is general consensus that the results of site characterisation should be synthesised by the development and progressive updating of a series of "site descriptive models" or "geosyntheses" (e.g. AMIGO 2007, SKB 1998, NWMO 2011). Such descriptive models provide a means for interpreting and presenting the results of investigations at a site, and providing a traceable justification for selection of conceptual models and parameters for use in the safety assessment.

14.7.3 Research data

All modelling work is underpinned by data from a variety of sources, including laboratory experiments, field tests, large-scale experiments, site investigation, literature searches and comparisons with natural phenomena. Not all data will be obtained in the format required by the models and it is unlikely that a complete data set will be available.

Some data will require processing prior to use in models. This is particularly true for geological and hydrogeological data obtained from field tests and site investigations. For example, initial data processing and upscaling take account of the fact that a rock layer may be non-uniform in its properties and that there will be variability on different length scales. Measurements taken on a relatively small length scale need to be "upscaled" in order to represent a larger rock mass (note that this is still an area of research).

Some data will require extrapolation or interpolation because the actual data available are incomplete or do not relate to the exact conditions within the repository system. For example, as it is not possible to conduct experiments over the very long timescales (thousands of years) for which it is required to assess the performance of the disposal facility, information concerning the evolution of the facility may need to be extrapolated from data obtained from much shorter timescale experiments. Expert judgement may be combined with the available empirical data to elicit a more complete data set or manage the consequences of uncertainty associated with the available data. This may involve the selection of probability density functions (PDFs) for certain parameters (see for example Nirex 2006a).

There is also the question of how much data will suffice. This is linked to the handling of uncertainty in safety assessments – this is discussed in Nirex 2006b for example. The overall aim of data gathering is to build sufficient confidence in the safety case that it provides a sound basis to inform the decision being taken at that stage of the facility development process. The accuracy and reliability of the models is clearly an important part of that confidence, however the quantitative performance assessments results are only one component of the overall safety case. They should be complemented with evidence from other sources, for example comparison with data from natural analogues.

14.7.4 Quality control and traceability of data

Documentation, record keeping and quality management are key requirements to the provision of information. The project plan should ensure that the data derived from scientific investigations is able to inform or test the conceptual or mathematical models. The handling of data uncertainties is also discussed in MeSA Issue Paper No. 6 (Mönig *et al.* 2011).

Peer reviews of methods and documentation may also be employed to provide additional confidence in the data quality and traceability. Although inventory and site-specific data are usually country-specific, there is merit in supplying appropriate process-model data to international databases, to facilitate cross-verification with other projects. However, to be useful for licensing purposes, the data must ultimately be controlled within the context of a specific project, as a controlled reference dataset. Such a reference dataset may be frozen for a particular time span by the application of a formal data clearance procedure (see for example NAGRA 2002b). This guarantees that all model applications in this time span are based on the same dataset and that, therefore, the results are consistent.

It will be important to maintain good records of all the relevant information over the lifetime of the repository project and beyond. This includes the waste inventory, design basis, and the site geoscientific data. Ensuring that the data are retained in a form that is accessible over decades may be an issue.

14.8 Model qualification

Since safety assessment models are used to support critical decisions, it is important to ensure the quality of the numerical model results. In conventional software quality assurance, this task is divided into verification and validation.

Verification aims at showing that the computer code, via the numerical model, correctly implements the intended mathematical model. Model verification is often done by comparing the results obtained with two independent solution methods. These can be a comparison of results of a numerical code with an analytical solution or, in the case of complex non-linear models, a comparison of results obtained with two independent numerical codes. Verification can also involve code inspection or walkthrough, or regression testing against a standard test suite.

Validation on the other hand should demonstrate that the model correctly represents reality. Validation is the harder task. In other technical disciplines, validation may be achieved by comparing model predictions to relevant laboratory and field studies. However, due to the long time and spatial scales involved in geological disposal, a complete comparison between safety assessment model predictions and experimental results cannot be done. The limitations of conventional validation are acknowledged in the NEA review (NEA 1991).

Since strict validation of the models used for safety assessments is in most cases impossible, alternative terms have been introduced in some countries. In particular, in some programmes (e.g. Ondraf/Niras, GRS), the term model qualification has been introduced. The intent of model qualification is to demonstrate that the model is consistent with the scientific understanding within the assessment basis, and that it adequately represents the considered phenomena and interactions relevant to the assessment case. Confidence in the models is increased by both model verification and by successful application to as many test cases as possible.

In other programmes (e.g. NDA RWMD, NWMO), the concept of model validation is retained. However, validation of the safety assessment models is viewed not as a specific end point that is met, but as an ongoing, iterative and progressive process that builds confidence in the model.

In either case, the modelling strategy should include elements of the following with respect to testing of the safety assessment models:

- independent peer review of the theory, including the conceptual and the mathematical models;
- a software quality assurance process that ensures that software changes are implemented in a formal manner with appropriate review of each step;
- verification that the computer codes accurately implement the mathematical models;

- benchmarking of new codes against the results of older codes (and the strategy with respect to maintenance of the older codes);
- testing of specific phenomena within the safety assessment model against experimental data, field data and/or detailed process models;
- comparison with similar system models;
- comparison with field-scale tests that can be conducted within the bounds of underground research laboratories;
- calibration to conditions at a specific site.

The nuclear reactor safety community offers some ideas for model validation. In particular, while reactor safety processes operate on scales of time and size that are testable, the cost of these tests is large. One strategy has been to identify the key phenomena, and to then establish (international) validation tests for these in a structured manner (e.g. Boyack and Ward 2000). Another strategy is the use of industry-standard models/codes, so that the model validation effort is shared.

- Within the geological repository community, there is already collaboration and sharing of information on large-scale tests. Underground Research Laboratories (URLs) have been used to conduct a variety of field-scale tests, and the results are often widely shared and analysed. For example, radionuclide transport in the host formation can be tested using migration experiments for non-sorbing tracers over timescales of order weeks and length scales of metres, such as the TRUE tests at Äspö, the MFR tests at AECL URL, and similar tests in the Belgium Boom Clay.
- With respect to the use of standard models, there has been an emerging trend in software towards the development and use of standard platforms such as Goldsim, COMSOL or AMBER. These are generic software applications that provide essentially programmable numerical solvers with a user-friendly interface. These platforms are widely used – including in most cases a large non-radwaste community – which provides both more testing of the underlying numerical software than is practical with custom-built software, and also shares the cost of keeping the underlying numerical solver up-to-date with new techniques. One aspect to keep in mind is that while the software platform itself may be well-tested, any models implemented using the software should be considered a separate software object, and would need to be separately verified and "validated".
- International projects can be useful fora for code intercomparison, which is usually not possible on a national level, since national programmes typically have a single primary system-level model. In the past, code intercomparison studies have been successfully performed within the OECD/NEA framework (e.g. HYDROCOIN, INTRACOIN, INTRAVAL).

In principle, natural analogues might be used to validate models; e.g., measurements of natural tracer profiles in clay layers can confirm models predicting that the transport in those media is essentially diffusive over large space and timescales. In practice, in most cases the uncertainties in initial and boundary conditions are high and, consequently, they have limited the use of natural analogues for model validation.

However, the use of the site as a natural analogue for itself is quite relevant. Once a site has been selected, the intensive study of that site over many years will lead to much information. If a model can explain the evolution of the site formation during the previous million years or certain features or processes observed (such as tracer profiles), we can be more confident in the predictions of the model for that site for the next million years.

Finally, the difficulties associated with model validation have contributed to the development of the safety case concept, with its emphasis on multiple lines of reasoning. Also, within a safety assessment, it is possible to adopt strategies that do not reduce model uncertainty but can bound the implications of the uncertainty, notably:

- use of alternative conceptual models;
- use of conservative or bounding models;
- use of stylised models (e.g. human intrusion).

Overall, the topic of model qualification is reasonably well understood. International collaboration on large-scale tests and on data is already widely practiced where practical. Two areas where national experience might be usefully reviewed are: review of formal software quality assurance standards/guidelines and documentation specific to repository safety assessment codes; and review of experience with the use of software platforms, especially for system-level modelling.

14.9 Conclusions

The 1991 NEA review noted a number of issues related to modelling strategy, as listed in Section 14.2.1. These continue to be aspects to be considered during the development of a specific modelling strategy in support of a safety assessment. However, these are all considered to be manageable.

Over the past 20 years, there have been significant advances in scientific understanding, particularly in the area of coupled processes. Along with the increasing computer power, this knowledge has resulted in a trend towards a more detailed description of several physical and chemical processes on a mechanistic level, and greater inclusion of coupled processes and geometrical complexity, particularly in the process-level models.

System-level models still continue to require simplifications in processes or geometry, although not as much as previously. The limiting factor in terms of system-level model complexity continues to be primarily computing power, rather than our ability to understand the model results or to provide model input data. There is perhaps greater emphasis on accompanying the more complex models with simple models to help interpret or illustrate the results.

An area where there is no widespread modelling strategy consensus is the treatment of biospheres in safety assessments. This is in part because of differences in regulations, which allow or encourage in several countries simplified handling of the biosphere, recognising that the biosphere is the most variable and probably least predictable part of the repository system.

With respect to computing power and software, there have been significant advances including our ability to create, solve and visualise large (million-node) models. Parallel processing is a capability that is not widely used at present, and a possible area where improvements in numerical simulation outside the radwaste community could be of benefit.

Data management remains an important topic. The data must be appropriately qualified. Site characterisation in particular generates large amounts of data, and ensuring traceability from the safety assessment back to these data requires planning. Approaches currently used to help with this include data clearance procedures, site descriptive models, and reference datasets. Planning is needed to preserve the site data, as well as inventory data and design information, at least over the decades of a repository programme.

As programmes have matured and shifted towards more site-specific assessments, there is a trend to apply more formal software quality assurance to what were previously research-type codes. The full implementation of this within the radwaste community has not yet been established, as many codes do not as yet ascribe to a formal software quality assurance standard.

Overall, there is wide consensus on the modelling strategies to support a safety assessment, and no major areas of disagreement have been identified. Certain topics continue to need attention within a specific project, such as the balance between process-level models and system-level models, data selection and preservation, and model validation. However these are well-understood topics and the specific approaches are generally site- and programme-specific.

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15. Indicators for safety assessment

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Abstract

The concept of indicators for the assessment of long-term post-closure safety of nuclear waste repositories has undergone considerable development during the last 15 years. This development has occurred in parallel with the development of the safety case, where indicators contribute to the demonstration of robustness of the system and the safety case and to transparency by a better illustration of the behaviour of the repository (sub)system(s). The increasing use of indicators in addition to dose and risk is also in agreement with the tendency to cover longer time frames by modelling in safety assessments, usually in the range of one million years. A variety of indicators is used in safety assessments. There is no harmonised categorisation and terminology but generally indicators can be divided into three groups with respect to their nature, namely concentration and content related, flux related and status of barrier related indicators. If classified by purpose frequently three main groups of indicators are distinguished, in this paper termed safety indicators, performance indicators, and safety function indicators. Safety indicators, e.g. doses to individuals, give an indication on the safety of the repository and are suitable for comparison with regulatory criteria. Performance indicators, e.g. evolutions of radionuclide fluxes between successive compartments of the repository, provide a deeper understanding of the system behaviour and might contribute to decisions related to repository design and optimisation. Safety function indicators, e.g. the thickness of a barrier susceptible to corrosion, are suitable for evaluating key parts of a repository system in a disaggregated fashion, which also means that acceptable safety on a system level may be compatible with poor performance with respect to a sub-set of the safety function indicators.

Keywords: Safety assessment, safety case, geological repository, radioactive waste, disposal.

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15.1 Introduction

Most national regulations relating to repositories for nuclear waste give safety criteria in terms of dose and/or risk, and these indicators are evaluated for a range of evolution scenarios for the disposal system using quantitative analyses. In recent years it has become evident that this comparison for an overall system safety assessment can be augmented with additional analyses and indicators in the safety case. It is now internationally accepted that the robustness of the safety case and the resulting confidence in the repository concept is strengthened by the use of multiple lines of evidence which includes complementary (also qualitative) safety arguments that can compensate for shortcomings in any single argument. One type of evidence and arguments in support of a safety case is the use of indicators complementary to dose and/or risk (NEA 2004).

Such complementary indicators can avoid to some extent the difficulties faced in evaluating and interpreting doses and risks that are expected to occur in a far future. In particular, individual human behaviour and near-surface processes, which are important factors in the calculation of dose and risk, are difficult or impossible to predict over long timescales. In contrast the possible evolutions of a well-chosen host rock and geological site can be bounded with reasonable confidence over much longer timescales of up to about one million years into the future (depending on the site). Hence, there is a trend in some recent safety cases towards evaluating indicators in addition to dose and risk, which show more clearly the repository's intrinsic performance without requiring any assumptions concerning the surface environment and the biosphere. The use of such indicators may support the statement that radionuclide release to the surface environment will be minor and of low consequence and, thereby, increase the robustness of the safety case, see e.g. Nagra (2002).

15.2 Methodology

The concept of safety and performance indicators has undergone considerable development during the last decade. While there is a consensus that using different indicators in addition to dose or risk in performance assessments is a good way to improve the understanding of the system and to support the safety case, concepts and perceptions vary between countries and organisations. Different approaches and levels of detail in regulatory guidance might increase this variability.

In the OECD/NEA brochure from 1991 (NEA 1991), which summarised methods for safety assessment of deep geological repositories, indicators other than dose or risk are not mentioned at all. It is generally stated that "estimates of long-term system performance are meant to be used as indicators of system performance or safety. These indicators can then be compared to the regulatory criteria established by the appropriate national and international authorities."

Since that time, international projects such as the European project Safety and Performance indicators (SPIN) (Becker *et al.* 2003) and the IAEA project "Safety indicators for the safety assessment of radioactive waste disposal" (IAEA 2003) were devoted to the development and testing of various other safety and performance indicators. The outcome of these projects has been used and further developed in national studies, e.g. in Germany (Wolf *et al.* 2008), Spain (Enresa 2001), and Switzerland (Nagra 2002). Recently, the concept of indicators was further developed and applied to repositories in different host formations (clay, rock salt and granite) within the EC project PAMINA (Becker *et al.* 2009). Safety function indicators have been introduced in the Swedish programme for a final repository for spent nuclear fuel (SKB 2006, SKB 2011). A review of the use of indicators by organisations from different member countries of OECD/NEA was performed during the MeSA project. An extract from this review, i.e. a table showing the different kinds of indicators used by each organisation and their characteristics are compiled in the annex of this paper.

The use of indicators other than dose or risk is also in agreement with the tendency to cover longer time frames in safety assessment calculations. In the brochure (NEA 1991) it is mentioned that some national authorities have considered it appropriate to introduce a time limit (e.g. 10 000 years) for consequence calculations. Now, a million years seems to be emerging as a commonly accepted time frame for calculations in recent safety assessments (NEA 2006, NEA 2009b).

This paper summarises the views of NEA experts in this field and identifies the main achievements in this area since 1991.

15.2.1 Analysis

Classification, terminology, definitions

There have been a number of systematic classification schemes and formal definitions proposed for complementary indicators on the basis of how they may be applied in a safety assessment, for example those derived in the SPIN and PAMINA projects which make a distinction between safety indicators and performance indicators (see below). These proposed classification schemes have not been universally adopted, however, in part because they are not consistent with the assessment methodologies applied in all national disposal programmes. Whilst several organisations apply a rigorous approach to integrating complementary indicators in a safety assessment for specific purposes and make a clear distinction between whole system safety and sub-system performance indicators, some do not recognise any distinction and treat all complementary indicators in the same general manner.

Setting aside the proposed classification schemes, a review of the complementary indicators used in safety assessments to date shows that they can roughly be divided into three groups on the basis of their nature and the information they provide:

i. concentration and content related indicators, that provide information on the radionuclide inventory and its distribution within compartments of the repository and the environment (e.g. *total radioactivity content of the wasteform* or *radiotoxicity concentration in groundwater*);

ii. flux related indicators, that provide information on the transport of radionuclides between compartments of the repository and their release to the accessible environment (e.g. *radioactivity flux from the engineered barriers to the geosphere* or *total integrated radiotoxicity flux from the geosphere to the biosphere over time*); and

iii. status of barriers related indicators, that provide information on the functioning and containment capability of the barriers in the repository system (e.g. *container thickness* or *buffer swelling pressure*).

These three groups are not fully independent. For example, the status of a barrier could have a significant impact on the flux of radionuclides across it and, consequently, the content of radionuclides in the compartments on either side. However, the slightly overlapping nature of these groups of indicators is not a problem because the indicators are complementary both to each other and to measures such as dose and risk.

Grouping indicators in this way means that their definitions are strongly dependent on the geometry of the repository system, for example the compartments must be clearly distinguished and described to allow the concentrations in them and the fluxes between them to be calculated. At a generic level, it is possible to relate these three groups of indicators to the main compartments in a typical repository concept, as illustrated in Table 15.1. Throughout the development of a repository and refinement of its design (e.g. to optimise the design to account for the geological conditions at a chosen site), the definitions of the indicators used could also be progressively refined as the assessment evolves from a generic to a site/design-specific basis.

Table 15.1: Relation of the three groups of indicators to the main compartments of a repository system

	Compartment			
Indicator type	Wasteform	Engineered barriers	Geosphere	Biosphere
Concentration and content indicators	✓	✓	✓	✓
Flux indicators	→	→	→	
Status of barrier indicators	✓	✓	✓	

This is only one possible way to consider grouping complementary indicators and others may be considered. Each organisation may choose their own approach to be consistent with their specific assessment context, and the expectations of regulators and stakeholders. It is important, however, that whatever classification or categorisation scheme is adopted, the chosen definitions are appropriately and clearly defined.

A frequently adopted classification scheme is according to the specific purpose of the indicator. Typical purposes are:

- quantification of the long-term safety of the repository;
- characterisation and illustration of the performance of the system or subsystems;
- judgement whether a safety function is fulfilled or not.

Of course, there are overlaps between these classes. An indicator that is applied to quantify safety might also give an indication on the performance of the system. Likewise, an indicator that identifies whether a safety function is fulfilled (or not) also provides information about the performance of a (sub)system. The results of the review undertaken in MeSA show a clear and logical difference between the reported primary purposes of safety indicators and performance indicators, even in cases in which this terminology was not used by the responding organisations (see Table 15.2).

Another important aspect is whether an indicator can be quantified by calculation (usually by integrated performance assessment models, but sometimes also by detailed process-level modelling). Indicators used for quantification of the long-term safety of a repository need to be calculated. However, an indicator used for characterisation and illustration of the performance of a subsystem might not always be calculable. A radiotoxicity flux out of the buffer gives information about the performance of a subsystem and needs to be calculated. Characteristics like groundwater age also provide some information about the performance of a subsystem but are directly derived from site characterisation and not by performance assessment (PA) calculations. The same is true for indicators that identify whether a safety function is fulfilled or not. Some of these indicators are calculated, others are measured values (see further discussion below). A problem with the differentiator "calculability" might be the intermixing of different time frames: whereas every future value of any indicator has to be calculated, every measured value like the present groundwater age can only characterise the present status of the repository or a subsystem. The groundwater age in the vicinity of the repository in 100 000 years can only be determined by calculation.

Table 15.2: Primary and secondary purposes for indicators

Category	Primary purpose	Secondary purposes
Safety indicator	Safety statements for the whole system	• Performance statement, whole system • Design optimisation • Communication • System understanding
Performance indicator	Performance statements for a system component	• Performance statement, whole system • Design optimisation • Communication • System understanding • Site selection
Safety function indicator	Performance statements for a system component	• Assessment activity • Design optimisation • Communication • System understanding

The terminology used for indicators by different organisations is rather inhomogeneous and not consistent between national programmes; identical or very similar concepts are sometimes denoted differently, while in other cases the same term is used with different meanings. For example, some indicators, which are described in this paper as performance indicators – such as fluxes from single barriers – are denoted in some national regulations as safety indicators. The classification given in the following section is based on experience from international fora and projects investigating the use of indicators in detail. It is not intended as a recommendation regarding classification.

The most recent work on indicators was performed within the PAMINA project (e.g. Becker and Wolf 2008; Becker *et al.* 2009). Because of the sometimes confusing terminology encountered in the literature, it was considered necessary to clearly define a number of concepts and terms at the start of the PAMINA work package on indicators (Becker and Wolf 2008). Some indicators illustrating the performance of the integrated repository system, e.g. containment factors which are the ratio of the radiotoxicity released from the repository system into the biosphere divided by the radiotoxicity in the disposed waste, are sometimes called safety indicators. It was agreed that the term safety indicator should only be used in its strict sense, i.e. as an indicator that gives an indication of the safety of the repository and for which a generally accepted reference value is available.

The IAEA (2007) defines a safety indicator as *a quantity used in assessments as a measure of the radiological impact of a source or practice, or of the performance of protection and safety provisions other than dose or risk. Such quantities are most commonly used in situations where predictions of dose or risk are unlikely to be reliable, for example long-term assessments of repositories. These are normally either (a) illustrative calculations of dose or risk quantities, used to give an indication of the possible magnitude of doses or risks for comparison with given criteria, or (b) other quantities, such as radionuclide concentration or fluxes that are considered to give more reliable indication of impact, and that can be compared with other relevant data.*

Note that the definition refers to calculation results, which are seen as indicators for the actual (real) impacts which might occur in the future. The definition is in line with definitions from SPIN and PAMINA, which are more detailed, with emphasis on the practical application in consequence calculations. In PAMINA a safety indicator was defined as *a quantity, calculable by means of suitable 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*. Since a reference value is of high importance for this indicator it was included in the definition.

The group of performance indicators fulfils a different task to that of the safety indicators. It was shown in SPIN that performance indicators related to release or transport are a good means to visualise the functioning of the system and to help understanding the co-actions and interactions of its components. The definition from IAEA (2007) for the performance indicator is quite general, i.e. *a performance indicator is a characteristic of a process that can be observed, measured or trended to infer or directly indicate the current and future performance of the process, with particular emphasis on satisfactory performance for safety*. It allows a variety of different interpretations. More specific is the definition given in SPIN, that a performance indicator *must provide a statement on the performance of the whole system, a subsystem or a single barrier, provide a nuclide-specific or integral measure, be a calculable, time-dependent or absolute parameter, allow comparison between different options or with technical criteria, and illustrate the functioning of the repository system*. This, however, seems overly focussed and overlaps with terms used by others for other purposes. In particular, it reflects the fact that the SPIN project focussed on indicators related to release or transport. A more simple definition given in PAMINA is: *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.*

Safety function indicators are associated with safety functions that may be defined as a role through which a particular part of a repository system contributes to safety. A safety function indicator is defined by SKB (2011) as *a measurable or calculable quantity that quantitatively characterises the extent to which the safety function under consideration is fulfilled*. For some safety function indicators it is also possible to define reference values to which they can be compared. Contrary to safety function indicators, which characterise properties of safety relevant elements, performance indicators as defined in the SPIN project characterise the efficiency of given barriers (waste form, canister, buffer, backfill, host rock, etc.) to impede release of radionuclides to the environment. Note that SKB initially justified the introduction of the new term “function indicator” (later transferred to “safety function indicator”) by saying: “In choosing the term ‘function indicator’, it was observed that the two terms ‘performance indicator’ and ‘safety indicator’ in this context normally refer to releases of radionuclide or resulting dose consequences (Becker *et al.* 2003). Those terms were thus avoided.” (SKB 2011).

In addition, there are calculable or measurable indicators with partly different objectives, which are sometimes also denoted as safety indicators. These characteristics are not strictly defined and usually they are not calculated by PA models. They are used by some organisations as arguments for the long-term performance of the disposal system in the safety case. The comparison of *calculated* radiotoxicity of the waste with the radiotoxicity of uranium ore is sometimes used to illustrate that, over sufficiently long timescales, the waste toxicity 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 repository at very long times to known natural systems which are generally considered to present a low risk. Other characteristics that may be cited are: *measured* groundwater age, salinity of groundwater, depth of formation, or *calculated* required thickness of shielding. Such indicators are often observations from site characterisation or properties derived for specific processes. They are often used as additional, often rather qualitative arguments in the safety case and some of them also give some indirect information about the performance of a system or subsystem or contribute to confidence in the models used in safety assessments. However, since they are not directly applied or calculated in the safety assessment, they are not considered here in detail. Several other similar terms are used in the literature, like “condition indicator”, “functional indicator” (IAEA 2007), or “function indicator”. But for the purpose of this paper these terms provide more confusion than help for the classification of indicators.

15.2.2 Safety indicators

Description and application

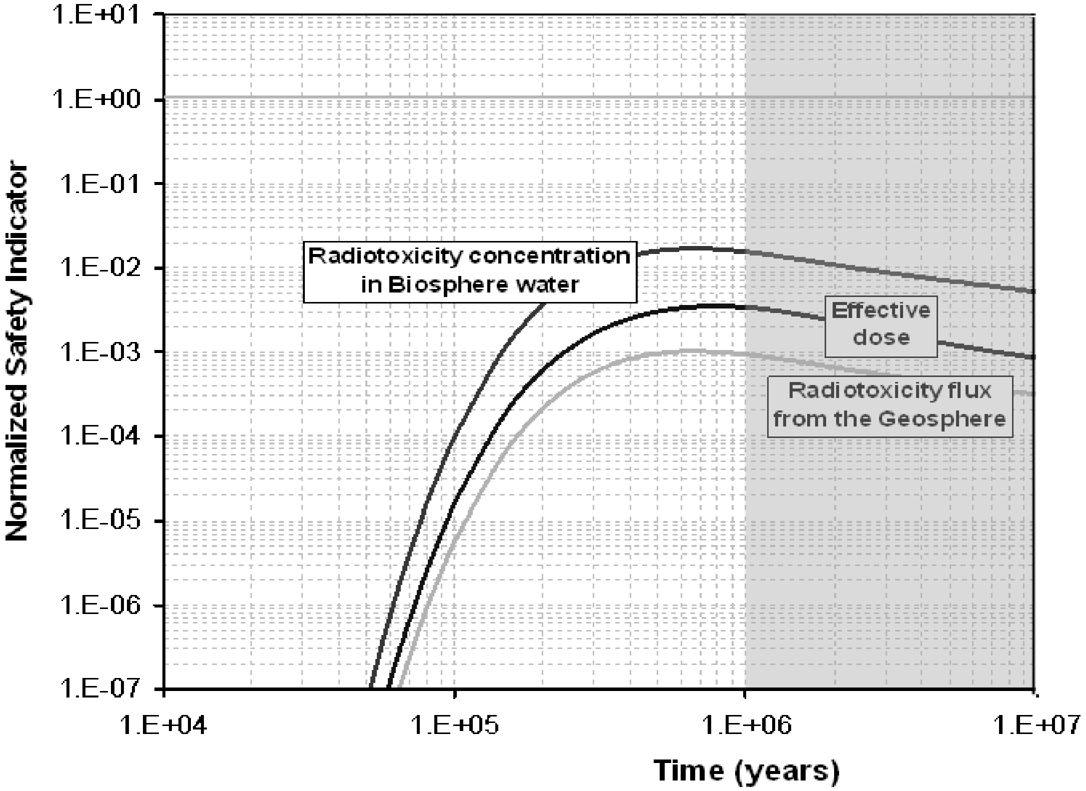
As already discussed above a safety indicator should give an indication of whether a repository can be considered safe regarding some safety aspect. Such a safety statement requires a numerical measure as well as a reference value (see Section 15.2.5). The most commonly used safety indicators in addition to the effective dose rate are radiotoxicity concentrations in the biosphere water and radiotoxicity fluxes out of the geosphere. These indicators have been proposed for granite formations (Becker *et al*. 2003) and identified as suitable also for rock salt and clay formations (Wolf *et al*. 2008, Becker *et al*. 2009). Safety statements derived from these indicators might be as follows:

- Individual dose rate [Sv/a]: Human health is not jeopardised by radionuclides released from the repository. Under certain assumptions concerning the biosphere and human habits, all biological effects to a human individual, i.e. the incorporation of radionuclides by humans via different exposure pathways remain so small that they have no adverse impact on human health.
- Radiotoxicity concentration in the biosphere water [Sv/m3]: The hazard from the ingestion of the biosphere water that contains trace amounts of radionuclides from the repository does not exceed the hazard from the ingestion of average drinking water (regarding the impact of radionuclides).
- Radiotoxicity flux from the geosphere [Sv/a]: The radiotoxicity flux from the geosphere to the groundwater is below the present natural radiotoxicity flux in the groundwater.

Frequently, the concept of individual radiological risk is applied in order to consider probabilities of the scenarios in the safety statement (SKB 2006, SKB 2011, Becker *et al*. 2009). This concept should be handled with caution, due to the difficulties in estimating scenario probabilities. In most cases these probabilities can only be guessed or roughly estimated – the use of experts in risk assessments to quantify information is unavoidable (NEA 2005). Another issue to be addressed when calculating risk indicators is the potential for risk dilution. In any case, it is nowadays seen as necessary to present not only the calculation endpoint "risk" but also, in a disaggregated manner, the entities (doses, probabilities) used for its calculation. Note that the IAEA (2007) glossary provides, amongst others, a disaggregated notion of the term "risk" which is, however, not often explicitly accounted for in the context of safety assessment: "A multiattribute quantity expressing hazard, danger or chance of harmful or injurious consequences associated with actual or potential exposures. It relates to quantities such as the probability that specific deleterious consequences may arise and the magnitude and character of such consequences. In mathematical terms, this can be expressed generally as a set of triplets, $R = \{<S_i|p_i|X_i>\}$, where S_i is an identification or description of a scenario i, p_i is the probability of that scenario and X_i is a measure of the consequence of the scenario. The concept of risk is sometimes also considered to include uncertainty in the probabilities p_i of the scenarios."

An example for the use of safety indicators in clay formations is given in Figure 15.1, where the three safety indicators mentioned above are applied. The indicators are normalised to their reference value for comparison. The graph shows that all three safety indicators are at least two orders of magnitude below their reference values over a time frame of 10^7 years. This example demonstrates that the combination of several indicators and the underlying safety statements, which are derived from independently determined reference values, could increase the overall confidence in the safety assessment.

Figure 15.1: Safety indicators calculated for a repository in a clay formation (Becker *et al.* 2009)



15.2.3 Performance indicators

Description and application

Safety indicators are useful for assessing the level of safety of the total system, but they usually do not provide much information about how the system works and how the level of safety is reached. Such information, however, is of high value for the safety case. It is essential to understand how the different barriers work together, where the radionuclides are mainly retained and how the system might be optimised. Further, performance indicators can be used to test the robustness of the system. For communication with licensing authorities as well as with the general public it is helpful to demonstrate the functioning of the system in an illustrative and understandable way. Such demonstrations can improve the confidence in the performance assessment.

This kind of information is provided by performance indicators. The definition of performance indicators given in SPIN (see above) allows a wider variety of characteristics to be used compared to the universe of safety indicators. They are typically concentrations or fluxes of radionuclides in or between specific parts of the repository system, or other descriptive measures that demonstrate specific properties of the system. Suitable indicators have been identified for repositories in granite formations (Becker *et al.* 2003) and also successfully applied to repositories in clay and rock salt formations (Becker *et al.* 2009, Wolf *et al.* 2008). Typical applications for the different performance indicators are shown in Table 15.3.

Table 15.3: Examples of performance indicators and application areas (modified, according to Becker *et al.* 2003)

Indicator	Application
Inventory inside or outside of compartments	Where are the contaminants? Demonstration of the functionality of the safety functions or multibarrier system.
Fluxes out of compartments	At what rate are contaminants transported? Demonstration of barrier/safety functions.
Time integrated fluxes	Which fractions of the contaminants leave the subsystems? Demonstration of the retention capacity of barriers.
Concentrations	Demonstration of containment, retention, dilution and distribution effects
Transport times	Demonstration of the retention capacity of barriers; quick overview on the safety relevance of radionuclides

Most performance indicators developed or considered within the SPIN and PAMINA projects are based on compartments. The compartments considered are the results of a division of the repository system into sub-systems, for which it is considered interesting to show the evolution of the performance indicators. Compartments can correspond to a component of the repository system, e.g. buffer or host clay layer. Some compartments can contain other compartments, e.g. the canister compartment can contain the waste matrix, the water in the canister and a precipitate.

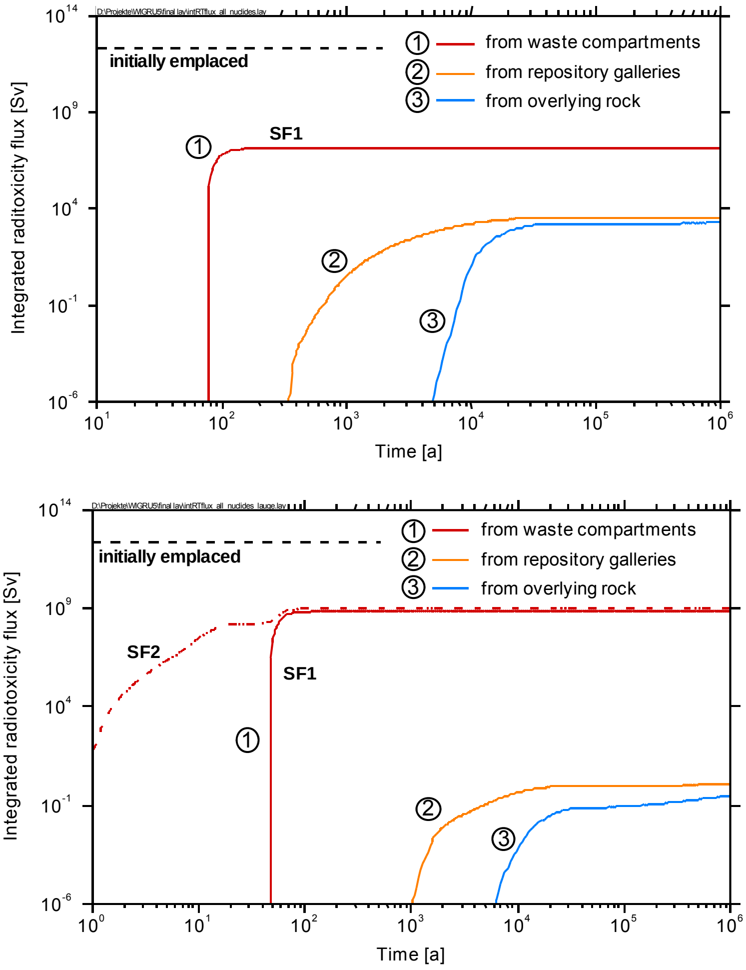
One example for the application of a performance indicator is given in Figure 15.2. In this study indicators have been calculated for a concept of high and intermediate level waste disposed in rock salt. Two scenarios are considered: (i) combined failure of shaft and drift seals and (ii) inflow from brine inclusions near the disposal boreholes. The integrated radiotoxicity flux from different compartments was identified as the most illustrative performance indicator. If this indicator is compared with the initially emplaced radiotoxicity inventory, the performance of each compartment can be very clearly demonstrated.

The total reduction of the radiotoxicity in the whole repository system is about nine orders of magnitude for the first scenario which considers the combined failure of shaft and drift seals, and 13 orders of magnitude for the second scenario which considers brine inclusions inside the repository. In the first scenario, the spent fuel waste containing compartment (SF2) comes into contact with brine intruding via shaft and drifts at times after 50 years. Due to the relatively late intrusion time, the brine does not reach other waste containing compartments in this scenario. However, a comparably high fraction of radiotoxicity is then released out of the repository, because the barrier function of the drifts and the shaft are significantly reduced. In the second scenario ("brine inclusions") a very early intrusion of brine leads to contact with the spent fuel containing compartments SF1 and SF2, and a higher radiotoxicity flux out of these compartments. However, due to the intact geotechnical barriers, the volume of brine inside the repository is small and the brine flow out of the repository is very low, much smaller than in the first scenario. Compared to the geotechnical barriers, the effect of the overlying rock is quite marginal – for the sum of all radionuclides, the reduction factor is in both scenarios below 0.5.

Also very useful is the analysis of single radionuclides. By comparing radionuclides with different characteristics (e.g. different half-lives, solubility limits or sorption coefficients), additional processes or effects in the repository system can be studied and explained.

The set of indicators proposed in Table 15.3 fulfils the goal of providing a measure of the level of effectiveness of a certain compartment in the given repository system to retard radionuclide transport. They could be used for comparison of different concepts, to optimise the system, e.g. to change the arrangement of the different waste sections in the repository. If the repository concept is changed, it could be necessary to test further indicators (e.g. analyses of certain nuclides as discussed above) and add them to the proposed set. The performance indicators are very important for the understanding of the modelled processes and they give valuable arguments for increasing the confidence in the safety of a repository system.

Figure 15.2: Integrated radiotoxicity flux from different compartments for the scenarios "failure of shaft and drift seals" (top) and "brine inclusions" (bottom). The initially emplaced radiotoxicity inventory is shown for comparison (Wolf *et al.* 2008)



Because of the important role played by safety functions in recent safety cases, SCK•CEN developed in the framework of the PAMINA project a set of performance indicators quantifying the contribution of the main safety functions to the containment of radionuclides in the geological repository system (Marivoet *et al.* 2010, Weetjens *et al.* 2010). The safety functions considered were containment, limitation of release and retardation. The proposed performance indicators were based on time-integrated activity or radiotoxicity fluxes released from the main compartments of the repository system. These performance indicators for safety functions should not be confused with safety function indicators, which are described in the following section.

15.2.4 Safety function indicators

Brief description of the safety function concept of SKB

The concept of safety function indicators has been mainly developed at SKB, although currently other organisations like Andra and Ondraf/Niras are also applying similar concepts. The primary safety function of the KBS-3 concept is to completely contain the spent nuclear fuel within canisters with a corrosion resistant copper shell over the entire assessment period (SKB 2006, SKB 2011). Should a canister be damaged, the secondary safety function is to retard any releases from the canisters. It is noted that the containment function is more prominent in the KBS-3 concept than in several other repository concepts for spent nuclear fuel or high level waste, e.g. Nagra (2002), Andra (2005). This is also reflected in the methodology and structure of the safety assessment for KBS-3, which focuses to a comparatively large extent on the containment capacity of the repository (SKB 2011). Containment is also the primary safety function for the disposal of HLW in rock salt described by Becker *et al.* (2009), but in this case is to be provided by geological and geotechnical components. In this concept, calculated stresses and pressures can be used as indicators for the integrity of the geological barrier, although the applicable criteria (dilatancy criterion, brine pressure criterion) are more complex than the definition of a single reference value. Thus, the results of (geo)mechanical modelling can also be interpreted as safety function indicators.

In the Swedish KBS-3 concept, understanding and evaluating repository safety in a detailed and quantitative manner is achieved through a more elaborate description of how the main safety functions of containment and retardation are fulfilled by the components of the repository. Based on the understanding of the properties of the components and the long-term evolution of the system, a number of safety functions subordinate to containment and retardation are identified.

In this context, a safety function of the KBS-3 concept is defined qualitatively as a role through which a repository component contributes to safety. For example, high isostatic loads could in the long term jeopardise the containing function of the canisters. Should the pore water of the buffer freeze, this could lead to a considerably increased isostatic load on the canister. A safety function related to the buffer and subordinate to containment would, therefore, be the buffer remaining in a non-frozen state.

In order to quantitatively evaluate safety, it is desirable to relate or express the safety functions to measurable or calculable quantities, often in the form of barrier conditions. For example, in the case of the buffer function relating to freezing, the buffer temperature is an obvious quantity to use in order to evaluate the extent to which this function is fulfilled. The buffer temperature is said to be a *safety function indicator* for the mentioned buffer function. A safety function indicator is, thus, a measurable or calculable quantity through which a safety function can be quantitatively evaluated.

In order to determine whether a safety function is fulfilled or not, it is desirable to have quantitative criteria against which the safety function indicators can be evaluated. The situation is, however, different from safety evaluations of many other technical/industrial systems in an important sense: the performance of the repository system or parts thereof do not, in general, change in discrete steps, as opposed to e.g. the case of a pump or a power system that could be characterised as either functioning or not. The repository system will evolve continuously and in many respects there will be no sharp distinction between acceptable performance and a failed system or a sub-system or regarding detailed barrier features. There are, thus, many safety function indicators for which no limit for acceptable performance can be given. The groundwater concentrations of canister corroding agents or agents detrimental to the buffer are examples of this kind of factor related to containment. Usually, they enter in more complex analyses where a number of parameters together determine, e.g. the corrosion rate of the canister. Most of the factors determining retardation are also of this nature.

Nevertheless, there are some crucial barrier properties on which quantitative limits can be put. Regarding containment, an obvious condition is the requirement that the copper canister should nowhere be penetrated, i.e. there should, over the entire surface of the canister, be a non-zero copper thickness. In addition to this direct measure of containment performance, a number of quantitative supplementary criteria can also be defined. These relate, for example, to the peak temperature in the buffer and to requirements on buffer density and buffer swelling pressure giving favourable buffer properties for maintaining containment. Most of them determine whether certain potentially detrimental processes can be excluded from the assessment. A *safety function indicator criterion* is, thus, a quantitative limit such that if the safety function indicator to which it relates fulfils the criterion, the corresponding safety function is upheld. In the example of buffer freezing discussed above, the safety function indicator criterion is that a buffer temperature exceeding –4 °C is required in order to avoid freezing.

It is emphasised that the breaching of a safety function indicator criterion does not mean that the repository is unsafe, but rather that more elaborate analyses and data are needed in order to evaluate safety (SKB 2011). The criteria are an aid in determining whether safety is maintained. If the criteria are fulfilled, the safety evaluation is facilitated, but fulfilment of criteria alone is not a guarantee that the overall risk criterion is fulfilled. On the other hand, compliance with the risk criterion could well be compatible with a violation of one or several of the safety function indicator criteria. A violation would be an implication of caution; further analyses could be required in order to determine the consequences on a sub-system level or a system level.

An example is the criterion that the groundwater cation charge concentration should exceed 4 mM in order for buffer erosion to be excluded. If this criterion is breached, buffer erosion must be quantitatively evaluated and its consequence in terms of reduced buffer density needs to be propagated to assessments of, for example, buffer swelling pressure and hydraulic conductivity. Alterations of the latter factors could, in turn, influence e.g. canister corrosion. A chain of assessments is, thus, initiated by the breaching of the first safety function, but the final outcome of a possibly increased corrosion rate does not necessarily have an unacceptable impact.

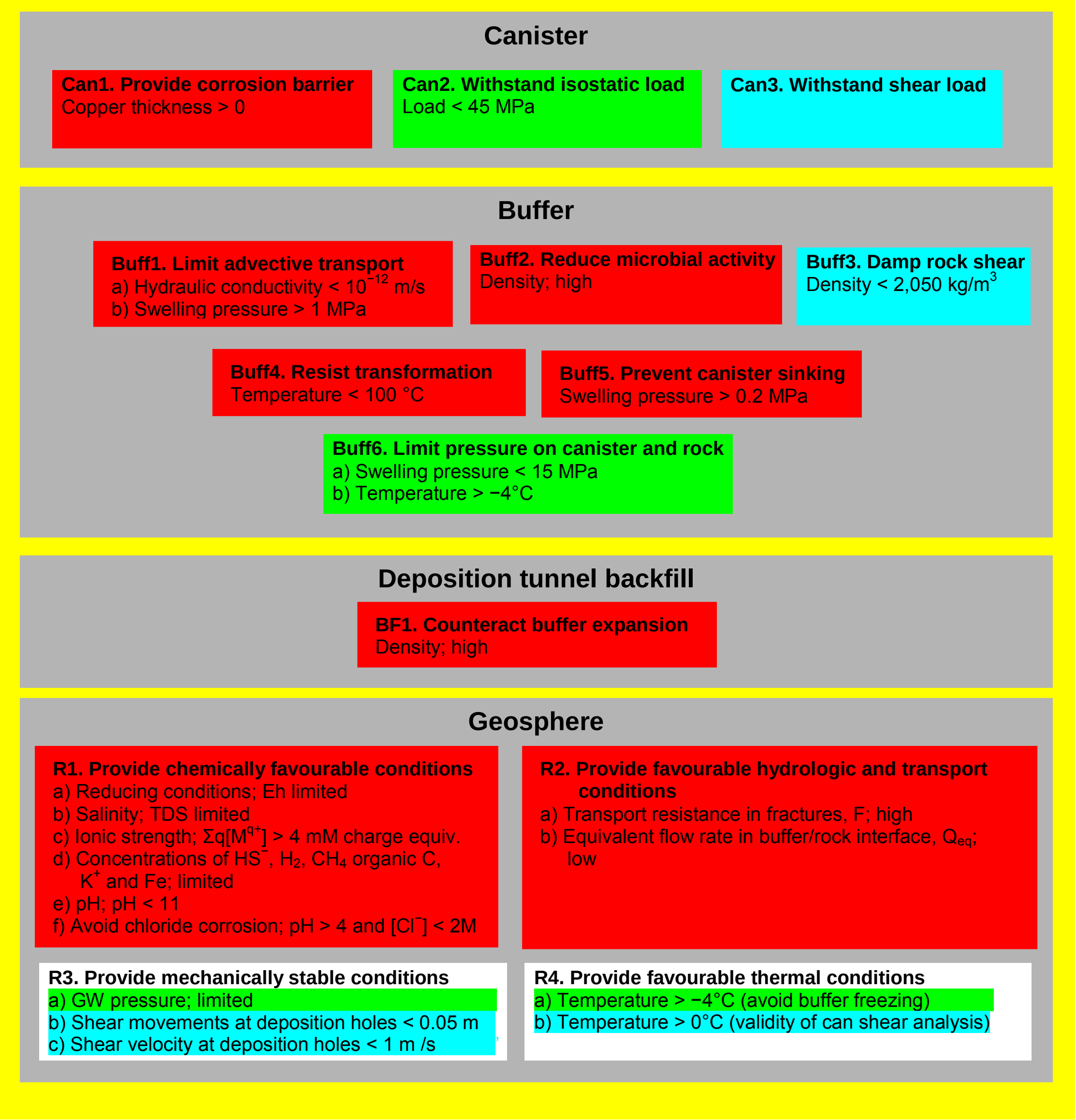
Safety functions are related to, but not the same as, design criteria (SKB 2011). Whereas the latter relate to the initial state of the repository and primarily to its engineered components, the former should be fulfilled throughout the assessment period and relate, in addition to the engineered components, to the natural system.

The safety functions are related: all safety functions of the buffer either support a safety function of the canister, or contribute to retardation in the buffer. Similarly, all safety functions of the host rock either support a safety function of the canister directly or indirectly via a buffer safety function, or contribute to retardation in the rock.

Description and application

A set of safety functions related to containment for a KBS-3 repository is presented in Figure 15.3. For the canister, the safety function indicator Can1 in Figure 15.3 is related to the main function of the copper shell, namely to provide a corrosion barrier. The safety function indicators Can2 and Can3 are related to the mechanical functions of the canister insert, namely to withstand isostatic loads and shear loads, respectively. The main role of the bentonite buffer is to limit advective transport, i.e. to ensure that diffusion is the dominating mechanism for both inward transport of canister corroding agents in the groundwater and potential outward transport of radionuclides. This is achieved if the buffer has a sufficient hydraulic conductivity, Buff1a, and a sufficient swelling pressure, Buff1b. For the geosphere, the safety functions can be grouped into four categories related to favourable *i*) chemical (R1), *ii*) hydrologic and transport (R2), *iii*) mechanical (R3), and *iv*) thermal (R4) conditions.

Figure 15.3: Safety functions (bold), safety function indicators and safety function indicator criteria



Note: 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 Can1 (red), Can2 (green) or Can3 (blue).

The application of safety function indicators is somewhat different from that of other indicators described in this paper. The safety functions with their indicators and associated criteria assist in the analysis essentially in three ways (see also the general discussion about the role of safety functions in MeSA Issue Paper No. 3 – Röhlig *et al.* 2011):

1. They provide an early identification of critical issues to be studied in the safety assessment.
2. In the analysis of a comprehensive main scenario describing a plausible evolution of the repository system, the safety function indicators provide a

structure for evaluating safety. The repository evolution is analysed in a number of time frames and for each time frame, safety is systematically evaluated through an account of the status of the safety function indicators during and at the end of that time frame.

3. The safety functions and safety function indicators are used in the derivation of additional scenarios for the evaluation of uncertainties not taken into account in the main scenario.

The following provides an example of the third application of safety functions. A scenario with canister failures due to isostatic collapse, relating to safety function indicator Can2 in Figure 15.3, is considered. In this canister failure scenario, all possible routes to this failed state are critically evaluated, including assessments of the most unfavourable external conditions, in this case pressure from a glacier overburden of maximum thicknesses, and initial conditions, in this case e.g. a maximum initial buffer density yielding a maximum buffer swelling pressure acting on the canister. The aim is to determine whether the scenario should be assigned a finite probability or whether it could be ruled out as a risk contributor and only analysed as a pure "what if" scenario.

15.2.5 Reference values

A reference value is a yardstick against which an indicator can be compared and repository safety and performance evaluated (IAEA 2003).

The need for reference values depends, to a large extent, on the purpose of the indicator and the assessment context. For indicators used to make a safety statement, a reference value is essential because, without one, the impact of the repository cannot be judged to be acceptable or not. The same is true for safety function indicators when they are used to make explicit judgements about the functional performance of the repository. On the other hand, for indicators used to increase understanding of repository behaviour (rather than judge performance) or to compare between different design options then reference values may not be necessary, although they could still be useful for providing context.

For indicators used to make a safety statement, it is essential to use a valid and defensible reference value. Reference values for the effective dose rate are usually defined by the regulator as a dose constraint (see Section "Regulatory context"). According to Becker *et al.* (2003) and the outcome of the PAMINA project (Becker *et al.* 2009), these vary within a relatively small range between 0.1 mSv/a and 0.3 mSv/a. However, NEA's long-term safety criteria (LTSC) working group found more significant differences among the current criteria used in different NEA member countries, which not only differ in their magnitude, but also with respect to the time frame over which they are envisioned to apply (NEA 2007 – see also MeSA Issue Paper No. 7 – Navarro *et al.* 2011). A further discussion can be found in (NEA 2009), where it is stated that "there are broad similarities in the quantitative safety criteria set by all national regulations over the post closure time frame up to about 10 000 years – all are expressed as dose or risk limits or guidelines, although there are some differences in the numerical limits or guidelines set. Differences however, arise at later times…."

Reference values for complementary indicators other than dose or risk are usually not provided by the regulator and, in most cases, it is the responsibility of the developer to propose and justify the values they use. In this case, when used to make a safety statement, it is important to take account of a specific safety aspect when determining a reference value. The same numerical measure for repository safety, even when calculated in exactly the same way, can yield different safety statements if referred to different safety aspects and combined with the appropriate reference values. For example, one can consider the safety measure *radiotoxicity flux in groundwater*. What is a safe level of this? Probably there is a river near the repository, which could serve as an exposure pathway. When considering the safety aspect *health of river fauna* or, somewhat nearer to human health, *integrity of drinking water from the river*, it is a good idea to compare the calculated flux with the natural radiotoxicity flux of the river. In large rivers, however, the natural flux can reach thousands of Sieverts per year, meaning that even a rather bad repository is "safe" with respect to this specific aspect. On the other hand, if the safety aspect *integrity of water from a well* is considered, the natural radiotoxicity flux in the local groundwater should be taken as reference, and this is normally several orders of magnitude lower than that of a river. Since the safety statements derived from these two reference values are completely different, the respective safety indicators should also be seen as different, even though based on the same calculated quantity.

A review of the use of complementary indicators in safety assessments to date shows that the definition of appropriate reference values is the most difficult aspect of their application. Reference values can be valid globally like the concentration of radiotoxicity in drinking water that is harmless for human health. The value may not yet be known exactly, but it is unlikely that it differs between, for example, Finland and Spain. Other reference values have a very local character and are only valid in a specific environment, e.g. natural radiotoxicity flux or concentration in groundwater. An issue for disposal programmes that have not yet identified and characterised a site is that it is then difficult to derive appropriate local-scale reference values. Several safety assessments have used proxy data from other sites or global or regional-scale average values when actual site-specific data are unavailable. Within the IAEA project "Natural activity concentrations and fluxes as indicators for the safety assessment of radioactive waste disposal" (IAEA 2005), several approaches for gathering local and regional data and using them – if necessary by averaging – for the derivation of reference values were investigated.

Typical concentrations in natural drinking waters to be used as reference values for the indicator *radiotoxicity concentration in biosphere water* are in a range of 10^{-5} Sv/m^3 to 10^{-6} Sv/m^3 (Wolf *et al.* 2008). Reference values for the *radiotoxicity flux from the geosphere* can be derived from natural toxicity fluxes, e.g. with groundwater or by erosion. Within the SPIN project, a value of 60 Sv/a was used. However, as mentioned for this indicator, a local reference value needs to be defined, which might vary over a broader range, depending on the respective site conditions.

Concerning risk, typical reference values might be taken from technical risks like road accident or air traffic fatalities. The so-called acceptable risk is the level of loss a society considers acceptable given existing social, economic, political, cultural, technical and environmental conditions. In environmental and especially in nuclear sciences there is the general agreement, that a risk of $1 \cdot 10^{-6}$ per year of suffering a serious health effect is an appropriate level as a regulatory constraint or target (e.g. HSE 1988, NEA 2005).

When indicators are used to increase understanding of repository behaviour or simply to set a context for the impact of the repository, then it is possible to compare the indicator with a number of different reference values, and not one single value, to provide greater context and to illustrate the variability in natural systems. For example, Nagra in the Opalinus Clay safety assessment (Nagra 2002) compared the indicator *radiotoxicity fluxes from the repository* to three different natural waters – the biosphere aquifer, and the waters from the rivers Rhine and Thur – and the indicator *radiotoxicity of the wastes* to the abundance of naturally-occurring radionuclides in both the Opalinus Clay and three different uranium ores of different grade.

15.2.6 Timescales

The original intent of using complementary indicators was to avoid some of the uncertainty inherent in calculations of dose and risk based on assumptions for human behaviour and climatic conditions in the very far future. As such there was an anticipation that complementary indicators, particularly those that can be considered as safety indicators, would be most usefully applied to very long assessment time periods.

This concept was reinforced by the IAEA (IAEA 2003, 2005) and in the SPIN project that concluded (Becker *et al.* 2003) that the effective dose rate is especially suitable for the time frame only up to a few ten thousands of years. Afterwards its application is restricted because of the uncertainties of biosphere parameters. The radiotoxicity concentration in biosphere water is a more robust indicator for longer time frames than the dose rate and potentially applicable in a time frame of up to 100 000 years. The radiotoxicity flux from the geosphere is only indirectly correlated to human health and therefore, it is more suitable for very long time frames beyond 100 000 years.

The preferential application of complementary indicators to different time periods is also supported by the most recent NEA report considering timescales in safety assessment (NEA 2009b) which noted that that the types of argument, and indicators of performance and safety used or emphasised, may vary between time frames.

This timescales approach is, however, only to a limited extent reflected in existing regulatory guidance documents which are mostly non-prescriptive, although some do provide suggestions of the type of calculations that could be made using complementary indicators. Nonetheless, a few regulations do explicitly address the issue. In Finland, for example, the regulations require dose constraints to be applied for the initial adequately predictable time period but, after the onset of glaciation and permafrost conditions, constraints on the activity release rates to the environment – a flux based complementary indicator – are applied in preference to dose (STUK 2001). In other countries that adopt a prescriptive approach to regulation, the time frames over which specific indicators need to be calculated is pre-defined. In the US, for example, regulations applicable to the proposed Yucca Mountain repository required that doses are calculated out to 1 million years, but environmental groundwater standards apply only to the first 10 000 years.

Another aspect relevant to timescales is that complementary indicators can be used to justify the cut-off time for the assessment by explicit comparison of the changing hazard posed by the waste (due to radioactive decay) with the hazard due to naturally occurring materials and, in particular, uranium orebodies. This approach was used in the Swiss Opalinus Clay safety assessment (Nagra 2002).

Despite the advantages of complementary indicators in assessments of far-future impacts, a review of their use in safety assessments to date shows, however, that most organisations calculate all indicators (dose/risk and complementary indicators) for all assessment time periods, and do not apply any preferred bias or weighting. There may be a number of reasons for this, but primarily the growing interest in using complementary indicators to evaluate sub-system performance and the evolving status of barriers over time (expressed as performance indicators or safety function indicators) means that they add value to the assessment at all time periods and not just in the far future.

15.2.7 Transferability

As stated in the chapters above, safety indicators give an indication of whether a repository can be considered safe. Safety indicators are, therefore, a measure for the safety of the total system. From this quality, or characteristic, of the safety indicators it can be reasoned, that they have to be applicable in general, provided that the characteristics of the safe state of a repository is specified in the same way for all repositories. This seems to be the case, at least in terms of qualitative transferability, as long as the indicator effective dose rate or a corresponding risk criterion is used. The safety statement, that human health is not jeopardised by radionuclides released from the repository under consideration, can be derived from the indicator effective dose rate, if the interrelation between effective dose rate and impact on human health is known. Quantitative differences might exist between different countries with respect to the defined effective dose rate or risk criterion, because assumptions about the effects of small doses differ to some extent. Quantitative differences also exist with respect to the expected duration of validity of the indicator in different countries. But beside this quantitative difference, there is agreement in principle about the effect that ionising radiation might have on human health (e.g. ICRP 2007). Therefore, the safety indicator effective dose rate is applicable in general, no matter which type of repository and host rock is under consideration, or which type of radioactive waste it contains. The only determining factors are amount and point in space and time of the release of radionuclides into the biosphere.

In other words, the safety indicator effective dose rate (or a corresponding risk) is a generally applicable indicator, because the interrelation between a certain effective dose rate and human health is always the same, independent of repository concept, host rock type and waste type.

The same is true for complementary indicators which, like the effective dose rate, are calculated from the concentration of activity in biosphere using specific conversion factors such as, for example, the ingestion dose coefficients for calculating radiotoxicity.

The statement on the transferability of the safety indicators effective dose rate and concentration of activity in the biosphere is substantiated by experience which shows that suitable safety indicators can be applied to repositories in all formations, and several countries select similar sets of indicators. Independent of the repository concept and the host rock, all safety assessments examine radionuclide fluxes out of the host formation or the overlying rocks as well as radionuclide concentrations in near surface aquifers.

A slightly different implication is deduced for the safety indicator radionuclide flux from the geosphere. Because natural radionuclide fluxes (as absolute flux through a given cross-section, unity Sievert per time) can differ by several orders of magnitude, the safety statement derived from this safety indicator is not in all cases the same, but it depends on the employed (local) reference value.

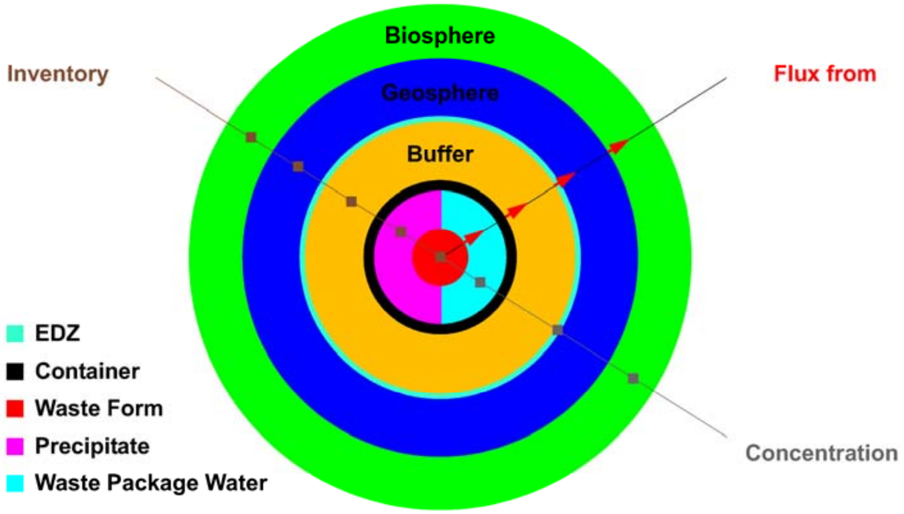
In contrast to safety indicators, performance indicators depend much more on the respective repository concept, including the host-rock formation. One important reason is the different safety and repository concepts and the resulting different structure of models used for near field calculations. For granite, usually the radionuclide release from one container is assumed to be independent from all others and calculated representatively for only one or a limited number of containers failed at a given time. This suggests a compartment structure as shown in Figure 15.4. The container representing one or a group of containers with radioactive waste is surrounded by a bentonite buffer, which itself is surrounded by the granite formation. Finally, the biosphere compartment forms the outer rim of the compartment structure. A similar structure may also be used for a repository in clay formations. A different picture occurs for altered evolution scenarios of repositories in rock salt. Here, typically different emplacement areas are considered, which are not independent of each other, since contaminated brine might be transported by convergence-driven advective flow through the drifts from one disposal area to the other and mixing processes may take place. This is taken into account by using different compartments for each of the disposal areas and by a compartment representing the drifts and shafts of repository.

Furthermore, there are indicators that are applicable to only one specific formation or concept. One example is the "closure time for plugs and seals in rock salt" (NRG 2000), which is comparable to the safety function indicators (see below). This kind of process has various consequences for modelling and is specific to rock salt formations. Seals and plugs are made of rock salt and will reach the permeability of undisturbed rock salt by compaction after a certain period of time. At this point they are regarded in the models to be no longer permeable, i.e. no more fluid flow through these barriers is possible after closure of the plugs and seals. Another example is the state of stress, which can serve as an indicator for the integrity of the geological barrier in a salt dome. As long as the applied load on the salt rock is below the dilatancy boundary, any deformation of the salt due to creep processes will not impair barrier tightness.

The potential usefulness of safety function indicators 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, the rock salt in the German concept, and the clay formation in the Belgian, French and Swiss concepts (NEA 2009a). Therefore, safety function indicators are concept specific and, thus, not generally transferable.

The preceding statements about the transferability of different indicators and different types of indicators differ considerably from some statements made by the institutions participating in the recent MeSA review. The answers in the questionnaire show that some institutions consider certain indicators to be universally applicable, whereas other institutions categorise the same indicators to be concept or even site-specific. This is comprehensible for indicators which are denoted identically, but defined in different concept- or site-specific ways, and for indicators which are compared to different reference values. But the divergences might also be based on different interpretations of the term “universally applicable” or just on the heterogeneous terminology in the field of indicators in general.

Figure 15.4: Compartment structure for a repository in granite (Becker *et al.* 2003)



15.2.8 Dependence on stage of repository programme

The results from the recent MeSA review show that a current area of development for indicators is to consider their use within different stages of a repository development programme, and particularly in the early stages for comparison of possible concept or design variants, during the stage of siting to compare alternative host rocks or sites, and prior to the construction stage for design optimisation. A quite new aspect is the link between complementary indicators and performance confirmation monitoring in the post-emplacement stage. Once waste has been emplaced, predicted performance can be compared with actual measured performance for certain indicators (e.g. canister corrosion rates) provided measurements are possible. If deviations are identified, then further analyses and investigations might be required.

In very general terms, the most advanced repository development programmes are also the ones that have the greatest experience in using complementary indicators. This observation may also reflect a broad view that the value of complementary indicators increases significantly when a preferred site has been identified and the emphasis changes from undertaking generic safety assessments to evaluating specific impacts to a particular community and environment, and when meaningful, local reference values for comparison with safety and performance indicators can be established. Further to these general views some specific aspects for the different kind of indicators can be given.

The use of safety indicators other than dose and risk probably becomes more important as repository programmes develop towards implementation. In an early stage use of one indicator like dose or risk might be enough to analyse a repository system and answer more generic questions by evaluating the impact of different concepts or repositories in different formations. As the repository programme approaches important decisions, e.g. site selection, the confidence in the overall safety and the use of additional safety statements based on additional indicators becomes more and more important. This is, for example, shown in the advanced Finnish programme, where other safety aspects besides human health are now included in the regulations (see below).

As discussed above, one important role of performance indicators is the understanding of the behaviour of single barriers or subsystems of the repository system. Performance indicators can be a helpful tool to be used in optimising layout and design of the repository and could also give valuable information about properties of a suitable site. With respect to this, performance indicators should already be used in an early stage of the repository programme, at least in a stage when the programme moves from a generic state to concept decision and/or site selection. Their role in communication with licensing authorities as well as with the general public, illustrating how the system behaves, is of increasing importance with further evolution of the repository programme, where confidence in the performance assessment becomes more and more relevant.

The use of safety functions – and the emphasis that can be put on them in a safety assessment – depends on the scientific understanding of the system being analysed. The establishment of a 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 concept- 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, it becomes important to demonstrate clearly how they were derived. 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 (NEA 2009a).

15.2.9 Regulatory context

National regulations always establish at least one safety indicator (usually dose or risk) which indicates whether the disposal system is able to comply with the given safety objectives. Such a quantity or safety indicator may be effective dose (defined in ICRP Publication 60), which specifies the expected overall effect radiation has on the body. The effective dose has been implemented into legislation and regulations in many countries worldwide, and provides a practicable approach to the management and of radiation hazards in relation to both occupational exposures and exposures of the general public.

While effective dose and/or risk are common safety indicators, the use of these indicators varies considerably across the countries surveyed (see MeSA Issue Paper No. 7 – Navarro *et al.* 2011). The NEA's Regulator Forum Project on long-term safety criteria (LTSC) also found significant variation among the current criteria, which not only differ in their magnitude, but also with respect to the time frame over which they are envisioned to apply. Also the bases for setting the criteria vary. This implies that numerical criteria of different countries cannot be compared in a meaningful way without also considering the underlying reasoning on what is an acceptable level of consequences today and in the future and how it should be evaluated (NEA 2007).

In all national regulations there are broad similarities in the safety indicators and criteria for the post-closure phase up to about 10 000 years, where dose or risk limits or guidelines are used. For later times, a few recent regulations use different indicators – e.g. nuclide-specific activity fluxes from compartments, inventories inside or outside of compartments, or concentrations at certain locations. This happens in recognition of the fact that increasing uncertainties, especially those concerning the long-term prediction of the biosphere, may make dose or risk quantities less meaningful. Because of these uncertainties, ICRP (ICRP 2007) and many national regulations define specific time windows for safety indicators and recommend or prescribe the use of indicators which complement the indicators dose or risk.

The need for complementary indicators is recognised by several regulators and was e.g. pointed out by the IAEA Coordinated Research Programme on Safety Indicators (1999–2003, IAEA 2003). Most regulators have a strong expectation that the developer will use such complementary indicators in their safety assessment. However, whether the use of complementary indicators is prescribed or only recommended in regulations differs from country to country.

Complementary indicators often are performance indicators which indicate how the entire system performs without directly predicting radiological consequences. Performance indicators have been selected and used by implementers when building the safety case in order to understand, quantify and explain how the disposal system works and to give additional arguments that underpin the statement that the repository is safe. Although, from a methodological point of view, performance and safety indicators provide different kind of statements, regulations often do not distinguish explicitly between these two types of indicators. Yet, some new regulations have included indicators, which have the character of a performance indicator, although they are not denoted as such, see e.g. CNSC (2006), SSI (2005). Usually, regulations provide no quantitative criteria for performance indicators.

If safety functions are defined for system components it is necessary to introduce a method to evaluate whether the components fulfil their intended function (see section on safety function indicators). For this purpose, safety function indicators are defined and target values or numerical criteria are assigned to these indicators in order to either allocate a certain performance, or to check and quantify the fulfilment of the safety function. Regulations usually do not specify which safety functions the proponent should assign to technical components, nor do they specify corresponding safety function indicators and criteria. The main reason for this is that, for technical components, the choice of safety functions and safety function indicators often depends on the repository concept so that a specification on the part of the regulator can hinder the development of an optimal system which a proponent should be free to develop. Nevertheless, some regulations specify safety functions for the geological barrier like the new German Safety Requirements (BMU 2009) where the "integrity of the confining rock zone" is required and a dilatancy and a fluid pressure criterion are explicitly mentioned.

15.3 Conclusions

The concept of indicators for safety assessments has developed considerably during the last 15 years in national and international projects and is now internationally accepted. This progress has occurred in parallel with the development of the safety case concept, where multiple lines of evidence are required. The use of safety indicators represents one type of evidence and arguments in support of a safety case. As they concern the overall safety of the repository system, safety indicators may support the statement of low consequences of any radionuclide release to the surface environment and increase the robustness of the safety case. Indicators that illustrate the performance of the system or safety functions support the safety case by increasing transparency and increasing confidence in the ability of the repository system and of its components to fulfil their safety roles.

A review performed during the MeSA project showed that a variety of indicators complementary to dose and risk is used in safety assessments in different countries. These complementary indicators usually fall into three categories, i.e. concentration or content related indicators, flux related indicators, and indicators related to the status of barriers or repository components.

Frequently complementary indicators are distinguished according to their purpose. This classification is based on experience from international fora and projects. *Safety indicators* give an indication on the safety of the repository and, particularly dose and risk are suitable for comparison with established acceptance criteria. *Performance indicators* are in particular suitable for understanding and evaluating system behaviour. *Safety function indicators* are suitable for evaluating key parts of a repository system in a disaggregated fashion.

The review demonstrated a growing use of complementary indicators in a design and engineering context, such as for evaluating the performance of design variants, design optimisation and site selection. This is a relatively new area of interest that was not usually discussed in early reports promoting complementary indicators.

Early thinking on complementary indicators was driven by concern over the inherent uncertainty in estimating potential dose/risk to people in the far-future when climate and human behaviours may be radically different to today. To remove the uncertainty associated with the exposure pathway, safety assessors focussed attention on the concentrations and fluxes of repository-derived radionuclides that would occur in the geosphere, and compared these indicators to the abundance of naturally-occurring radionuclides as an alternative end-point to the assessment calculations. This approach is still valid, but now forms only one part of the growing suite of complementary indicators that has been proposed and tested.

Safety indicators, e.g. doses to individuals, give an indication on the safety of the repository and are suitable for comparison with regulatory criteria. Consequently, most national regulations relating to repositories for nuclear waste give safety criteria in terms of dose and/or risk, and these indicators are evaluated for a range of disposal system evolution scenarios using quantitative safety assessment. Many regulatory systems recognise the potential value of indicators additional to dose and risk, but they take considerably different stances when it comes to prescribing (formally) or recommending (informally) their use in safety assessments and safety cases. Often, guidance in the form of recommendations is provided, but prescriptive requirements are avoided because such requirements might hinder repository optimisation by the implementer.

The development of indicators is on-going. In particular, with the increasing use of safety functions various indicators are being developed with respect to the safety functions of individual repository components. With the greater use of indicators it might also be expected that increasingly they find their way into regulations.

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Annex 15.1

Summary of specific non-dose/risk indicators reported by each organisation, extracted from the MeSA review

Trans = transferability. U = universal, C = concept specific, S = site specific, T = specific but under certain conditions transferable

Cat = category. SI = safety indicator, PI = performance indicator, SFI = safety function indicator, NC = not categorised

Grp = group. TA = transport, all nuclides, TN = transport, specific nuclides, B = barrier status,

Purp = purpose. SSS = safety statement, whole system, PSS = performance statement, whole system, PSC = performance statement, component,

PCV = performance comparison, design variants, D = design optimisation, V = model validation, A = assessment activity, S = support system understanding, C = communication.

Specific Indicator	Description	Classification			
		Trans	Cat	Grp	Purp
SCK-CEN					
Concentration in groundwater	Aquifer above host clay formation	U	SI	TA	SSS
Flux out of host formation	Aquifer above host clay formation	T	SI	TA	SSS
Containment factor	Ratio of released radiotoxicity (up to 1 Ma)/initial radiotoxicity at time of disposal	U	PI (SI)	TA	PSS
Transport time through clay barrier	-	T	PI	TN	PSC
Evolution of radiotoxicity inventory in compartments	-	U	PI	TA/TN	PSS/PSC
Flux from compartments	-	U	PI	TA/TN	PSC
Time-integrated flux from compartments	-	U	PI	TA/TN	PSC
Time-integrated flux related to safety functions	-	U	PI	TA/TN	PSC
FANC					
Extent of the potentially contaminated zone	In the biosphere and the part of the geosphere located outside the disposal system	U	NC	TA/TN	SSS
Activity and radiotoxicity concentration in the liquid and solid phases	In the biosphere and the part of the geosphere located outside the disposal system	U	NC	TA/TN	SSS
Flux of activity/radiotoxicity released out of the disposal system	At the boundaries of the disposal system	U	NC	TA/TN	SSS/PSS/ PCV/D
Total activity/radiotoxicity released out of the disposal system	At the boundaries of the disposal system	U	NC	TA/TN	SSS/PSS/ PCV/D
NWMO					
Radiotoxicity concentration in surface waters	Current reference lake above repository	U	NC	TA	SSS
Radiotoxicity flux to surface	100 km^2 watershed-scale	U	NC	TA	SSS
Total waste radioactivity	Repository (neglects losses other than decay)	U	NC	TA	SSS/A
Nuclide flow rate across various boundaries	Repository barrier/site boundary	U	NC	TA/TN	PSC/V
Dose rate	Repository/site	U	NC	TA/TN	SSS
Age of groundwater	Site	U	NC	TA	SSS/PSS/ C
RAWRA					
Source term	Water activity on the interface repository/host structure	C	SI	TN	SSS
Groundwater activity	Activity of groundwater on the interface host structure/biosphere	S	SI	TN	SSS
Container lifetime/future version	Probable durability	C	PI	B	D
NRI					
Concentration of radionuclides in water	PA	U	SI	TA	-
Posiva					
Complementary safety indicator I	-	U	-	TA/TN	
Complementary safety indicator II	-	U	-	TA/TN	

Specific Indicator	Description	Classification			
		Trans	Cat	Grp	Purp
Andra					
Advection / diffusion	Host rock, waste disposal tunnels, galleries, shaft	S	PI	Groundwater	PSC
Radionuclide mass transport rock v. shafts	Host rock, waste disposal tunnels, shaft	C/S	PI	TN	PSC
Diffusion process in rock and seals	Host rock, waste disposal tunnels, galleries, shaft and access ramp	C/S	PI	TN	PSC
Radionuclide molar flux (maximum)	Host rock, waste disposal tunnels, galleries, shaft and access ramp	U	PI	TN	PSS
Radionuclide molar flow (mass over assessment period)	-	U	PI	TN	PSS
Radionuclide molar flow (time of maximum flow)	-	U	PI	TN	PSS
Distribution of activity concentration	-	U	PI	TN	PSS
BGR					
State of stress (dilatancy criterion)	Isolating rock zone	C	SFI	B	PSC/A/D/S/C
State of stress (fluid pressure criterion)	Isolating rock zone	C	SFI	B	PSC/A/D/S/C
GRS-K					
Alternative indicator (no specific term)	Outer border of isolating rock zone	U	SI	TA	SSS/PSS/D
Stress (implicitly required)	Within isolating rock zone	U	PI	B	PSC/D
Fluid pressure (implicitly required)	Within isolating rock zone	U	PI	B	PSC/D
Temperature (implicitly required)	Within isolating rock zone	U	PI	B	PSC/D
GRS-B					
Radiotoxicity concentration in biosphere water	Surface near aquifer (GBI)	U	SI	TA	SSS/C
Power density in groundwater	Surface near aquifer (GBI)	S	SI	TA	SSS/C
Radiotoxicity flux from the geosphere	Interface host rock/overburden	S	SI	TA	SSS/C
Radiotoxicity in compartments	Waste segment, repository, overlying rock, total	U	PI	TA/TN	PSC/S/C
Radiotoxicity flux from compartments	Fluxes out of compartments above	U	PI	TA/TN	PSC/S/C
Integrated radiotoxicity flux from compartments	Fluxes out of compartments above	U	PI	TA/TN	PSC/S/C
Radiotoxicity concentration in groundwater	Near-surface groundwater	U	SI	TA	SSS
Radiotoxicity flux from geosphere	Near-surface groundwater	T	SI	TA	SSS
Radiotoxicity inventory in compartments	System compartments	T	PI	TA	S
Relative integrated radiotoxicity flux from compartments	System compartments	T	PI	TA	PSC/S
Index of Radiological Insignificance (RGI)	Barrier system within and including the isolating rock zone	T	SI	TA	SSS/C

Specific Indicator	Description	Classification			
		Trans	Cat	Grp	Purp
VerSi I1	Barrier system within and including the isolating rock zone	U	PI	TA	site selection
VerSi I2	Barrier system within and including the isolating rock zone	U	PI	TA	site selection
VerSi I3	Isolating rock zone	U	PI	TA	site selection
NRG					
Effective dose rate	Biosphere	U	SI	TA/TN	SSS/C
Radiotoxicity concentration in biosphere water	Biosphere water (rivers)	U	SI	TA/TN	SSS
Power density in groundwater	Groundwater	U	SI	TA/TN	SSS
Radiotoxicity flux from geosphere	Flux from geosphere to biosphere	U	SI	TA/TN	SSS
Relative activity concentration in biosphere water	Biosphere water	U	SI	TN	SSS
Activity in compartments	Waste container, concrete buffer, gallery, clay, biosphere	C	PI	TA/TN	PSC/S
Activity flux from compartments	Flux from: waste container, concrete buffer, gallery, clay	C	PI	TA/TN	PSC/S
Time integrated activity flux from compartments	Flux from: waste container, concrete buffer, gallery, clay	C	PI	TA/TN	PSC/S
Radiotoxicity in compartments	Waste container, concrete buffer, gallery, clay, biosphere	C	PI	TA/TN	PSC/S
Radiotoxicity flux from compartments	Flux from: waste container, disposal cell, host formation	C	PI	TA/TN	PSC/S
Time integrated radiotoxicity flux from compartments	Flux from: waste container, disposal cell, host formation	C	PI	TA/TN	PSC/S
Activity concentration in compartment water	Waste container, disposal cell, gallery, biosphere	C	PI	TA/TN	PSC/S
Radiotoxicity concentration in compartment water	Waste container, disposal cell, gallery, biosphere	C	PI	TA/TN	PSC/S
Activity/radiotoxicity concentration in biosphere water divided by A/R concentration in waste package water	Biosphere / waste package	C	PI	TA/TN	PSC/S
Transport time through compartments	Geosphere	S/C	PI	TA/TN	PSS/S
Time to plug closure	Borehole plug	S/C	PI	B	PSC
ENRESA					
Radionuclide concentration in the biosphere water	In the water course used by the receptor (well or river)	U	SI	TA	SSS
Radiotoxicity flux from the geosphere	At the interface between the geosphere and biosphere	U	SI	TA	SSS
Power density in biosphere water	In the water course used by the receptor (well or river)	U	SI	TA	SSS
Fraction of UO2 matrix altered vs time	UO2 becomes oxidised/altered due to the alpha radiolysis in the water in contact with it	C	PI	B	PSC/C
Canister failure distribution	Carbon steel canisters fail due to generalised corrosion	C	PI	B	PSC/C
Water travel time in the geosphere (granite)	The water travel time is calculated from the repository to the discharge point to the biosphere	S	PI	TN	PSC/C/S
Solute transport time through the near-field	A measure of the time necessary for a given solute to move from the inner surface of the bentonite barrier to the bentonite-granite interface	S/C	PI	TN	PSC/S

Specific Indicator	Description	Classification			
		Trans	Cat	Grp	Purp
Solute transport time through the geosphere	A measure of the time necessary for a given solute to cross the geosphere from the outer surface of the near-field to the biosphere	U	PI	TN	PSC/C/S
Inventory of radionuclides in each compartment	The inventories present in each compartment are calculated	U	PI	TA/TN	PSC/C/S
Radionuclide fluxes between compartments	Fluxes are calculated at the interfaces between compartments	U	PI	TA/TN	PSC/C/S
Time-integrated radionuclide flux from compartments	Time-integrated fluxes are calculated at the interfaces between compartments	U	PI	TA/TN	PSC/C/S
Time-integrated molar flux from compartments	Time-integrated fluxes are calculated at the interfaces between compartments	U	PI	TA/TN	PSC/C/S
Radionuclide inventory outside compartments	The system is divided into a set of consecutive compartments, from the waste to the biosphere. This indicator provides the inventory that has moved beyond a given compartment.	U	PI	TA/TN	PSC/S
SKB					
Minimum copper thickness	Canister	C	SFI	B	PSC
Ionic strength of groundwater	Geosphere, near-field	C	SFI	B	PSC
A range addition to the two above (see SR-Site report)	Either canister, buffer, deposition tunnel, geosphere	C	SFI	B	PSC
Finnish activity constraint	Geosphere/biosphere interface	U	NC	TN	SSS
Natural content	Biosphere	S	NC	TN	SSS
Geosphere transmission	Geosphere	U	NC	TN	PSC
Nagra					
RTI of waste on ingestion	Throughout the system (once the waste starts to disperse)	U	SI/PI	decay	hazard
RTI flux to biosphere	Geosphere/biosphere interface	U	SI/PI	TA	SSS
RTI concentration at top of host rock	Top of host rock	U	SI/PI	TA	SSS
RTI distribution	Within each of the main system compartments	U	SI/PI	TA	PSC/S
Diffusive transport time through host rock: half life	Outer boundary of host rock	S	SI/PI	TN	PSC/S
Steady state transport distance	Across buffer and host rock	S	SI/PI	TN	PSC/S
RWMD					
Concentration of radiotoxic or chemically toxic elements in the biosphere over time	Biosphere	U	SI	TA	PSS
Radiotoxicity flux from the geosphere to the biosphere over time	Geosphere	U/S	SI	TA	PSS
Radiotoxicity inventory over time in components of the geological disposal system	Not defined at the present time and could be all components	U/C	PI	TA	PSC
Radiotoxicity flux over time from components of the geological disposal system	Geosphere/Near-field	U/S/C	PI	TA	PSC

Specific Indicator	**Description**	**Classification**			
		Trans	**Cat**	**Grp**	**Purp**
Cumulative radiotoxicity flux up to given times from components of the geological disposal system	Not defined at the present time and could be all components	U/C	PI	TA	PSC
Containment factor defined as the activity released from the GDF divided by activity disposed of, over time	Not defined at the present time	U/C	PI	TA	PSS
Transport time through components of the geological disposal facility	Not defined at the present time	U/S/C	PI	TA	PSS
US [DOE/EPA/NRC]					
Flux across defined accessible environment boundary	(<or=) 5km from repository (accessible environment)	S	SI	TA	SSS
Radionuclide concentration in groundwater	(<or=) 5km from repository (accessible environment)	S	SI	TN	SSS
Radionuclide concentration in groundwater	(<or=) 18km from repository (accessible environment)	S	SI	TN	SSS
Engineered barrier containment time requirement	-	U	PI	B	PSC
Post-containment engineered barrier release rate limit	-	U	PI	TA	PSC

16. Treatment of uncertainties

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Abstract

One of the drivers for geological disposal of radioactive wastes is the removal of the uncertainties associated with leaving the waste at the surface, where it is accessible to humans and vulnerable to the dynamic nature of the Earth's surface over very long timescales. This paper, therefore, discusses developments in approaches and methods for the treatment of uncertainty in safety assessments for the disposal of radioactive waste. The three broad types of uncertainty in NEA (1991), namely, scenario uncertainties, model uncertainties, and data or parameter uncertainties remain. There have, however, been considerable developments in the treatment of uncertainties in safety assessments since 1991. More data have been collected and this has allowed the development of increasingly realistic performance and safety assessment models and assessments. Epistemic uncertainty has been reduced in many cases. Statistical methods continue to play a key role in the quantification of uncertainty in general, and may be the only approach for the treatment of some types of aleatory uncertainty. Iteration is an important aspect of performance and safety assessment, and results from previous iterations and findings from uncertainty and sensitivity analyses are used to identify which areas of uncertainty most need to be reduced in order to increase confidence in assessed impacts (e.g. dose, risk) and the safety case. This iterative link between safety assessment and research and development (R&D) programmes is an important aspect of developing overall confidence in the safety case. The paper discusses examples of approaches used in the treatment of uncertainty in several safety assessments.

Keywords: Uncertainty, safety assessment, safety case, geological repository, radioactive waste, disposal.

16.1 Introduction

As part of the NEA MeSA project, a series of issue papers is being produced, each focused on a specific topic related to safety assessment. The topics addressed are:

A. Gesellschaft für Anlagen- und Reaktorsicherheit (GRS) mbH, Braunschweig, Germany.

B Radioactive Waste Management Directorate, NDA Harwell Office, Building 587, Curie Avenue, Harwell, Didcot Oxfordshire OX11 0RH, UK.

C. Ondraf/Niras, Avenue des Arts, 14, Brussels, Belgium.

D. U.S. Department of Energy, Office of Civilian Radioactive Waste Management, Las Vegas, Nevada, USA.

E. Sandia National Laboratories, Las Vegas, Nevada, USA.

F. Nuclear Waste Management Organisation (NMWO), 22 St. Clair Ave E, Toronto M4T 2S3, Canada.

Topic 1. Safety assessment in the context of the safety case.

Topic 2. Safety assessment and safety case flowcharts.

Topic 3. System description and scenarios.

Topic 4. Modelling strategy.

Topic 5. Indicators for safety assessment.

Topic 6. Treatment of uncertainties.

Topic 7. Regulatory issues.

The present paper addresses the treatment of uncertainties (Topic 6). The treatment of uncertainty needs to be an integral part of performance assessment and safety case development because uncertainties will always be present in long-term assessments of repository safety. This is clearly reflected in the NEA Safety Case Brochure (NEA 2004) in which the special challenges associated with communicating uncertainty and risks are addressed:

> "A key output from safety assessment is the identification of uncertainties that have the potential to undermine safety. Thus, safety assessment needs to be integrated within the management strategy. In the safety case, the connection needs to be made between key uncertainties that have been identified and the specific measures or actions that will be taken to address them, especially with regard to the R&D programme, in order eventually to arrive at a safety case that is adequate for licensing."

In (NEA 2004) various approaches to the treatment of uncertainties during safety case development and safety assessment are discussed, e.g:

> "Some uncertainties can be reduced by methods including site characterisation, design studies, fabrication and other demonstration tests, experiments both in the laboratory and in underground test facilities. As a programme matures, studies will increasingly focus on key safety-relevant uncertainties and the specific data and measurements needed to resolve these."
>
> "In other cases, it may be preferable to avoid the sources of uncertainty or mitigate their effects by modifications to the location or design of the repository."
>
> "Robust and reliable systems are amenable to a well-founded and convincing analysis of safety. Safety assessments must nevertheless capture, describe and analyse residual uncertainties that are relevant to safety, and investigate their effects. These include uncertainty about whether all the relevant features, events and processes have been considered, uncertainty in their description and how they should be modelled, and uncertainty in the data that is needed in an analysis."

This strategy was summarised in (Posiva 2008) in four key-words: identify, avoid, reduce and assess which we will discuss in the following in more detail.

The identification and communication of uncertainties is usually an essential part of all the reports related to the development of the safety case. The development of a disposal system is based on the idea of robustness, which involves avoiding concepts and components the behaviour of which would be difficult to understand and predict. The stepwise repository implementation process allows the reduction of uncertainties by means of continuous R&D efforts and design studies. At advanced stages of the repository development, site characterisation and optimisation become important processes contributing to the reduction of uncertainties. *However, some uncertainties will always remain and have to be assessed in terms of their relevance to the final conclusions on safety*.

This iterative strategy, in which the assessment of uncertainties guides the avoidance or reduction of any uncertainties that might otherwise compromise the safety case, is illustrated in Figure 16.1 [adapted from Figure 6-9 of Posiva (2009)]. This figure can be viewed as an elaboration of the management of uncertainties in the example generic assessment strategy flowchart shown in Figure 16.2 (after Figure 12.4 in Schneider *et al*. 2010, developed as part of MeSA Paper No. 2), and, in particular, the iterative loop shown in red in Figure 16.2. The questions shown on the right-hand side of Figure 16.1 provide a structure to the following discussions.

Figure 16.1: Iterative management of uncertainties (adapted from Figure 6-9 of Posiva 2009)

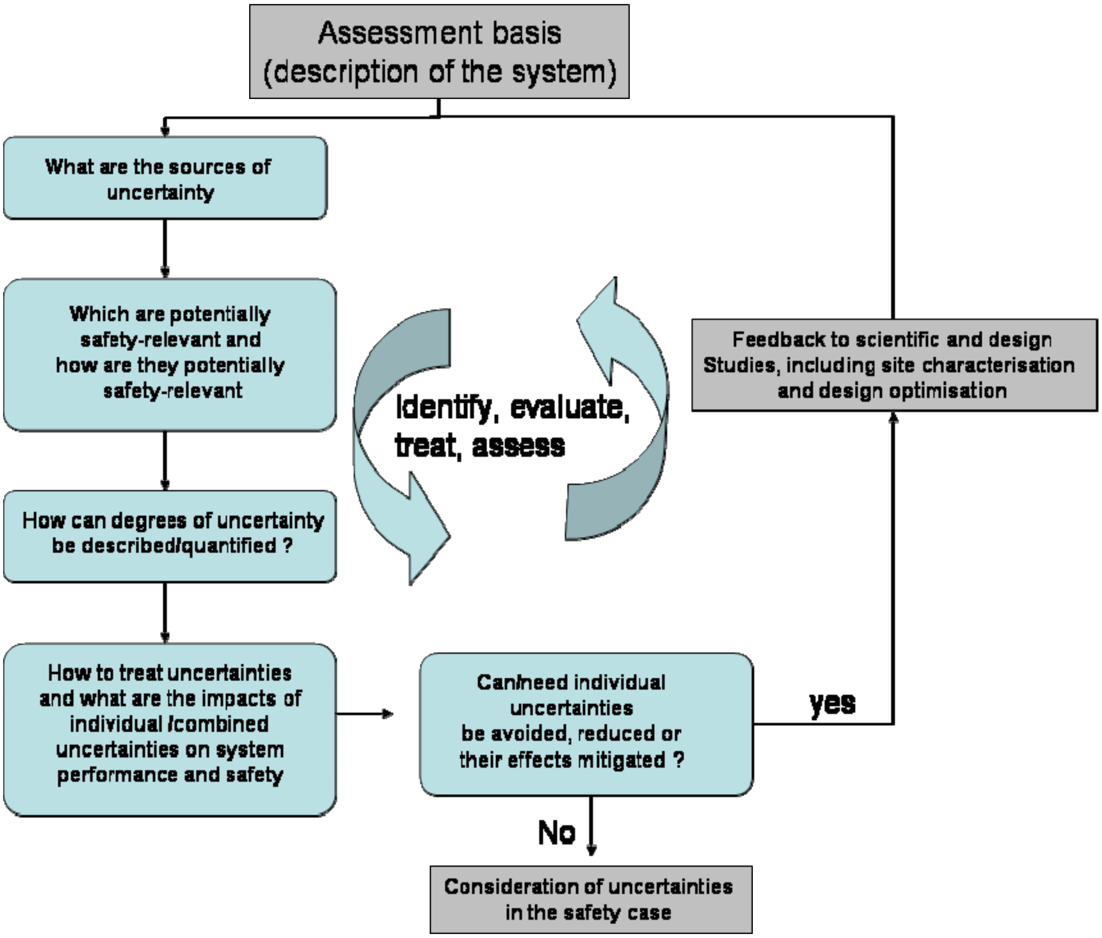
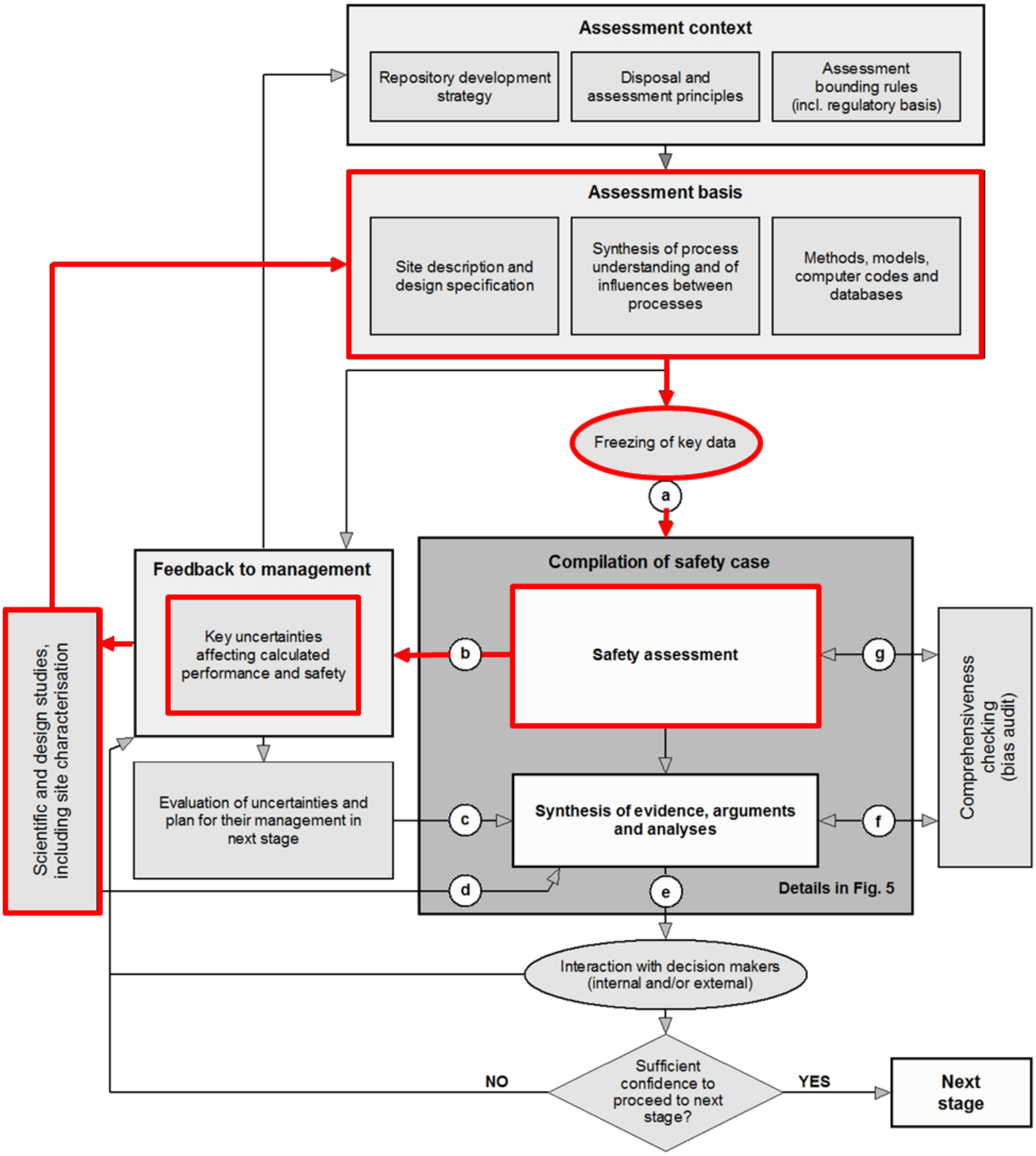


Figure 16.2. Example of a high-level generic flowchart, showing in red the feedback loop elaborated in Figure 16.1 (adapted from Figure 12.4 of MeSA Paper No. 2 – Schneider *et al.* 2010)



The remainder of this paper is structured as follows:

- Section 16.2, sources and classification of uncertainties, addresses the question: what are the sources of uncertainty on the basis of the understanding of the system evolution or the assessment basis?
- Section 16.3, safety relevance of uncertainties, addresses the questions: which uncertainties are potentially relevant and how are they potentially relevant?

- Section 16.4, description and quantification of uncertainties, addresses the question: how can degrees of uncertainty be described/quantified?
- Section 16.5, impact of uncertainties, addresses the questions: how are the uncertainties treated in safety assessment and what are the impacts of individual or combined uncertainties on system performance and safety?
- Specific mathematical techniques, including sensitivity and uncertainty analysis, are discussed in Section 16.6.
- Conclusions are given in Section 16.7.

An annex at the end of the paper gives some specific examples of the handling of uncertainties in safety assessments in national radioactive waste disposal programmes.

16.2 Sources and classification of uncertainties

16.2.1 Scenario, model and parameter uncertainties

Different classes of uncertainties were described in NEA (1991). The general classification system has not changed since that time. Internationally, there is now a high level of consensus on the types and sources of uncertainties in safety and performance assessments, although somewhat different terminology may be used in different countries. Typically, the uncertainties considered in safety and performance assessments are classified in the following way (Poole 2006; Galson and Khursheed 2007):

- Scenario uncertainties: Scenario uncertainties arise because it is not known for certain how the repository system will evolve over time.
- Model uncertainties: Model uncertainties arise from an incomplete knowledge or lack of understanding of the behaviour of engineered systems, physical processes, site characteristics and their representation using model abstractions and computer codes. It may be possible to model the relevant features, events, and processes (FEPs) using alternative conceptual models that equally well represent the available data. Model uncertainties may also be introduced by uncertainties in the boundary conditions appropriate for the model calculations.
- Data and parameter uncertainties: These uncertainties are associated with the values of the parameters used performance and assessment models. They arise because data may be difficult to measure or unavailable. Certain parameters for safety and performance assessments will be required for properties which are not only uncertain but are also spatially variable. The characterisation of such variability may lead to additional uncertainty.

One must be aware, though, that the classification system above essentially arises from the way safety and performance assessments are conducted. All three classes of uncertainties are related to each other, and particular uncertainties can be handled in different ways, such that they might be dealt with in one class or another for any particular set of safety or performance assessment calculations, depending on programmatic decisions and practical constraints. For example, in some safety and performance assessments, the uncertainty associated with future climate change is classified as a scenario uncertainty, and treated by the establishment of separate scenarios. In other safety and performance assessments climate change uncertainties may be treated as parameter uncertainties.

16.2.2 Classification according to origin or cause

Classification of uncertainties as scenario, model or data/parameter uncertainties relates to the impact of the uncertainties on the understanding and modelling of the evolution and performance of a disposal system. Such a division can help to structure a safety assessment.

Uncertainties can, however, also be classified from a more phenomenological perspective according to their origin or cause. Data or parameter uncertainties in particular arise from a number of sources. There may, for example, be conceptual uncertainties in the models used to process data and generate parameter values for other models. Other sources include:

- measurement errors, sparsity of measurements, or biases in field or laboratory data (note that sparsity of measurements can give rise to uncertainty in the quantification of spatial variability in heterogeneous media);
- transferability (or lack thereof) of data measured at one site, under one set of experimental conditions, or at a particular spatial or temporal scale, to the actual site, conditions or scales of interest to safety assessment; and
- related to the above, the uncertain evolution over time of conditions within and around a repository.

Ondraf/Niras categorises uncertainties on the basis of whether they relate to (i) upscaling, which refers to the applicability of the phenomenological data obtained from observations or laboratory experiments over relatively short intervals of space over the larger spatial scales of interest in safety assessment, (ii) transferability, which refers to the applicability of the phenomenological data representative of the host formation in one location to another location or a larger zone and (iii), evolving conditions, which refer to the impact on the phenomenological data obtained today of phenomena occurring over time that may affect the disposal system, such as phenomena triggered from within the disposal system (for example, the effect of the thermal phase on clay properties) or external events (for example, human intrusion or climate changes). Similarly, in carrying out its qualitative safety assessment (QSA), Andra considered uncertainties related to (a) the input data to the project (e.g. the waste inventory), (b) the inherent characteristics of the components, (c) processes affecting evolution (including the applicability of models), (d) technological uncertainties and (e) external events.

This type of classification according to their origin or cause can help, for example, to focus “brainstorming” discussions with phenomenological experts on how uncertainties might arise, and to reduce the chance of any significant uncertainties being overlooked. Although the opinions of experts regarding uncertainties are inevitably subjective, it is clearly desirable that the decisions based on expert judgement are transparent and well-founded. To this end, the safety assessor may issue general guidance on how expert elicitation should be undertaken, and specific instructions about the types or sources of conceptual (model) uncertainties that the expert should identify, as well of the types or sources of data (parameter) uncertainties (see e.g. Section 2.3.5 of SKB 2006e). For example, experts may be asked how they take account of the views of the scientific and technical community in arriving at their personal judgements, or how they use their knowledge of generic or related systems when they evaluate a particular system-specific issue. They may also be asked to comment on the quality of different sources of information in arriving at an overall judgement. Further examples of such guidance are given in Section A4.3.2 of Nagra (2002a).

A review of approaches to guide expert judgement was made in the frame of the PAMINA project (Bolado *et al.* 2008). However, it could be interesting to examine such guidelines further to determine whether and when more formal approaches to expert judgement are warranted for safety assessment and in particular for system description and scenario derivation.

16.2.3 Irreducible and reducible uncertainties

It is widely recognised that each uncertainty has a specific nature regardless of its classification. In this respect, irreducible and reducible uncertainties can be distinguished:

- Irreducible uncertainties are those related to the inherent randomness of events that may occur in the future (e.g. the timing of major earthquakes). These uncertainties are irreducible because no amount of knowledge will determine when or if a chance event will occur. Irreducible uncertainties are sometimes also called aleatory, stochastic, or Type A uncertainties. In other publications, they are termed variation, variability, or statistical inexactness.
- Reducible uncertainties reflect the state of knowledge about relevant processes and the appropriate values to use in quantifying those processes in safety or performance assessment. In principle, such uncertainties can be reduced by carrying out more site characterisation activities, laboratory experiments, making more measurements etc. Reducible uncertainties are sometimes also called epistemic, subjective, or Type B uncertainties. Elsewhere, they are simply called uncertainties (as opposed to variation or variability), imprecise knowledge/ignorance or inexactness due to human judgement.

Again, however, and depending on how they are defined, some uncertainties may have characteristics of both of these types (Marivoet *et al.* 2008).

Even though the different nature of uncertainties is generally acknowledged, most performance/safety assessment programmes for radioactive waste disposal do not assign particular uncertainties to the possible categories in a systematic way.

16.2.4 Phenomenological analysis

In the last decade new methods have emerged with respect to the way uncertainties are treated in performance and safety assessments. Understanding of the phenomenology of complex processes at the scale of a repository, as well as their interdependencies has increased significantly. This deeper understanding has been facilitated for example by improved laboratory setups capable of representing more realistically repository conditions, a growing number of results from experiments running over decades such as waste dissolution and radionuclide migration experiments, and the larger number of underground laboratories in different countries.

The deeper understanding of the FEPs contributing to the evolution of a disposal system, together with the increased availability and quality of relevant data, has allowed more realistic modelling of the disposal system, or its parts, as compared with previous representations, which tended necessarily to be simpler and more conservative.

It has also become possible to represent more of the relevant FEPs and their associated uncertainties from a phenomenological perspective. Following this approach, the phenomenological description of the disposal system and the associated uncertainties can be structured according to key thermo-hydro-mechanical-chemical (THMC) processes and conditions affecting the evolution of the system. In the so-called phenomenological analysis of the repository situations (PARS), described in Andra (2005), repository evolution was divided into situations corresponding to a space and time interval within which a few major phenomena dominated the evolution of the components of the system. Similarly, Ondraf/Niras (2007) analysed the phenomenological evolution of the near-field of the Belgian waste disposal concept to illustrate the THMC effects under specific conditions (e.g. oxic conditions corresponding to the early period shortly after repository closure, the thermal phase lasting for a few thousand years after closure). This phenomenological description based approach is further described in MeSA Issue Paper No. 3 (Röhlig *et al.* 2011). It has provided the basis for the analysis of uncertainties in the long-term safety of the disposal system and for the subsequent classification of scenario, model and parameter uncertainties as a function of their potential effects on long-term safety. Further examples are discussed in the following section.

16.3 Safety relevance of uncertainties

The most critical uncertainties can generally be said to be those relating to the main safety functions of a disposal system. As discussed in MeSA Issue Paper No. 3 (Röhlig *et al*. 2010), discussions with subject experts on what are the safety-relevant uncertainties are guided by tools that generally make use of the concept of safety functions, such as the qualitative safety assessments (QSA) employed by Andra and the safety statements of Ondraf/Niras.

Sometimes it can be demonstrated that the uncertainty in a particular parameter is not important to safety. The calculated safety indicator, e.g. dose rate or radiological risk, and its uncertainty or bandwidth will not significantly be affected whatever value a parameter takes, since safety is controlled by other processes.

For example, in Nirex Generic Post-closure Performance Assessment for UK's intermediate level and certain low-level radioactive waste (Nirex 2003) the uncertainty in the retardation due to sorption to rock of a very short-lived radionuclide was considered unimportant since there was confidence that the un-retarded groundwater travel time would be much greater than the half-life of the radionuclide, and such that the radionuclide would decay to negligible levels before groundwater could reach the surface.

All concepts for deep geological repositories for radioactive waste rely on a multi-barrier system, each barrier associated with one or several specific safety function(s), with margins to allow for uncertainty. If there is a very high level of confidence in a single safety function, then some of the uncertainties connected with the secondary safety functions might become unimportant in comparison. For example, the Swedish and Finnish concepts for repositories for spent fuel are able to claim considerable confidence in high-integrity waste containers designed for zero releases. For this reason, uncertainties in some secondary safety functions such as retardation provided by the host rock might therefore be less important.

16.4 Description and quantification of uncertainties

There are a number of ways in which uncertainties in, for example, the probability of scenarios or the values to be assigned to model parameters can be quantified. The approach chosen will generally depend on how much information is available to support quantification, and on how important the parameter is to the evaluation of safety. The following discussion draws mainly on work by SKB in the SR-Can safety assessment (SKB 2006 a-e), by Nagra in Project Opalinus Clay (Nagra 2002 a, b) and by the EU in the PAMINA project (PAMINA 2006-2009).

The most straightforward way of quantifying a parameter uncertainty is by the specification of ranges. For example, in Project Opalinus Clay (App. 1 of Nagra 2002a), phenomenological experts were asked to assign parameter values that they considered to be:

- expected or most likely; and
- pessimistic, in that radiological consequences calculated using this value would be towards the high end of the range of possibilities supported by current understanding.

For some key parameters, experts were asked to select optimistic values, in order to illustrate the full range of radiological consequences arising from a particular uncertainty.

In SR-Can (Section 2.3.7 of SKB 2006e), experts were asked, if possible, to provide two ranges:

- the range outside which it is judged extremely unlikely that a parameter value would, in reality, lie; and
- the range within which it is judged likely that a parameter value would, in reality, lie.

If this was not possible, the experts were asked to define as precisely as possible the meaning to be attached to the ranges that they specified (e.g. the solubility of one element may be correlated with those of others).

Other methods used in SR-Can for quantifying parameter uncertainties generally required more information and involved subjective percentiles and probability distribution or density functions (PDFs), the derivation of which is discussed further in Section 16.6. In each case, the experts have to justify the percentiles or PDFs chosen. In Project Opalinus Clay, Nagra (2002) also defined PDFs for some key parameter values in order to support a limited number of probabilistic safety assessment calculations. As well as quantifying an uncertainty in a given parameter, experts were also asked to list other parameters to which the parameter in question was correlated.

Formal procedures (structured protocols) for eliciting statements on the probabilities of key parameters from experts have been reviewed in the EU PAMINA Project (Bolado *et al.* 2008; 2009). Procedures aim to:

- train experts in the coherent quantification of probabilities;
- identify and minimise any biases experts may have;
- define and document the problem at hand without ambiguity;
- provide the expert with all the relevant information;
- elicit expert opinions using the most suitable techniques (which can vary between different experts);
- check and document the rationale and the coherence of each expert in his/her judgements; and
- make a final verification of the whole process.

Such procedures can be used to assess probabilities of events and the values and distributions of uncertain parameters. They include methods for translating qualitative opinions on probabilities and correlations to quantitative statements, that attempt to minimise discrepancies between actual beliefs and assessed probabilities.

In the context of PAMINA, protocols were developed and applied to conceptualise a scenario in which a repository is abandoned without proper closure (Grupa 2006), and to characterise uncertainty in solubility limits for a generic Spanish repository (Bolado *et al.* 2009). In general, however, formal procedures have not commonly been used to date in safety assessments, other than those in the UK and US. Nevertheless, the guidance for expert elicitation given in Project Opalinus Clay (see Section A4.3.2 of Nagra 2002a) overlaps to a large extent with the above-listed aims of the formal procedures discussed in PAMINA (Bolado *et al.* 2009).

Not all uncertainties can be expressed or managed quantitatively. In these cases, safety assessment will generally use conservative model assumptions or parameter values, that are confidently expected to over-estimate radiological consequences, irrespective of a given uncertainty. An uncertain but favourable FEP may, for example, be omitted from a model, or a parameter may be set to an deliberatively unrealistic, but conservative, value. In SR-Can, experts were allowed to provide conservative model assumptions or parameter values, provided the conservatism was clearly documented, together with the motivation for adopting this approach (Section 2.3.5 of SKB 2006e). In Dossier 2005 (Andra 2005), a distinction was made between phenomenological, conservative, and penalising choices concerning models and parameters as follows:

- Phenomenological (or best estimate) model: the model that, all other parameters being fixed, is deemed to yield results fitting best those obtained by experiments and/or observations. This choice is theoretically made without reference to any impact. A phenomenological model or value must be based on a representative number of measurements and argumentation demonstrating that it is the most representative according to reliable data.
- Conservative model: model used to obtain a calculated impact that falls within a range of high values (with all other parameters fixed elsewhere). In the simplest case, where the impact increases (or decreases) as the parameter value increases, a value is chosen from the upper (or lower) range of available values. If no site-specific measurement is available, the model uses internationally-available data as long as these data are explicitly presented in the literature and can be transposed to the studied case.
- Penalising model: model not referring to phenomenological knowledge, chosen conventionally to lead with all certainty to an impact greater than the one calculated with possible values.

In Project Opalinus Clay, on the other hand, decisions regarding conservatism and the inclusion or exclusion of phenomena in safety assessment were viewed as the responsibility not of subject experts, but rather of the safety assessors themselves (see Section A4.3.2 of Nagra 2002a). This separation of the work of subject experts, who were responsible for developing and evaluating the scientific basis for safety assessment, and that of safety assessors, was intended to avoid inadvertent or undocumented bias in the treatment of uncertainties (e.g. each individual or group adding their own, conservative margins).

The quantification of disposal system evolution and performance requires the development of mathematical models and their implementation as numerical simulation software; this introduces another source of uncertainty (PAMINA 2008), that relates to poor or incomplete knowledge of the relevant behaviour, simplified or incomplete representation of the system or processes, or human error in the execution of the models.

The uncertainties in a given model can be addressed through verification and “validation” studies, or “model qualification” as it is described in some programmes. The main strategies for estimating or minimising model uncertainties include (see MeSA Issue Paper No. 4 – Gierszewski *et al.* 2011):

- independent peer review of the theory, the conceptual and mathematical models;
- a software quality assurance process that ensures that software is designed, developed and changed via a formal change control process with appropriate review of each step;
- verification that the computer codes accurately implement the mathematical models;
- benchmarking of new codes against the results of older codes (this requires a strategy for the maintenance of the older codes);

- testing the representation of specific phenomena within the safety assessment model against experimental data, field data and/or detailed process models;
- comparison with similar system models;
- comparison with data from field-scale tests, underground research laboratory experiments and analogue systems;
- calibration to conditions at a specific site.

In the context of a safety assessment, it is also possible to adopt strategies that do not reduce model uncertainty but which can bound the implications of the uncertainty, notably:

- use of alternative conceptual models;
- use of conservative or bounding models;
- use of stylised models (e.g. human intrusion).

16.5 Impacts of uncertainties

NEA (1991) noted that uncertainties are, and always will be, associated with assessment results and that such uncertainties can partly be reduced by additional model development and by collecting additional and more accurate data. Since uncertainties will persist reflecting the variability in present and possible future states of the system, probabilistic methods may be employed to propagate uncertainty through the safety assessment, from statistically characterised input distributions to uncertain distributions of output metrics, such as dose.

Uncertainty descriptions of an outcome of a model help a decision-maker put the numerical result(s) into a risk-context. A commonly used measure of merit for the uncertainty distribution of an outcome is the mean or expected value of the distribution. The mean of a distribution is often regarded as a more conservative metric than the median and the mean is therefore used more commonly in a regulatory context. Some national regulations and disposal programmes also put emphasis put on certain quantiles of the distributions (e.g. the 75th or 95th percentile of calculated dose).

The development of methods and tools to improve the treatment of uncertainty in safety assessments is actively pursued in practically all the national programmes and was the focus of a recent international programme (Marivoet *et al.* 2008). Part of the PAMINA Project "RTDC2 – Treatment of Uncertainty" focuses entirely on uncertainty methods and strategies. Some specific examples of the approaches adopted in different national programmes are given in the annex to this paper. More general discussion is given in the following sections.

16.5.1 Treatment of scenario uncertainty

The treatment of uncertainties related to future evolution and the occurrence of future events over the long timescales considered in post-closure safety cases for radioactive waste disposal represents a significant challenge. These uncertainties need to be addressed in a systematic way. One important issue for scenario analysis is comprehensiveness, in particular, consideration of as far as is possible all of the relevant FEPs. In many disposal programmes, the comprehensiveness of the range of scenarios considered is verified by using (preferably site-specific) FEP databases (see also MeSA Issue Paper No. 3 – Röhlig *et al.* 2011).

An important class of scenario uncertainties is related to inadvertent future human intrusion into the repository. It is generally accepted that such human actions have to be taken into account when assessing safety of the disposal system. Any assessment of human intrusion over an extended period will be speculative owing to the inability to predict in detail the evolution of society and future human behaviour. As a consequence, regulatory guidance is often provided for dealing with the problem. In most existing regulations the consideration of stylised human intrusion scenarios is seen as an appropriate way of treating these uncertainties (e.g. Beuth and Marivoet 2009).

16.5.2 Treatment of uncertainties for a given scenario

The definition and assessment of a given scenario requires several categories of information, each of which is subject to uncertainty (Marivoet *et al.* 2008):

- i) the initial conditions;
- ii) the internal FEPs and the couplings among them;
- iii) the external FEPs;
- iv) the timescales in which the various elements of the scenario definition are relevant.

The IAEA ISAM Project (IAEA 2004) defined external FEPs as those that can be considered to be scenario generating FEPs – changes in their status may result in the generation of additional scenarios. In contrast, changes in internal FEPs were considered to result in different conceptual models, rather than different scenarios. For example, external FEP categories include climate processes and effects and future human actions.

Different approaches may be employed for the treatment and management of the uncertainties listed above, depending on the context of the safety case (Poole 2006). Various approaches are discussed in the following subsections using examples from different PA studies.

Demonstrating that uncertainty is not important

Sometimes it can be demonstrated that the uncertainty in a particular parameter is not important to safety. The calculated safety indicator, e.g. dose rate or radiological risk, will not be significantly affected whatever value the parameter takes, since safety is controlled by other processes.

For example, in UK Nirex Limited's Generic Post-closure Performance Assessment for geological disposal of intermediate-level and certain low-level radioactive wastes (Nirex 2003) the uncertainty in the retardation (by sorption) of a very short-lived radionuclide was shown to be unimportant since there was confidence that the groundwater travel time would be much greater than the half-life of the radionuclide and such that, even without any retardation, the radionuclide would decay to negligible levels before it could reach the biosphere.

Bounding the uncertainty

Sometimes insufficient data are available and it may not be possible for performance or safety assessment modelling to represent certain features of the disposal system in detail. In order to deal with such situations, it is usual to make a number of simplifying assumptions, some of which may involve taking a conservative view, i.e. assumptions made such that the calculated safety indicators such as dose rate or radiological risk will be over- rather than under-estimated. The adoption of such conservative assumptions may be an acceptable way of addressing certain issues and treating particular uncertainties without introducing unnecessary complexity to the analysis.

For example, the solubility of radionuclides in groundwater or porewater may be an important factor in the long-term safety of a repository. Sometimes, however, certain radionuclide solubility data may not be available for the geochemical conditions that may be established in the repository once the waste canisters have failed. In this case, one approach is to assign very high or even unlimited solubilities to the radionuclides in question (e.g. Nirex 2003). For the majority of radionuclides this is a very pessimistic assumption. If radionuclides treated in this way do not contribute significantly to the calculated safety indicators (dose rate or risk) even under such pessimistic assumptions, then the uncertainty can be said to have been bounded.

The approach of making conservative assumptions can add to the robustness of the safety case; however, it can also detract from the credibility of the safety case, since it can mask the true range of uncertainty in the output metric, making an estimate of the mean less credible. This may be important when considering optimisation (NEA 2010).

Furthermore, sometimes coupling of processes, one of which has been represented conservatively, can produce non-physical results that adversely impact the credibility of the safety assessment. An example is the unlimited solubility assumption described above. If this is combined with a fluid transport process in which the volume of fluid is very small, the aqueous modeled concentrations may become unrealistic, and this can result in unrealistically high radionuclide transport rates under certain conditions. Care must be taken, therefore, that apparently conservative assumptions made with respect to one process do not result in non-conservatism at the system level.

Ruling out the uncertainty

Certain scenarios and processes can be excluded from further consideration.

For example, impact of a large meteorite is often not considered explicitly in performance or safety assessment. This event can be shown to have a very low probability of occurrence and, in addition, even if such an event were to occur then the immediate consequences of the impact would be much larger than those associated with the repository.

Another approach to ruling out specific processes and their associated uncertainties is by making changes to the design of the disposal system. For example, following review of the SAFIR-2 safety assessment, weaknesses in the Ondraf/Niras concept were highlighted, namely:

- the feasibility and especially the operational safety were not very clear, and perhaps questionable;
- the engineered barrier system was rather complex and, with the remaining uncertainties on near field evolution, it was difficult to guarantee full containment during the thermal phase.

In accordance with its safety strategy (Ondraf/Niras 2009), Ondraf/Niras took the formal assessment of the SAFIR 2 report as an occasion to re-evaluate the design in order to strengthen the proposed solution for long-term management of high-level waste. A multi-criteria analysis of different designs was performed and the results from this showed a clear preference for a so-called "supercontainer" concept. This new design concept was adopted, primarily because of the necessity to increase the longevity of the cast iron overpack (Van Geet and Weetjens 2011). This was achieved by use of a cement-based buffer which would surround the overpack and would prevent localised corrosion by providing a high-pH environment that would passivate the overpack surface. The new design also provides permanent radiological shielding (which eliminates the need for remotely-controlled underground operations and improves protection of the workforce), and complements the role of the host rock by contributing to the delay and attenuation of and radionuclides that are eventually released from the overpack.

Applying stylised assessment approaches

Various uncertainties are associated with the assessment of inadvertent future human actions, e.g. probabilities and modes of intrusion, and uncertainties related to radiological consequences of an exposure, such as the dietary habits and lifestyle of a potentially exposed group. It is difficult to treat these types of uncertainty with any of the above mentioned strategies. Therefore, they are usually dealt with using stylised approaches, that are agreed at a general level between the implementer and the regulator, or that are regarded as internationally suitable. An example of an internationally-derived stylised approach for use in safety assessment is the "reference biospheres" approach which was developed during the IAEA BIOMASS project (IAEA 2003).

Addressing the uncertainty explicitly

In many cases it is appropriate to address a particular uncertainty explicitly in performance or safety assessment calculations. Probabilistic safety assessment techniques in which the uncertainty is explicitly represented by probability density functions (PDFs) or cumulative density functions (CDFs) are discussed in the next section, including a description of the role of expert judgment in defining PDFs and CDFs.

16.6 Mathematical techniques

An important aspect in performance/safety assessment and safety case development is to quantify the impact of uncertainties on the end-point of the numerical calculations (e.g. usually the dose rate or a related risk figure), as well as on intermediate performance measures or indicators (e.g. radionuclide flux – see MeSA Issue Paper No. 5 – Noseck *et al.* 2011). Different mathematical techniques may be used, depending on how the assessment is carried out. Such methods can be used to investigate which parameters and uncertainties contribute significantly to the overall uncertainty in the calculational end-point. Epistemic parameters that are most important to the given output metric are candidates for further characterisation, in order to reduce uncertainty.

The principle methodological approaches and mathematical techniques are described in (NEA 1991), but the understanding of their advantages and limitations has increased considerably over the last few years, and this has inspired some interesting methodological developments (Capouet *et al.* 2009).

16.6.1 Derivation of PDFs or CDFs

In order to perform probabilistic uncertainty and sensitivity analyses, uncertain parameters can be assigned a probability density function (PDF) or cumulative density function (CDF), which is then used in a sampling process (e.g. Helton and Davis 2003). In general, there are two primary approaches used to quantify uncertainty, depending on the amount and quality of the available data. The fitting of continuous distributions to the data is appropriate for situations with a relatively high amount and quality of data, while the use of subjective assessment of probabilities is appropriate when the data quality and amount are low (Mishra 2002).

Standard statistical techniques are available for estimating the distribution parameters in data-rich situations, including probability plots and various parameter estimation techniques, such as linear regression or maximum likelihood estimation. For data-poor situations, there are more subjective assessment techniques that rely on the maximum entropy principle and the use of empirical CDFs. There are also expert elicitation protocols that are appropriate when the data is sparse and difficult to obtain, but the influence of the data on the outcome is high (e.g. Budnitz *et al.* 1997). These latter approaches must be thoroughly documented, particularly in data-poor situations, or run the risk of being non-transparent. Nevertheless, they have been used with success in a variety of situations, e.g. as applied to the assessment of uncertainty in the seismic hazard for a given repository site (CRWMS 1998).

It is important to note that not all uncertainties have a significant impact on the final result of the performance assessment, i.e. they are not always risk-significant. The need to explicitly incorporate uncertainties in risk analyses of complex industrial facilities, and specifically the need to do this for the probabilistic safety assessment of nuclear power plants and for the performance assessment of radioactive repositories, triggered the development of specific expert elicitation protocols (e.g. USNRC 1990; Kotra *et al.* 1996). The applicability to radioactive waste disposal of some of the available expert judgement protocols has been tested in PAMINA (Bolado *et al.* 2010).

16.6.2 Uncertainty analysis

Uncertainty analysis is a key component of safety assessment that analyses how the uncertainties associated with the different elements (data, assumptions, etc.) of the assessment propagate through it and affect the uncertainty and confidence in the results (e.g. dose, risk) (Marivoet *et al.*, 2008).

The national agencies and research organisations responsible for repository development programmes have, since the early stages in their programmes, devoted significant effort to develop and implement appropriate measures and methods to deal with uncertainties (Bechtel 2002), and significant experience has been gained in the application of uncertainty analysis methods during safety assessment. In the most advanced programmes, the treatment of uncertainties in recent published safety assessments has reached a high level of maturity and comprehensiveness.

The approach to uncertainty analysis may be either essentially deterministic, as it is the case in many countries of continental Europe, or probabilistic, as it is the case particularly in the UK and US radioactive waste disposal programmes. In some probabilistic safety assessments, each scenario is assessed separately, and its probability is not quantified. In fully probabilistic approaches, which are further discussed in MeSA Issue Paper No. 3 (Röhlig *et al.* 2011), the probability is thoroughly considered and mathematically aggregated with assessed consequences, taking account of uncertainty. The choice between the various approaches is primarily driven by regulations. Many programmes consider that deterministic and probabilistic approaches complement each other, and several programmes apply alternative methods in parallel to increase the confidence in the results obtained.

Aspects deserving further efforts have been identified in the various programmes. Most countries have ongoing programmes of work to further develop the treatment of uncertainty in the safety assessment and safety case, usually with the aim of treating all classes of uncertainties in a more systematic fashion.

16.6.3 Sensitivity analysis

There is a wide consensus that sensitivity analysis is an important part of performance and safety assessment for radioactive waste repositories, and can contribute significantly to confidence in the safety case. All organisations dealing with performance and safety assessment for geological disposal of radioactive wastes undertake sensitivity analysis to some extent. The methods applied, however, vary considerably (Capouet *et al.* 2009).

Deterministic sensitivity analysis is used to investigate the reaction of the model to variation in single parameter values, model modifications, scenarios or assumptions. Such sensitivity analysis represents a tool for analysing the sensitivity of the system against to individual uncertainties and helps to increase understanding of the functioning of the system.

A more powerful technique, Monte-Carlo based probabilistic sensitivity analysis is mostly used to analyse model sensitivity to multiple parameter uncertainties. Usually Monte-Carlo based probabilistic analyses are performed as “global” whole system analyses by varying several or all relevant parameters simultaneously and taking into account possible interdependencies (correlations). Model uncertainties can also be included by mapping them to specific parameters that are varied between discrete values (e.g. to switch between different conceptual models).

Probabilistic sensitivity analysis is the preferred approach to global sensitivity analysis within most radioactive waste management organisations, since it can account more appropriately for the effect of parameter distributions. Probabilistic safety assessment has become more tractable over recent years because of advances in the availability and power of computers.

Probabilistic performance or safety analysis typically consists of two steps. Firstly, a number of runs of the system model are conducted using parameter values sampled at random (or by some other sampling scheme). Secondly, the results are analysed with a combination of any or all of the following techniques:

- correlation and regression methods;
- non-parametric statistical test;
- variance-based methods;
- graphical methods.

In most probabilistic sensitivity analysis studies, linear correlation or regression methods have been applied. These are suitable for systems with a close-to-linear behaviour, and linear regression of rank-transformed data improves the regression model fit for non-linear but still monotonic systems. However, highly non-linear systems and non-monotonic relationships are not amenable to these methods. The drawbacks of the mentioned methods for probabilistic sensitivity analysis can be avoided by applying variance-based sensitivity analysis, which is suitable for non-linear and even non-monotonic systems and yields quantitative results which, in principle, can address not only sensitivities to single input parameters but also to interacting parameter sets. Some methods (e.g. Sobol, FAST) have been applied to repository systems for the first time during recent years. Specific problems have surfaced that are not explicitly addressed in the relevant literature, but which seem to be essential for repository performance models. More research is necessary and planned.

Although there is consensus that sensitivity analysis is a necessary element of a safety assessment, at present there is no single general scheme for performing sensitivity analysis for repository systems and interpreting results (Capouet *et al.* 2009).

16.7 Conclusions

The conclusions in (NEA 1991) are still valid, namely that:

- Uncertainties are, and always will be, associated with assessment results.
- Uncertainties can be reduced by additional model development and by collecting additional and more accurate data; however, intrinsic uncertainties will persist reflecting the variability in present and possible future states of systems.

In (NEA 1991) it was noted that “statistical methods are being increasingly relied on when extensive measurements of the needed data are not feasible”. Statistical methods are important for the treatment of uncertainty in performance and safety assessments and over the last few years various improvement and refinements have been made in the application of statistical methods to performance and safety assessments for radioactive waste disposal, for example, in relation to the derivation of parameter distributions (PDFs or CDFs) from expert elicitation and for analysing the results from probabilistic calculations.

Since 1991 more data has been collected and this has allowed the development of increasingly realistic performance and safety assessment models and assessments. Epistemic uncertainty has been reduced in many cases. However, probabilistic methods will continue to play a key role in the quantification of uncertainty in general, and may be the only approach for the treatment of some types of aleatory uncertainty.

Iteration is an important aspect of performance and safety assessment, and results from previous iterations and findings from uncertainty and sensitivity analyses are used to identify which areas of uncertainty most need to be reduced in order to increase confidence in assessed impacts (e.g. dose, risk) and in the associated safety case. This iterative link between safety assessment and the research and development programmes is an important aspect of developing overall confidence in the safety case.

Understanding from research and development programmes should also be fed directly into safety case arguments where it can help to put the uncertainties associated with assessment results into a proper context. For example, explicitly presenting the research undertaken on the corrosion of waste container materials and the confidence this gives in the longevity of the containers, may be more helpful to confidence building with some stakeholders than calculations based on a derived parameter distribution for container failure probabilities. Generally speaking, the use of multiple lines of reasoning such as this in a safety case can be very helpful in putting uncertainties into perspective and demonstrating confidence in the overall safety case despite remaining uncertainties.

It should not be forgotten that one of the drivers for geological disposal of radioactive wastes is the removal of the uncertainties associated with leaving the waste at the surface, where it is accessible to humans and vulnerable to the dynamic nature of the Earth's surface over very long timescales. Thus, when discussing the implications of uncertainties in a safety case, it is not merely their mathematical treatment in the safety assessment that is important – the context of the uncertainties, and what has been done to reduce or mitigate them (e.g. through appropriate siting and engineered barrier design), need to be discussed using reasoned and logical arguments.

In terms of addressing uncertainties in performance and safety assessment, the three broad types identified in (NEA 1991), namely, scenario uncertainties, model uncertainties, and data or parameter uncertainties remain. There have, however, been considerable developments in the treatment of uncertainties in safety assessments since 1991. Most methods for treating uncertainties fall into one or more of the following five strategies:

- Demonstrating that the uncertainty is not important to the safety assessment.
- Bounding the uncertainty.
- Ruling out the uncertainty (for example ruling out uncertain events on the basis of very low probability or because should the event happen, there will be more serious consequences elsewhere).
- Applying stylised assessment approaches. This approach may be adopted to avoid speculation as to essentially unknowable uncertainties such as the development of future human societies and human behaviour. It is normal practice for the assessment to be based on present day behaviours and technologies.
- Addressing the uncertainty explicitly by conducting uncertainty and sensitivity studies using deterministic and/or probabilistic methods.

While many performance and safety assessments will use most of the above strategies for dealing with different types of uncertainty, the preferred strategies are to a large extent dictated by the different national regulatory requirements and also, to some extent, the disposal concepts under consideration.

Regulatory requirements in particular govern the extent to which probabilistic safety assessment is used to quantify risks and handle uncertainties. The US regulations (and to a lesser extent the Swedish and UK regulations) require or imply a probabilistic approach, but this is not so in other countries.

16.8 References

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Annex 16.A

National approaches

Internationally a range of methodological approaches is adopted to deal with the various kinds of uncertainties. They range from purely probabilistic to almost purely deterministic approaches. In the following subsections examples are provided that illustrate these aspects.

United States of America – Yucca Mountain Project

The approach to the evaluation of uncertainty taken in the Yucca Mountain Project is to address two classes of uncertainties: aleatory and epistemic. Examples of aleatory uncertainties in the Yucca Mountain safety assessment are the time of occurrence and eruptive size of an igneous event, and the time and magnitude of a seismic event. Examples of epistemic uncertainties are spatially averaged values for parameters such as permeabilities, porosities, and sorption coefficients. Rates, for example the rates defining a Poisson process, such as igneous intrusion, can also be considered an epistemic uncertainty.

In the long term, post-closure safety assessment reported in Chapter 2 of the Yucca Mountain License Application (USDOE 2008), epistemic uncertainty is incorporated through Latin hypercube sampling (LHS) of uncertain input parameter distributions (Helton and Davis 2003). There are about 400 uncertain epistemic parameters in this safety assessment (called the Total System Performance Assessment-License Application or TSPA-LA); however, not all of these have a strong influence on the output, so an LHS sample size of 300 realisations was large enough to produce a stable result. Aleatory uncertainty was included in the TSPA-LA by several different techniques, depending on the scenario. Sometimes this was based on a fixed number and timing of events, with interpolation at other times (as described below). In other cases, it was through random Monte Carlo sampling.

Figure 16.A-1 illustrates the process used to model seismic events for the 10 000-year performance assessment. Two iteration loops are involved. In the outer loop, epistemically uncertain parameters are stochastically sampled from their defined distributions using Latin hypercube sampling. In the inner loop, representing aleatory uncertainty, a fixed set of event times and magnitudes is used. For each combination of event time and magnitude (magnitude or consequence here is represented by the waste package damage area), the conditional annual dose is calculated (i.e. the annual dose not weighted by the probability of the event). Mathematical interpolation is then used to fill in the conditional annual dose for other event times and magnitudes. An integration is then performed to give the expected annual dose curve (i.e. weighted by the probability of occurrence) for this particular LHS sample of the epistemic uncertainty. The outer loop gives 300 such calculations of the expected annual dose, each with a different sampling of the epistemically uncertain input parameters. Based on the resulting distribution of 300 expected annual dose histories (where the expectation is over aleatory uncertainty), statistic histories are computed that characterise the range of

epistemic uncertainty, including the mean annual dose history and the 5th- and 95th-percentile histories for the epistemic uncertainty in the expected annual dose. The LHS method for the outer loop is the same for all scenarios in the Yucca Mountain performance assessment, but various other numerical techniques are employed to compute the expectation over aleatory uncertainty (USDOE 2008).

Figure 16.A-1: Addressing epistemic and aleatory uncertainty in the Yucca Mountain License Application for the Seismic Ground Motion Scenario (Figure 2.4-8 in USDOE 2008)

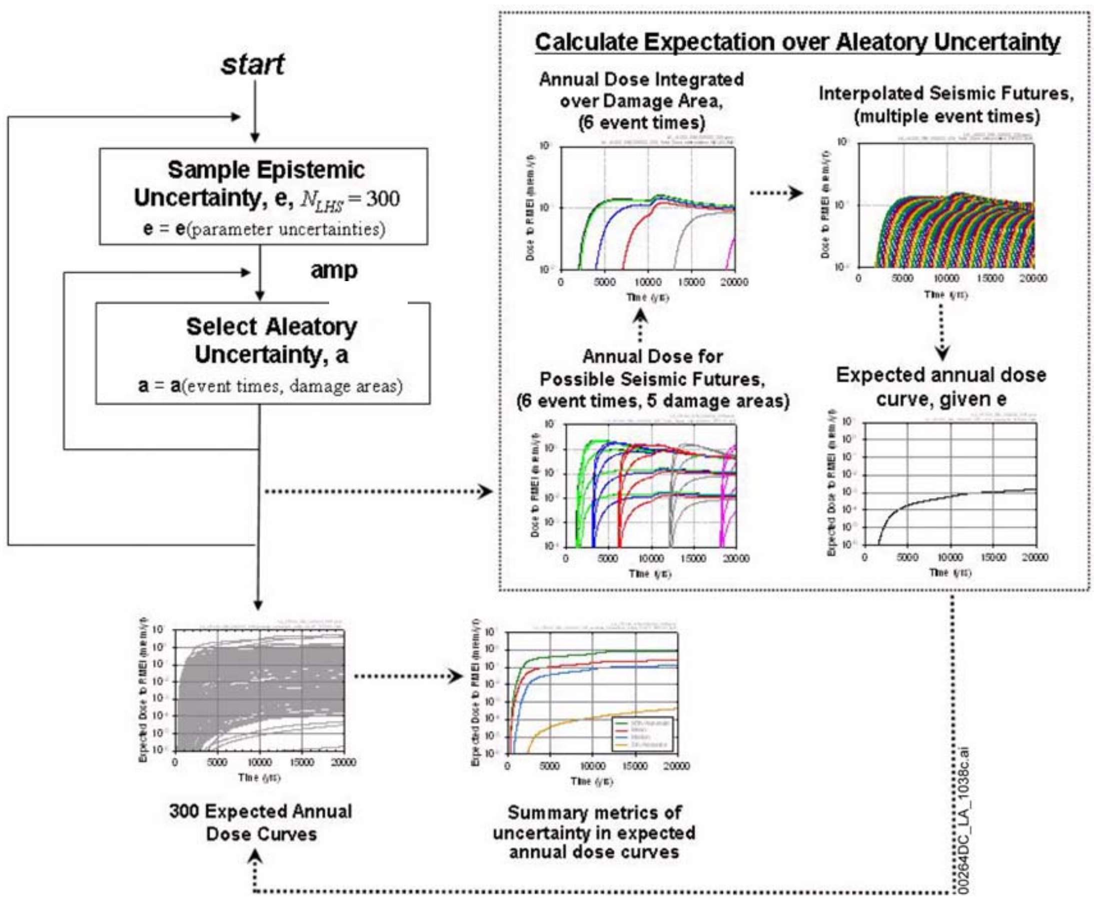


Figure 16.A-2 shows various ways that sensitivity analyses can be presented for review and evaluation. At the top left of the figure are 300 expected annual dose results summed over all scenario classes (called “total expected annual dose”). At the top right is an illustration of the dependence of total expected annual dose uncertainty on epistemic uncertainty of input parameters as a function of time, as measured by the partial rank correlation coefficient (PRCC). The six parameters that have the greatest influence on annual dose are plotted. The closer the PRCC is to +1 or –1, the more influence it has on calculated dose. The (red) curve representing the stress-threshold for stress corrosion cracking initiation (SCCTHRP) becomes less important over time as the (green) curve representing the temperature dependence of the Alloy-22 corrosion rate (WDGCA22) becomes more important over time. In particular, susceptibility to seismic-ground-motion-induced stresses causing cracks in the waste packages dominates earlier results since through-going openings due to general corrosion are not yet feasible (not counting the one to several waste packages that may be sampled as having failed at the time of waste emplacement in any given realisation). However, at long times, radionuclide

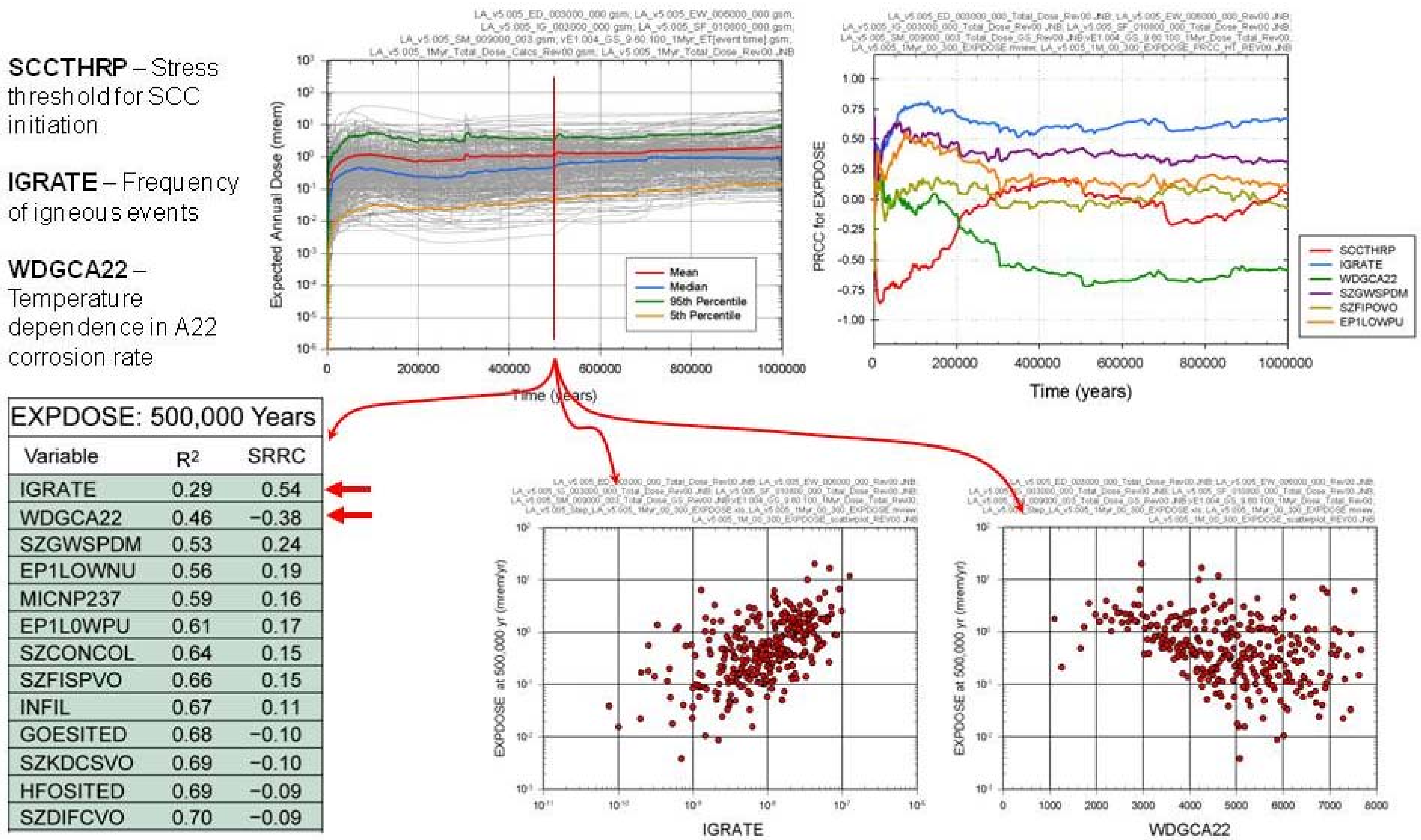
releases through openings in the waste packages caused by general corrosion begin to dominate the dose. The negative correlation demonstrated by the green curve is because this general corrosion parameter is a slope parameter. Higher values of this parameter give higher rates of corrosion at early times when temperatures are high, but much lower rates of general corrosion at late times. Because temperatures are only high for a relatively short span of the total 1 000 000-year history, doses are dominated by the late-time values of the corrosion rate, which are much lower for higher values of this slope parameter.

On the bottom right are scatterplots of total expected annual dose versus the two most important uncertain input parameters, at a specified time (500 000 years). Igneous event frequency (IGRATE) is an epistemically uncertain parameter that was indicated to be important in the PRCC plot (blue line at the top). This is confirmed by the scatterplot at 500 000 years, which indicates a strong linear trend between total expected annual dose and the uncertain annual rate of occurrence of igneous events. As the likelihood of an event increases, the expected dose will increase. Similarly, the strong negative dependence of total expected annual dose on WDGCA22, shown in the PRCC plot, is confirmed by the trend in the scatter plot.

Another sensitivity analysis technique, besides the PRCC history plots and the scatter plots, is stepwise rank regression, which fits a linear regression model to the rank-transformed input and output variables. The results of this model for the data at 500 000 years are shown in the table in the lower left of Figure 16.A-2. Input variables appear in the table in the order that they contribute to uncertainty in the output variable (total expected annual dose). This method again shows that the total expected annual dose is most sensitive to the epistemically uncertain parameters IGRATE and WDGCA22 at the specified time.

These examples illustrate some of the techniques and methods to analyse and illustrate the effects of uncertainties. Based on these and many other evaluations, the burden on the proponent for a repository system then becomes explaining why it is acceptable to move to the next stage of repository developments in the face of the uncertainties just analysed and explained.

Figure 16.A-2: Displaying uncertainty analysis results for evaluation (USDOE 2008)



SCCTHRP – Stress threshold for SCC initiation

IGRATE – Frequency of igneous events

WDGCA22 – Temperature dependence in A22 corrosion rate

EXPDOSE: 500,000 Years		
Variable	R²	SRRC
IGRATE	0.29	0.54
WDGCA22	0.46	−0.38
SZGWSPDM	0.53	0.24
EP1LOWNU	0.56	0.19
MICNP237	0.59	0.16
EP1L0WPU	0.61	0.17
SZCONCOL	0.64	0.15
SZFISPVO	0.66	0.15
INFIL	0.67	0.11
GOESITED	0.68	−0.10
SZKDCSVO	0.69	−0.10
HFOSITED	0.69	−0.09
SZDIFCVO	0.70	−0.09

Switzerland: Opalinus Clay

The approach to the evaluation of uncertainties in (Nagra 2002) combined qualitative reasoning with quantitative deterministic and probabilistic performance and safety assessment. All potentially relevant uncertainties identified in the course of deriving the system concept were considered, and their effects qualitatively assessed. Many of these uncertainties were small and/or their consequences minimised by the selection of the site and the design. Other uncertainties turned out to be of low relevance in terms of their potential to perturb overall system performance. Uncertainties that fell into this category were not considered further in defining the assessment cases.

The starting point for the performance/safety assessment was a description of the expected/likely evolution of the barrier system based on a detailed scientific understanding of the key processes that affect safety. Sensitivity analyses, including probabilistic analyses, were used to identify whether there were any sudden or complex changes in performance as parameters and model assumptions were varied, and these assisted both in the identification of assessment cases, so they focus mainly on uncertainties to which the system or system components are most sensitive, and in understanding the outcome of the analyses of assessment cases.

Sensitivity to individual parameter variations, using the reference case as a starting point, was considered using the reference model chain, and simplified "insight" models were used to examine specific issues. Specific parameters addressed were:

- the SF / HLW canister breaching time;
- the rate of groundwater flow through the Opalinus Clay host rock;
- the degree of radionuclide sorption in the Opalinus Clay;
- parameters describing the surface environment.

Finally, a probabilistic sensitivity analysis was performed using the reference model chain in which the input parameters were varied stochastically in order to investigate the effect of varying several parameters simultaneously.

The deterministic sensitivity studies showed that the individual components of the repository system would behave as expected within the range of the expected parameters values. This means that for small to moderate deviations of parameter values, system performance will not be significantly affected. Even if larger changes are made, system performance is in general still good. The probabilistic analyses confirmed these results; i.e. the system is "well behaved", the results are as expected, and no complex patterns are observed. For all waste forms, releases to the biosphere were shown to be dominated by just a few radionuclides, which are highly soluble and have low sorption coefficients across the range of geochemical conditions covered by the probabilistic sensitivity analysis, although the solubility limits and sorption coefficients of other radionuclides vary considerably.

The impact of various uncertainties on the level of safety provided by the barrier system was illustrated by means of a broad range of assessment cases. Owing to the robust behaviour of the system in the sensitivity analyses for the reference case, further cases were identified and selected by expert judgement, guided by:

- understanding of the system and its evolution;
- understanding of the behaviour of radionuclides in the reference case, and sensitivity to various conceptual assumptions and parameter variations.

The assessment cases were divided into a number of groups according to the issues or types of uncertainty that they addressed. The groups corresponded to scenarios that differed from the reference scenario and that, therefore, explore scenario uncertainty. Each of these groups is further divided according to alternative conceptualisations, which explore conceptual uncertainty. Finally, a specific conceptualisation may be evaluated using different parameter sets, thereby exploring parameter uncertainty.

The assessment cases were grouped into different scenarios.

Alternative scenarios were characterised by a fundamentally different behaviour of the system. They included unlikely, but still possible evolutions of the system in which the very slow release of dissolved radionuclides through the clay barriers was severely changed. In comparison to the reference case, the alternative scenarios considered different release pathways than those through the homogeneous low-permeability clay barriers, or different radionuclide transport mechanisms than the slow advective-diffusive transport of dissolved radionuclides assumed within at least a part of the system.

"What-if?" cases were set up to test the robustness of the disposal system. In contrast to the reference case and the alternative scenarios, the "what-if" cases are outside the range of possibilities supported by scientific evidence. To limit the number of "what-if" cases, they were restricted to those that tested the effects of perturbations to key properties of the pillars of safety.

The analyses of the assessment cases in the deterministic calculations were complemented by probabilistic analyses to ensure that no unfavourable parameter combinations were overlooked for key conceptualisations. The results demonstrated the robustness of the disposal system with respect to various detrimental phenomena and uncertainties.

Finland: Olkiluoto

Nykyri *et al.* (2008) report that in the evaluation of Olkiluoto as a potential repository site, uncertainty was evaluated deterministically. Uncertainties were addressed by including bounding cases in the safety assessment.

Results from these analyses indicated acceptable performance except in one "what-if" scenario case which was considered very unlikely. Finnish regulations state that a deterministic result over a certain magnitude from a "what-if" case must represent a case that is less likely than one in a million per year. The burden is then on the implementer to show that this particular "what-if" case is either under the allowable annual dose rate or is less likely than the one in a million per year threshold.

17. Regulatory issues

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Abstract

In this paper, the influence of regulations and regulatory expectations on the strategy and methodology of safety assessment is outlined. The paper is one of seven issue papers on safety assessment methodology developed in the NEA MeSA project. The seven papers are: (1) The safety assessment in the context of the safety case, (2) safety assessment and safety case flowcharts, (3) system description and scenarios, (4) modelling strategy, (5) indicators for safety assessment, (6) treatment of uncertainties, and (7) regulatory issues. The NEA issued a brochure on safety assessment methodology in 1991. Since then, national and international regulations and regulatory expectations have evolved in pace with the evolution of safety assessment capabilities and the specific role of the safety assessment within the safety case. National and international regulations are of interest not only for regulators, but also for proponents, since they constitute a reference for all national disposal programmes, which commit themselves to the current state of the art in safety assessment.

Keywords: Safety assessment, safety case, geological repository, radioactive waste, disposal.

17.1 Introduction

In the process of developing a repository for radioactive waste, safety assessments are used for several purposes. They improve the understanding of the disposal system, help to evaluate siting, design and engineering options, and demonstrate compliance with quantitative or qualitative regulatory performance criteria. Several of these aspects are subject to regulatory control and guidance and, thus, the methodology of safety assessment is strongly driven by regulations. However, there is a bi-directional relationship between safety assessments and regulations because research and development as well as practical experience in the field of safety assessment feeds back into the development of regulations, which tend to reflect the available assessment capabilities. For this reason, international and national regulations are of interest for all national disposal programmes, which commit to using the state of the art in safety assessment.

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Since 1991 when the NEA issued a brochure on safety assessment methodology (NEA 1991), national and international regulations and regulatory expectations have evolved to keep pace with the evolving safety assessment capabilities and the specific role of the safety assessment within the safety case. Several international initiatives and projects have developed recommendations, common views and opinions which have influenced the development of national and international regulations. Especially the work of ICRP, IAEA, and OECD/NEA has to be mentioned in this context. A common regulatory view on the treatment of uncertainties in safety assessments has been expressed recently by a group of European safety authorities and technical support organisations in the framework of the European Pilot Study (Bodenez *et al.* 2008, Vigfusson *et al.* 2007).

On the national level, several regulations and guidelines for safety assessments have been developed or revised in the NEA member countries during the last decade. These include the CNSC guides (Canada), the STUK guideline (Finland), the regulations of SKI and SSI (Sweden), of NRC and EPA (USA), HSK[1]/ENSI (Switzerland), ASN (France), and of the Environment Agency (UK), and the Safety requirements in Germany. Safety guides are under development in Belgium and Japan.

On the international level, the ICRP has issued important recommendations with regard to the assessment of compliance with dose and risk constraints. Since 1991, the ICRP publications 77, 81, and 103 (ICRP 1998a, b; 2007) show a broadening view on the meaning of dose and risk constraints, and on the assessment of compliance for very long time frames.

The IAEA safety fundamentals 111-F and SF-1 (IAEA 1995, 2006a), and the joint convention (IAEA 1997) have grounded the general requirement for safety assessments in the framework of radioactive waste disposal. Requirements regarding the methodology of safety assessment (which are not legally binding but represent good practices for national programmes to follow) have been defined in the IAEA (2006b) document WS-R-4 which will be replaced by a more general document (DS 354) in the future. More explicit guidance was given in 1999 by the IAEA safety guide WS-G-1.1 (IAEA 1999) which is limited to near surface disposal facilities but will be superseded by a Safety Guide that will also cover deep geological disposal facilities (DS 355). The IAEA has also developed and applied a safety assessment methodology for near surface disposal facilities in the ISAM and ASAM projects, respectively (IAEA 2000, 2007b).

Many NEA initiatives, activities and projects have addressed topics relevant to safety assessment including the concept of the safety case. These documents have provided important input for the development of national regulations and IAEA recommendations. The development of the safety case concept, which was stimulated by the NEA Córdoba Workshop in 1997, has led to a series of related NEA publications including the 2004 NEA Safety Case Brochure (NEA 2004). The current state of the art in the development of safety cases was reflected in the 2007 NEA Safety Case Workshop and in the INTESC project. Several critical aspects of safety assessments were addressed in detail by the NEA projects on integrated performance assessments (IPAG), timescales, engineered barrier systems (EBS), and long-term safety criteria (LTSC).

Within the framework of the MeSA project, a desk study was conducted by considering the key question of how safety assessment methodology is influenced by regulatory requirements and expectations. The study considers major regulatory trends, but also the variety of national approaches and the level of detail of regulatory requirements. Another objective was to identify where the regulator provides a framework and basis for the safety assessment and where he deliberately gives leeway to the proponent.

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[1] As of 1 January 2009, the former HSK, which was attached to the Swiss Federal Office of Energy, completed its transition into a formally independent body called ENSI, the Swiss Federal Nuclear Safety Inspectorate.

17.2 Context of the safety assessment

Safety assessment is a systematic analysis of the hazards associated with geological disposal facility and the ability of the site and designs to provide the safety functions and meet technical requirements. Regulators generally define quantitative and qualitative criteria that if met will be protective. The proponent therefore aims to meet these criteria or stay well below the corresponding limit values by a judicious selection of the site, engineering design, construction method, operations, and closure. The use of the term safety assessment is not uniform across all national programmes. Performance assessment is sometimes used as an alternative. Some programmes use safety assessment to denote an assessment limited to the operational phase and performance assessment for the post-closure phase. Another term that is often used is the safety case which is considered to include not only the safety assessment (both pre- and post-closure) but also other arguments that either support the safety assessment or add to the confidence in the safety assessment. It is also commonly understood that safety assessments are analyses that cannot and do not constitute absolute proof of safety, but efforts are made to design and conduct these analyses such that a high confidence in their results is achieved (see also MeSA Issue Papers No. 1 – Van Luik *et al.* 2011 and No. 2 – Schneider *et al.* 2011).

National regulations generally require the proponent to prepare a safety assessment as a prerequisite to licensing. However, even before reaching the licensing stage, safety assessments play a crucial role in the evolution of the disposal concept. At early stages of the project, safety assessments are used to compare alternative sites and or designs and also to identify data gaps and for guiding research. As the project advances and more data become available, the sophistication of the safety assessment also increases to include more processes, couplings between processes, space-time dependence, and to better account for model and parameter uncertainties.

The wider audience for safety assessment includes not only the developer and regulator(s) but also other stakeholders such as the potentially affected populations, political entities, the scientific establishment, and environmental groups. To be effective, the safety assessment needs to be transparent (NEA 2009). The chance of losing transparency increases as the safety assessment becomes more complex. This is one reason why it is not uncommon that safety assessments have a layered structure with simpler abstracted models (more transparent) based on more complex (less transparent) process models. Alternate models including models to analyse “what if” situations may be used to explain the robustness of the proposed concept (see also MeSA Issue Paper No. 4 – Gierszewski *et al.* 2011).

Elsewhere in this paper, the use of varied indicators to bolster confidence in the safety case is discussed (see also MeSA Issue Paper No. 5 – Noseck *et al.* 2011). Other arguments such as those based on natural analogues, accelerated experiments, plans for performance confirmation, and plans for monitoring of both engineered and natural components may be advanced to add to confidence. Together with the main safety assessment results, such additional arguments constitute some of the main components of a safety case. The recent trend is to use the term safety case for describing the proponent’s overall proposal (see also MeSA Issue Paper No. 1 – Van Luik *et al.* 2011).

17.3 Safety concept

The safety concept is the conceptual understanding outlining why the disposal system is safe, irrespective of identified uncertainties and detrimental processes, i.e. why the disposal system is expected to be *robust* (see also MeSA Issue Paper No. 2 – Schneider *et al.* 2011). The safety concept includes a description of the (potentially time-dependent) safety functions, i.e. roles of the natural and engineered repository components.

Regulators usually require that the safety concept should implement the defence-in-depth principle (e.g. ASN 2008). Defence-in-depth is usually understood as "the application of more than one protective measure for a given safety objective, such that the objective is achieved even if one of the protective measures fails" (IAEA 2007a). For disposal systems, defence-in-depth is not allowed to rely on human actions in the long-term because this would impose undue burdens on future generations. Therefore, it has to be implemented and achieved by system design. The multi-barrier and multi-safety-function concepts are implementing the defence-in-depth principle by redundancy and diversity of barriers and safety functions, respectively, which is a necessary prerequisite to achieve a safe and robust system.

Although safety concepts usually rely on several barriers, strict application of the multi-barrier concept is not required in all programmes (NEA 2009). The latter would e.g. require that a total failure of the geological barrier – could be compensated by the action of other barriers, and this is usually not given for most repository concepts which rely on the geological barrier (e.g. for isolation). Regarding the hypothetical total failure of the geological barrier, a demand for a strict application of the multi-barrier concept would be inadequate if there is no reasonable cause for such an event, if the event had an extremely low likelihood, or if the decrease of radiotoxicity of the wastes would justify a lower level of defence-in-depth in the long-term. However, redundancy and diversity are not only present on the level of barriers, but also on the level of safety functions of various components. Focussing on safety functions instead on barriers alone allows to demonstrate the complex defence-in-depth layout of the disposal system in a more detailed way.

Across the different countries, regulations do not use a consistent terminology for safety functions. Terms like "barrier functions", "component functions" or "environmental safety functions" are used with a similar meaning. Safety functions have become an important element of the safety concept and, hence, of the entire safety assessment: general safety functions like "preventing water circulation" or "limiting radionuclide release" allow the proponent to illustrate the main elements of the safety concept in a transparent way. In addition to providing a means with which to explain defence-in-depth, safety functions may help to formulate scenarios by assuming that one or more of the identified components will fail to serve their assigned safety function, thus, creating a scenario for unexpected but plausible disposal system evolutions.

The Finnish regulator (STUK 2010), based on the Government Decree GD 736/2008, states that the long-term safety of disposal shall be based on safety functions achieved through mutually complementary barriers so that a deficiency of an individual safety function or a predictable geological change will not jeopardise the long-term safety. Performance targets (or criteria) based on high quality scientific knowledge and expert judgement shall be specified for the performance of each safety function. The safety functions shall be used for the design of components and for scenario development. For example, STUK (2010) states that the base scenario shall assume the performance targets for each safety functions taking account of incidental deviations for the target values.

17.4 Assessment strategy

Despite the differences in the national regulatory frameworks, a common international understanding on the main elements and goals of a safety assessment has evolved (Bodenez *et al.* 2008). As mentioned before, the idea behind safety assessments is not only to demonstrate compliance with regulatory requirements by comparing aggregated assessment results with safety standards, but also to demonstrate that the system under consideration has been well understood and that it is sufficiently robust. In this sense the assessment strategy is "… to perform safety assessments and define the approach to evaluate evidence, analyse the evolution of the system and thus develop or update the safety case" (NEA 2004, see also MeSA Issue Paper No. 2 – Schneider *et al.* 2011).

Safety assessments are performed throughout the process of site selection and repository development, e.g. for optimisation purposes, and regulators often expect to be kept informed early in this process even if regulations do not require this explicitly. Doing so will likely facilitate the process of repository development and licensing and may be regarded as a part of the assessment strategy. Quality management strategies which are used to deal with huge amounts of data and which ensure that the data and models used in the safety assessment are consistent and adequate and remain so during all updates may be understood as another part of the assessment strategy (see also MeSA Issue Paper No. 4 – Gierszewski *et al.* 2011).

17.4.1 Treatment of uncertainties

Assessment strategies are strongly motivated by the need for an adequate treatment of uncertainties. Sources of uncertainties which are inherent to the concept of final disposal in geological formations are the considerable length of the assessment time frame and the incomplete knowledge of the natural system, its evolution, and interaction with the materials of the repository. This leads to uncertainties in data, assumptions, conceptual and physical models which have to be considered in the safety assessment.

Regulators expect that uncertainties which can not be shown to be irrelevant are avoided or reduced as far as possible e.g. by means of site selection, site characterisation, repository design, and process-oriented research in order to increase the knowledge of the system's properties, state and behaviour. Uncertainties connected to the assessment results can to some extent be counterbalanced by using multiple lines of evidence, either as a complement to the entire safety assessment or to parts of it. In order to reduce uncertainties concerning the quality of procedures used for data collection and assessments regulators often require the application of auditable quality assurance measures to avoid inconsistencies or errors in the data or models (Vigfusson *et al.* 2007) and the use of systematic approaches in avoidance of methodological mistakes.

Regulators expect uncertainties to be identified, to the extent possible quantitatively characterised or bounded, and their impact on safety clearly articulated in the safety case (see also MeSA Issue Papers No. 1 – Van Luik *et al.* 2011 and No. 6 – Mönig *et al.* 2011). Moreover, the way uncertainties are treated and propagated in the safety assessment should be traceable and substantiated. Complementary strategies like scoping and bounding assessments, deterministic and probabilistic approaches, realistic best estimates, conservative estimates, and alternate lines of evidence may be prescribed by regulations for specific assessment objectives. The requirement to build all scenarios into a single overall probabilistic assessment (variously called total system simulation, environmental system simulation, system simulation approach, probabilistic system(s) assessment, global probabilistic risk approach, total system performance assessment) alone is nowadays considered to be insufficient by many regulators (Vigfusson *et al.* 2007) without adequate basis for the complex model and the results.

When conservative estimates are required, care has to be taken that conservativeness is not inherent to a single assumption but has to be judged with regard to the indicators for safety. The judgment as to whether an estimate is conservative requires a good understanding of the system (Vigfusson *et al.* 2007). Conservative approaches are, therefore, always connected to best-estimate approaches which try to approximate the "true" system behaviour.

Expert judgment is a ubiquitous, but not always visible ingredient in the treatment of uncertainties. Regulators usually recognise that expert judgement may be useful in both the quantification of uncertainties and in their qualitative treatment where reliable quantification is not practical. It is usually considered that it is a matter for the proponent to decide whether, where and how to use expert judgement. If expert judgement is used, it has to be documented in a traceable and transparent way and the proponent must apply appropriate quality standards. The role of the experts is not seen as a substitute for scientific research, but instead experts can be employed to synthesise disparate and sometimes conflicting sources of information to produce an integrated picture (Vigfusson *et al.* 2007). Uncertainties originating from any differing or contradictory expert elicitation have to be explained in the safety case (see also MeSA Issue Paper No. 1 – Van Luik *et al.* 2011).

The safety assessment also has to deal with irreducible uncertainties that are not amenable to quantification. There is e.g. uncertainty about the likelihood of human intrusion, uncertainty whether calculated doses have the same radiological impact on future species as on present species, and uncertainty whether all relevant processes, events, evolutions and uncertainties have been identified and considered in the safety assessment. The confidence in the safety of the disposal system relies on the subjective judgement that such uncertainties are sufficiently low in view of the measures that have to be taken to reduce them. The regulator has to give guidance under which circumstances he is willing to accept uncertainties that can not be quantified. Many regulators accept the possibility of human intrusion on the condition that the repository has been placed in great depth and far away from natural resources which are the main counter measures against human intrusion. Also, the repository may be designed to reduce the likelihood of human intrusion or the possible consequences. The possibility that relevant FEPs might not have been discovered may be accepted on the condition that systematic procedures for FEP screening, which aim at comprehensiveness, have been applied or that the state of the art in science and technology is evaluated periodically.

17.4.2 Role of timescales and time frames

Assessment strategies often account for different time frames (sometimes called time windows) and timescales which are based on considerations of radioactive decay, the ability to predict future evolutions including human habits, the timescales of geological, hydrogeological, geographical or biological changes, or the periods of monitoring, institutional control and knowledge preservation. Some regulations require subdividivision of the assessment time frame into sequential time frames which again are connected to specific assessment strategies.

The time frame over which the safety indicators have to be evaluated, varies considerably between national regulations and sometimes has to be determined and justified by the proponent as adequate for the wastes and repository system concerned. Cut-off times specified in national regulations are derived from the declining radiological toxicity of the waste, from peak radiological consequences (which depend on the chosen host rock), from increasing uncertainty with time, or from the need for adequate coverage of transient or perturbing processes (NEA 2007).

In the last decades, there has been a development of the view of ICRP and national regulators on the meaning of dose and risk constraints for times very far in the future. Precise predictions of doses and risks to humans beyond times around several hundred years into the future are now regarded as impossible or at least very difficult, due to the large uncertainties that are connected to human behaviour, needs, and skills. Also the uncertainties regarding the climate and biosphere increase considerably with time. Calculated values of dose and risk for times far in the future are, therefore, not perceived as predictions, but as indicators which quantify the capability of the system to provide isolation of the waste and containment of radionuclides.

In view of the uncertainties connected to very long time frames, especially with regard to the biosphere, dose and risk indicators have to be quantified on the basis of stylised assumptions or scenarios, although the perception of how much stylisation is required and how much predictive modelling is possible varies from country to country. The definition of stylised assumptions or scenarios is an important task that requires input from the regulator since it might be very difficult for a proponent to defend his own stylised assumptions with well founded scientific-technical arguments in a licensing procedure.

Sometimes regulations allow the exclusion of unlikely scenarios from the consequences analysis for times very far in the future because the assessment of such scenarios is unduly speculative and the radiological hazard has decreased. Another approach is to decrease the required level of detail in the treatment of uncertainty for such scenarios.

17.5 Indicators and criteria

17.5.1 Safety indicators

National regulations always establish at least one safety indicator (usually dose or risk) which provides an indication of the ability of the disposal system to comply with the given safety objectives. This requires the definition of acceptance criteria.

The *effective dose* (ICRP 1991) specifies the expected overall effect radiations have on the body. The weighting factors involved in the definition of the effective dose account for both, the different effects of different types of radiation and their individual effects on individual organs, which may be – depending on the type of body exposure (external exposure, inhalation, ingestion, etc) – exposed to the radiation. The effective dose has been implemented into legislation and regulations in many countries worldwide, and provides a practicable approach to the management and limitation of radiation risk in relation to both occupational exposures and exposures of the general public.

Despite the fact that the effective dose is a frequently used safety indicator, regulatory answers to the question which indicators are able to serve as safety indicators, as well as the practice of how safety indicators are defined and used varies considerably across the countries. As stated in the European Pilot Study (Vigfusson *et al.* 2007): “There is a wide range of regulatory attitudes with regard to this question. Concepts are different not only with respect to the indicators to be considered (e.g. concentrations, dose, risk), but also to the degree and way they prescribe how these indicators should be calculated (deterministic vs. probabilistic approaches, requirements to consider certain scenarios, critical groups etc.) and the rationale for the standards to be applied. Differences also exist about the roles of such standards as limits, targets, or constraints and – in the case of a probabilistic approach – about which statistics are appropriate for demonstrating compliance.”

National differences can not only be found with regard to the definition and use of safety indicators, but also with regard to the respective criteria. The NEA’s Regulator Forum Project on long-term safety criteria (LTSC) found a significant variation among the current criteria, which not only differ in their magnitude, but also with respect to the time frame over which they are envisioned to apply. Also, the bases for setting the criteria vary and may be influenced by (1) the acceptability of levels of risk, (2) the comparison with numerical radiological protection criteria used for current practices, (3) the comparison with existing levels of natural radiation, (4) or a combination of these. This means that numerical criteria of different countries can not be compared in a meaningful way without considering the underlying country-specific reasoning regarding what are acceptable levels of consequences today and in the future and how those should be evaluated (NEA 2007).

The perception that dose-based regulations ask for deterministic and risk-based regulations for probabilistic approaches is not necessarily correct (Röhlig and Plischke 2009). Dose values can also be calculated by probabilistic assessments and risks can be estimated using deterministic assessments. It is, therefore, possible and – with regard to the specific shortcomings of each approach – also advisable to use a mixture of deterministic and probabilistic analyses. In fact, most regulations follow this strategy.

Whatever approach is chosen, probabilistic or deterministic, the proponent should show where the uncertainties come from, what their implications are and that the uncertainty space has been reasonably well explored.

17.5.2 Complementary indicators

In all national regulations there are broad similarities in the safety indicators and criteria for the post-closure phase up to about 10 000 years, where dose or risk limits or guidelines are used. For later times, some recent regulations use different indicators – e.g. nuclide-specific activity fluxes from compartments, inventories inside or outside of compartments, or concentrations at certain locations. This approach recognises the fact that increasing uncertainties, especially those concerning the long-term prediction of the biosphere, may make dose or risk quantities less meaningful. Because of these uncertainties, ICRP (ICRP 2007) and many national regulations define specific time windows for safety indicators and recommend consideration of the use of indicators which complement the indicators dose or risk.

Indicators complementary to dose and risk are not only used to demonstrate compliance, but also to build confidence in the safety and to demonstrate the robustness of the disposal system (see MeSA Issue Paper No. 5 – Noseck *et al.* 2011). The need for complementary indicators is recognised by several regulators and was e.g. pointed out by the IAEA Coordinated Research Programme on Safety Indicators (1999 – 2003) (IAEA 2004a). Most regulators have an expectation that the developer will use such complementary indicators in their safety assessment. However, whether the use of complementary indicators is prescribed or only recommended in regulations differs from country to country.

Complementary indicators often are performance indicators which indicate how the entire system performs without directly predicting radiological consequences. Performance indicators have been selected and used by implementers when building the safety case in order to understand, quantify and explain how the disposal system works and to give additional arguments that underpin the statement that the repository is safe. Although, from a methodological point of view, performance and safety indicators provide different kind of statements, regulations often do not distinguish explicitly between these two types of indicators. Yet, some new regulations have included indicators, which have the character of a performance indicator, although they are not denoted as such, see e.g. CNSC (2006), SSI (2005). Usually, regulations provide no quantitative criteria for performance indicators.

17.5.3 Safety function indicators

If safety functions are defined for system components it is necessary to introduce a method to inspect whether the components fulfil their intended function. For this purpose, safety function indicators are defined and target values or numerical criteria are assigned to these indicators in order either to allocate a certain performance, or to check and quantify the fulfilment of the safety function (see MeSA Issue Paper No. 5 – Noseck *et al.* 2011). For example, a waste container may be assigned the safety function of containing waste, whereas the number of years that the container will serve this function is set as safety function indicator. As a design target, based on the site conditions, a safety function indicator value of say 50 000 years might be defined.

Regulations usually do not specify which safety functions the proponent should assign to technical components, nor do they specify respective safety function indicators and criteria. The main reason for this is that, for technical components, the choice of safety functions and safety function indicators often depends on the repository concept so that a specification on the part of the regulator can hinder the development of an optimal system which a proponent should be free to develop based on available technology. Nevertheless, some regulations specify safety functions for the geological barrier like the new German Safety Requirements (BMU 2009) where the "integrity of the confining rock zone" is required and a dilatancy and a fluid pressure criterion are explicitly mentioned.

17.6 System description

The system description includes a description of the present situation at the site, the elements of the barrier system and their initial state. It also includes a description of the corresponding uncertainties and of possible deviations in the implementation of the system (see also MeSA Issue Paper No. 3 – Röhlig *et al*. 2011). Depending on the viewpoint, the system description may also encompass the expected evolution of the disposal system as far as relevant for safety. Uncertainties and detrimental processes or events that could potentially affect the evolution of the system should then be addressed.

Most national regulations require that the repository system implements defence-in-depth by using multiple, diverse, and reasonably robust barriers or functions. A proponent may choose any way of implementing such a concept, and the system of barriers or safety functions he relies on in order to implement defence-in-depth should be part of the system description.

An appropriate system description provides the foundation for the safety case where what is "appropriate" depends on the stage of the programme. Early on, at the site selection stage, it is reasonable to make assumptions about general site characteristics of the geosphere and biosphere, to use data from roughly analogous locations and to consider generic design choices. However, the same is not true at the later stages of the programme, particularly at the licensing stage. At the licensing stage, the system description has to be based on traceable site-specific data with appropriate quality assurance qualifications (see also MeSA Issue Paper No. 4 – Gierszewski *et al*. 2011) and has to include a clear identification and description of system components important to safety (including their safety function or roles, their expected performance and evolution, and their design requirements). If data are transferred from "analogue" sites, it has to be shown that transferability is established and the site is indeed a reasonable analogue to the disposal site. In addition, data have to be adequate to justify safety arguments without the need for excessive assumptions. Of necessity, the system description evolves as site characterisation and design evolves and so do safety assessments. Several stages may be recognisable such as: initial literature review, surface based geological investigations, experiments in underground laboratories, work at analogue sites, observations during actual construction, conceptual engineering design, tests on scaled engineering components, and tests on full sized engineering components.

Most national regulations are focused on defining safety criteria and do not specify how a proponent may meet these. However, a regulator may choose to provide regulatory guidance as a basis for the proponent to select an assessment approach. The US regulation at 10 CFR Part 63 applicable to the proposed Yucca Mountain repository requires the applicant to inform the regulator of any information that can significantly affect the basis of the safety assessment included in the license application or after the granting of a license, any change in the basis of which the license was granted. This requirement implies that the applicant should be able to update its safety assessment to include any new information on site and design to determine whether such change significantly affects the safety case or the licensing basis. The regulation at 40 CFR 194 applicable to the operating WIPP repository for transuranic waste requires similar assessments of the consequences for planned and unplanned changes to the disposal system; in addition, the applicant is required to update the safety assessment, taking into account any new information, every five years as a part of the recertification process to confirm that the collective effect of numerous small changes does not jeopardise compliance with the safety criteria.

The objective of system description is to provide sufficient detail so that the basis of the safety case can be understood and if needed the safety case can be reproduced by a qualified independent party. Because of the multiple disciplines involved and the rather long time needed to obtain a system description at varied space and timescales, the logical synthesis of information is unique to the repository programmes. Proper synthesis requires that data collected by various techniques at various scales in different disciplines is interpreted together to develop a coherent and consistent description of the system.

17.7 System evolution and scenarios

Quantitative safety analyses involve the evaluation of the impact on safety of potential future evolutions of the disposal system, described through a set of scenarios. It is commonly expected that these scenarios are described, developed and treated in a systematic way (see MeSA Issue Paper No. 3 – Röhlig *et al.* 2011). Hence, some guidance on the classification and development of scenarios, as well as on the objectives of the assessments associated with the different categories of scenarios is usually provided by regulators.

17.7.1 System evolution

The development and selection of scenarios requires a good understanding of the possible evolutions of the disposal system and, therefore, of the features, events and processes that may significantly affect these evolutions. Nonetheless, the safety assessment cannot be expected to produce a detailed, step-by-step description of the evolution of the disposal system over millions of years covering the full complexity of all the phenomena involved. Implementers are, however, requested to demonstrate understanding of the safety functions e.g. isolation and containment, and of the processes central to repository safety (Vigfusson *et al.* 2007).

17.7.2 Scenario classification

The extent to which regulators provide guidance on the classification of scenarios is directly related to the requirements on the approach to treat uncertainties on potential future evolutions of the disposal system. Requirements on scenario classification are indeed quite limited in countries where potential future repository evolutions are treated within a probabilistic framework (e.g. total system performance assessment, TSPA) as such approaches reduce the need for defining different categories of scenarios. In such cases, the dose calculated for individual scenarios is weighted as a function of scenario probability to develop an overall distribution of doses with time. It should be noted, however, that given the impossibility of predicting future human actions, human intrusion is usually treated separately from the probabilistic analysis (the WIPP is an exception).

Alternatively, requirements on scenario classification are usually provided by regulators fostering the use of deterministic approaches, or the combination of deterministic and probabilistic approaches, to tackle the issue of uncertainties regarding the future evolution of the disposal system. Scenarios are often classified on the basis of their likelihood and the possibility of quantifying their likelihood (e.g. human actions). However, the objective of the assessment may also be considered to distinguish specific types of scenarios. The definition of a central scenario depicting the expected evolution and of a set of alternative scenarios is a common trend amongst regulations where different classes of scenarios are identified. Scenarios that do not have to be considered in the safety assessment may also be specified. The categorisation of alternative scenarios varies widely from one country to another. In this paper, plausible alternative scenarios are distinguished from unlikely and arbitrary alternative “what-if” scenarios.

Central scenarios

Central scenarios (also termed likely or expected evolutions) include all the scenarios which are aimed at representing the foreseeable and desired evolution(s) of the disposal system with respect to the most likely effects of certain or very probable events or phenomena. Thus, the system can be considered as designed with a view to these scenarios. The foreseeable evolutions of the repository can be represented by one or more central scenarios. The performance targets defined by the proponent for each barrier may have to be assumed in central scenarios. All regulations require comparison of the dose calculated for a central scenario to a prescribed dose constraint. One regulation (STUK 2001) also requires comparison of activity releases to activity release constraints.

Plausible alternative scenarios

These scenarios represent less likely but still plausible modes of repository evolutions (e.g. barrier degradation more rapidly than expected, human intrusions, …) as well as scenarios portraying extreme natural events (e.g. extreme ice-age or a major seismic event) but that are still within the range of realistic possibilities.

Considering this category of scenarios is a common trend of regulations. It is usually required to compare the radiological risk calculated for these scenarios to a prescribed risk constraint. However, several regulators consider that the likelihood of occurrence of some events cannot be evaluated. Some of these scenarios are subject to stylisation, e.g. human intrusion. In other cases, the calculated dose has to be compared to the dose constraint as for the central scenario but without this comparison constituting an absolute acceptance criterion (AFCN/FANC *et al.* 2004). It is also the position of some regulators that the acceptability of the calculated consequences related to altered evolution scenarios must be appraised on a case-by-case basis depending on the bounding property of the scenario taken into account, the likelihood of the events and phenomena that are described therein occurring, the degree of conservatism in the hypotheses used in the study, and the level, extent and duration of contamination (AFCN/FANC *et al.* 2004, STUK 2001).

For some regulators, the influence of the declined performance of system components and/or the complementarities between the different components should be analysed by means of plausible altered evolution scenarios. These types of analyses allow demonstration that the performance of the repository system is at least adequate for any possible evolution considered to be within the scope of the safety case (Vigfusson *et al.* 2007).

A range of possible future human actions can be envisaged having the potential to breach the natural or engineered barriers, or significantly impair the performance of a disposal system. Because future human actions are unpredictable and scenarios that involve them need to make stylised assumptions, these are often considered as a specific scenario category. With regard to the consequences of human actions, a distinction can be made between the following cases:

- activities that indirectly alter the isolation and/or containment performance of the disposal system or the site situation (e.g. by changing groundwater chemistry or the hydrological conditions in the repository or its surroundings);
- repository evolutions resulting from the interruption of the disposal project (e.g. unclosed repository that is not monitored);
- human intrusions that directly damage the isolation/ containment performance.

The latter case is often systematically treated in regulations. A distinction is usually made between inadvertent and intentional human intrusion. Regulators generally consider that the only ones to be taken into account relate to inadvertent intrusion, most often associated with a loss of memory of the existence of the repository. The incorporation of these scenarios reflects a certain arbitrariness as all future human activities that are liable to lead to such intrusions cannot be known or even presupposed. Two different types of consequences are commonly identified in regulations:

- immediate consequences for the intruders;
- deferred consequences for other individuals and people in the area, associated mainly with the migration of radionuclides by gas or water in a configuration where one part of the barriers has been bypassed and leads to radiological consequences.

Several regulations require considering the radiological impact on the intruder. However, it is generally considered that a person coming into direct contact with high-level waste might receive any radiation dose up to and including a fatal dose. These high consequences are closely linked to the chosen strategy of "concentration and containment" and, thus, comparison of the dose rate received by the intruder with a regulatory limit is often considered as not pertinent. The absence of regulatory limits for that particular situation is somehow compensated by the necessity to minimise the probability of occurrence of intrusion through deep disposal, site selection and or by means of markers.

Many regulators consider that human intrusion will most probably result in a limited and local disturbance of the repository. Deferred radiological consequences associated with this disturbance have to be assessed and usually compared to a radiological criterion. A regulatory limit specific to this particular situation is sometimes prescribed by the regulator. Several regulations require optimisation of the design as far as possible to reduce consequences associated with the by-pass of barriers created by an intrusion. It is also the position of several regulators that the assessments should also explore the consequences of intrusion on the long-term behaviour, performance and resilience of the disposal system (e.g. Environment Agency and Northern Ireland Environment Agency 2009, EPA 2005, NRC 2004).

Arbitrary alternative scenarios

The treatment of arbitrary scenarios other than those relating to human intrusion is considered or required by several regulators. These scenarios, often called "what-if" scenarios, can be defined as imposed or conventional scenarios for which the occurrence of an event or random phenomenon is postulated. It is generally possible to exclude these scenarios from all plausible evolutions of the disposal system through design or the level of knowledge available. A typical example of this type of scenario is postulated failure of a barrier for undefined reasons.

These scenarios are mainly used for assessing the robustness of the disposal system and the relative importance of some of its components or functions. Due to the arbitrary nature of the perturbations, no regulatory criteria are associated with this type of evaluation. Robustness of the disposal system can be evaluated through comparison with the central scenario findings at some specified end-points and for the radiological impact. The time and the magnitude of the deviation of the response may be analysed and appreciated on the basis of the perturbation amplitude. Arbitrary scenarios can also be used to explore or illustrate certain properties of the system. "What-if" scenarios may help to provide multiple lines of reasoning and hence build confidence in the safety case.

17.7.3 Scenario development

The systematic development of scenarios for the safety case is considered by several regulators as of fundamental importance as it constitutes a key element of the management and analysis of uncertainties. In most regulatory environments, only a qualitatively sufficient set of scenarios is deemed necessary. Nonetheless, it is expected that this set of scenarios is comprehensive in the sense that it should illustrate the possible evolutions of the disposal system and their associated consequences in a credible manner.

The favored means of developing and selecting scenarios is generally a traceable, structured and transparent approach either for identifying FEPs and their combination into scenarios or for deriving scenarios by altering the degree in which components or subsystems fulfill their intended functions (see MeSA Issue Paper No. 3 – Röhlig *et al*. 2011). Combining FEPs to scenarios is often called a bottom-up approach whereas the derivation of scenarios by degrading the fulfillment of safety functions is often described as a top-down approach. In practice, both approaches are often used simultaneously in a complementary way; as a result regulations usually do not favour one approach against the other.

Regulators may provide guidance on the steps to be followed to develop scenarios (e.g. ASN 2008) or require reporting on how one or several methods have been used to identify and describe relevant scenarios representing sequences of events and conditions that can affect the future evolution of the repository.

The degree to which requirements or guidance on the development of scenarios is provided by the regulator varies significantly from one country to another. However, some common trends can be identified:

- Scenarios have to be developed in a systematic, transparent, and traceable manner.
- Although regulators usually specify events and processes that should as a minimum be considered in the scenario analysis, it is for the proponent to justify which events and processes to include in assessment models, and how to represent them in the models. Additionally, the proponent has to justify that all relevant processes and events have been identified and that all possible future evolutions of the disposal system have been considered in the development of the scenarios.
- Stylisation is regarded as appropriate for human intrusion.

The main differences between the different regulatory approaches relate to:

- The number and the type of events and processes that should, as a minimum, be considered.
- Opinions on the needs and possibilities for estimating scenario probabilities and on the appropriateness of aggregating such estimates.
- Whether or not a specific approach to the development of scenarios is required.
- Whether or not specific FEPs or scenarios are prescribed.
- Whether the set of scenarios being considered should cover all possible evolutions of the disposal system or only a qualitatively sufficient set of evolutions for which associated consequences are envelopes of those of all possible evolutions.
- Whether or not the increasing simplification and stylisation with time is reflected in regulations.
- Whether or not the regulator takes over the responsibility for defining stylised assumptions.
- Whether stylisation is regarded as appropriate for the biosphere and for the impact of climate change.

Underlying assumptions taken into account when developing scenarios may be best estimate, conservative or stylised, or some combination of all three. The adoption of a stylised approach may be justified by the lack of knowledge and the necessity to manage the existence of irreducible uncertainties such as those inherent to future human actions. For instance, there is consensus that only current and past human technology should be considered within a limited number of human intrusion scenarios. Regulators may also provide guidelines on the stylisation of specific scenarios to aid the proponent in justifying the assumptions on which the development of these scenarios was based. For instance, the manner that shall be used to calculate the drilling frequency when assessing the likelihood and consequences of drilling events for the WIPP is provided in the regulatory guide 40 CFR 194 (EPA 2004).

17.8 Modelling strategy

The aim of modelling studies is to help in understanding the characteristics and behaviour of the disposal system and its component parts. Such studies are ultimately focused on examining the movement of radionuclides from the repository to receptors at or near the surface in order to estimate the resulting impact. Models that examine e.g. the performance of individual barriers are an important part of this.

Demonstration to the regulators, through the safety case, that the expected performance of the repository will meet regulatory expectations at all times is essential for licensing. Consequently, the developer's modelling strategy, and the resulting presentation in the safety case, should be closely aligned with the relevant regulations and regulatory guidance, i.e. based around the time frames, scenarios, indicators and criteria discussed earlier. Quantitative regulatory limits and associated time frames can vary considerably between different countries and include differing limits or targets for dose or risk at different times, and, in some countries, nuclide specific concentration limits or fluxes. These criteria clearly have a large influence on the modelling strategy adopted by different developers.

Regulatory bodies consider that implementers need to provide support for confidence in their models, but recognise that there is no single "best" or "correct" way to carry out modelling studies. Consequently, regulations tend not to be too prescriptive in defining particular modelling approaches. Where particular modelling approaches are preferred by the regulators, this is generally given as guidance, to emphasise the available flexibility in approach. However, some regulators provide quite specific guidance on how to carry out certain parts of the safety assessment, for example on:

- how to treat the biosphere (e.g. by prescribing stylised approaches for how to identify potentially exposed groups of people, how to convert geosphere releases into dose, how to handle future climate changes, and how to address potential changes in future human behaviour);
- the estimation of radionuclides in representative groundwater volumes (for the Yucca Mountain project).

The need to evaluate and manage the various types of uncertainties in safety assessments is an important regulatory requirement. With respect to modelling, there are a number of conclusions that can be drawn from examination of national regulatory documentation:

- There is now a better overall appreciation of the limitations of modelling studies, in particular:
    - the large uncertainties associated with predicting far into the future and the consequential need for more qualitative based reasoning and complementary evidence to demonstrate safety at longer times;

  - the need to avoid over-interpreting model results;
  - the need to manage the uncertainties introduced through the simplifications necessary in developing models of real systems.

- Justification for the choice of model or interpretation is sometimes an explicit requirement. However, comparison of the model results with those from other available models is not commonly an explicit requirement, though some developers undertake such comparisons (see MeSA Issue Paper No. 4 – Gierszewski *et al*. 2011).
- There is agreement on the need to justify the range of applicability (scales in space and time, heterogeneity…) of models chosen and the underlying parameter values, and in some cases there is a requirement to carry out sensitivity analysis.
- The desire to avoid underestimation of the releases from a repository is common to all regulations. However, there are slight differences in the way this is translated into regulatory requirements and also the terminology used. For example, the Finnish regulations (STUK 2001) specifically request that the results of the overall safety analysis should "…with a high degree of certainty …overestimate the …radioactive release likely to occur". Other regulations variously specify the use of realistic or best estimate data and assumptions where possible, with evaluation of the uncertainties in the results that this introduces. In practice, safety assessments usually employ a combination of the best estimate approach with the strategy of conservatism, in that certain conservative assumptions are made during "best estimate" scenario analysis (Vigfusson *et al*. 2007). Also, the system understanding gained by best estimate approaches is important to judge whether alternate approaches are conservative or not.
- The modelling approach adopted in practice includes many stylised elements (e.g. in relation to the biosphere or future human actions), which seek to err on the side of conservatism. Stylisation is a way of bypassing unquantifiable uncertainties. Stylisation needs to be avoided, however, for those components of the repository system where avoidance is possible. For example, it would usually be inappropriate to adopt a stylised approach for modelling the performance of an important barrier, for then the safety case would provide no information about the capabilities of the barrier (Vigfusson *et al*. 2007).
- Regulatory prescription regarding probabilistic and deterministic assessment methods is varied. For some countries the use of both methods is required or encouraged, and guidelines are given. However, in many regulatory documents the choice of one or other or both is left to the developer.

Regulators often decide to use or develop independent models (Winterle and Campbell 2008). Due to budgetary and staff constraints these may be simplified compared to the models used by the proponent. However, simplified models may be better suited to enhancing the understanding of the disposal system and they may permit more rapid adaptation for exploring technical uncertainties and alternative features, events, processes or concepts. In this context, it is important that the regulator has the technical capability to adapt his models and that the applied codes provide sufficient flexibility.

The assurance of data and information as well as of model and software development quality is a common theme across national regulatory documentation. In particular, the need for "traceable" and "transparent" links to the source data and references is seen as essential by most regulators. Traceable and transparent documentation of the elicitation of scientific knowledge underlying the modelling, of the transfer of this knowledge to conceptual and from there to numerical models, and of measures enhancing confidence into models (e.g. benchmarking, comparison with lab or field tests or to observations in nature) is also considered to be of particular importance (Vigfusson *et al*. 2007).

17.9 Conclusions

Regulations and regulatory expectations have evolved considerably since the issuing of the NEA brochure on the methodology of safety assessment in 1991. The evolving safety case concept has led to a more sophisticated understanding of the role of safety assessment in the demonstration of repository safety and in the development and optimisation of a disposal system. Regulations nowadays recognise more precisely the implications of the enormous length of the assessment time frame for the demonstration of compliance and for the assessment methodology that should be used. In view of the inherent limitations of assessment methods, the outcomes of the safety assessment are now seen as lines of argumentation which are accompanied by others in order to build confidence in repository safety.

Regulators expect that the proponent does not only assess compliance with quantitative radiological criteria, but also demonstrates that the disposal system is robust and that its behaviour and evolution is well understood. The improvement of system understanding should be a main objective for all assessment methods. This affords a sufficient level of realism even though conservative approaches are unavoidable with regard to the given uncertainties.

Regulators ask the proponent to provide sufficient arguments in order to create confidence in the results of the safety assessment and in the safety of the repository. It is good for the proponent to provide evidence or statements not only expressing his own confidence, but also relating to that of the regulators and other relevant stakeholders. This includes the call for complementary methods to determine the level of protection provided by the repository, e.g. by the use of indicators which are complementary to dose and risk. Also, assurance of data and modelling tool quality, appropriate quality management and transparency and traceability of the assessment process are considered as essential.

The regulators themselves have to provide qualitative and quantitative safety criteria and guidance on how to build confidence in safety assessment results. The treatment of uncertainties and, in particular, of uncertainties which cannot be quantified, like e.g. those associated to human intrusion, also calls for guidance by the regulator. The specification of guidance on time frames and timescales for the safety assessment is another important regulatory task. When giving guidance, regulators usually consider how much freedom the proponent needs to optimise the system and to demonstrate that it is safe.

Usually, regulators are responsible for the review of the proponent's safety assessment. In this context, regulators assess compliance with legislation and regulations and conduct their own assessments in order to gain confidence in the proponent's assessment results and to develop an independent understanding of the system.

In view of the fact that it is difficult to change the fundaments of a safety case at late stages of a repository programme, it is reasonable that regulators expect to be involved or informed early in the process. Yet, the regulators still have to keep their independence as this is an essential part of the national safety culture and of fundamental importance for the confidence of the stakeholders.

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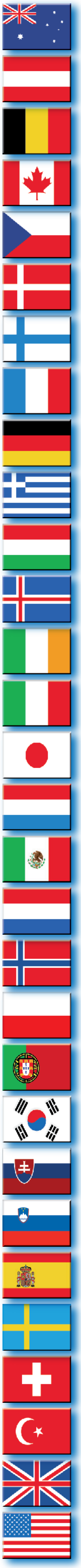

Methods for Safety Assessment of Geological Disposal Facilities for Radioactive Waste

Safety assessment is an interdisciplinary approach that focuses on the scientific understanding and performance assessment of safety functions as well as the hazards associated with a geological disposal facility. It forms a central part of the safety case, and the results of the safety assessments provide evidence to support decision making. The goals of the NEA project on "Methods for Safety Assessment for Geological Disposal Facilities for Radioactive Waste" (MeSA) were to examine and document methods used in safety assessment for radioactive waste disposal facilities, to generate collective views based on the methods' similarities and differences, and to identify future work. The project reviewed a number of approaches used by various national and international organisations. Following the comprehensive review, a generic safety case with a safety assessment flowchart was developed and is presented herein. The elaboration of the safety concept, the use of safety functions, the implication of uncertainties and the formulation of scenarios are also discussed.

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