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The Nature and Purpose of the Post-closure Safety Cases for Geological Repositories

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Radioactive Waste Management Committee

THE NATURE AND PURPOSE OF THE POST-CLOSURE SAFETY CASES FOR GEOLOGICAL REPOSITORIES

"Safety Case Brochure 2012"

Updated figure on page 13.

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Foreword

In 2004, the NEA published a brochure approved by its Radioactive Waste Management Committee (RWMC) and written by its Integration Group for the Safety Case (IGSC). The brochure, entitled Post-closure Safety Case for Geological Repositories: Nature and Purpose (NEA, 2004a), was intended to stimulate the preparation of comprehensive evidentiary arguments for repository system long-term safety, typically extending to hundreds of thousands of years.

This document, like its 2004 predecessor, defines and discusses the purpose and general contents of post-closure safety cases for geological repositories for long-lived radioactive waste. The aim of this update is to make this document a more useful point of reference for those involved in the development of safety cases and for those with responsibility for, or interest in, decision making in radioactive waste management. It is hoped that this document will be of interest to safety experts in other fields of applied science and engineering.

The reason for replacing the previous brochure on the nature of the long-term geologic repository safety case is to reflect that over the last eight years there has been progress in terms of: *i)* scientific understanding, particularly advances in understanding and modelling coupled processes; *ii)* advances in computer and hence modelling capability; *iii)* experience in writing competent cases for the safety of specific proposed repositories. The role of modelling in support of the safety assessment has generally become more balanced with other lines of evidence. There has been some evolution concerning the definition of safety functions and the means for using them to more transparently describe system evolution over time. Uncertainties are being addressed more effectively. And there have also been some developments concerning the use of alternative safety indicators. This is not a tutorial on any of these points, they are simply the motivation for rewriting and modifying the description of the safety case published in 2004 (NEA, 2004a).

This update of the 2004 brochure is based on experience gained since then by national organisations and in international projects, and aims to make this experience available to a wider audience. It draws on the experience of experts in radioactive waste management and geological disposal safety studies as assembled by the OECD/NEA Radioactive Waste Management Committee and its Integration Group for the Safety Case. The update is particularly informed by:

- work done to define and expand the state of the art in performance assessment by the NEA's 2007 symposium on the status of safety case preparation among its member countries (NEA, 2008b);
- the NEA's initiative on *International Experiences in Safety Cases for Geological Repositories (INTESC)*, which gathered recent safety case development experience within the IGSC (NEA, 2009);
- the results from European Commission (EC) work reflected in the report PAMINA: Performance Assessment Methodologies in Application to Guide the Development of the Safety Case) (EC, 2011);

- the results of the NEA MeSA initiative Methods for Safety Assessment of Geological Disposal Facilities for Radioactive Waste (NEA, 2012);
- a number of safety reports recently submitted by national waste management organisations and by their national or international peer reviews.

In addition, a new international standard for geological repositories was published by the International Atomic Energy Agency (IAEA) in 2011.

Acknowledgements

The NEA wishes to express its sincere thanks to the Safety Case Task Group for revising the brochure. Members include Professor Klaus Röhlig (Clausthal University of Technology, Germany), Mr. Allan Hedin (SKB, Sweden), Mr. Abraham Van Luik (US DOE, USA) and Mr. Arjen Poley (NRG, The Netherlands). Gloria Kwong and Claudio Pescatore of the NEA Secretariat also participated in the drafting group. The NEA further wishes to express its gratitude to both the core group and members of the Integration Group for the Safety Case (IGSC) for their valuable comments. Finally, the NEA would like to acknowledge Mr. Felix Altorfer (ENSI, Switzerland) for his expertise in completing this update.

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Executive Summary

A safety case is a formal compilation of evidence, analyses and arguments that quantify and substantiate a claim that the repository will be safe. An initial safety case can be established early in the course of a repository project. Such a preliminary safety case then evolves into a more comprehensive safety case as a result of work carried out, incorporating experience gained and information obtained throughout the stepwise evolution of the project.

For example, early safety cases (e.g. safety cases used to assist early site characterisation efforts) might rely on rather generic assumptions about the properties of a host rock and the layout of a repository, whereas the safety case for authorisation of repository construction would require sufficient factual basis and detail to provide the necessary confidence for the regulator to determine that the repository would be safe.

Generally, safety case updates after construction is authorised would incorporate information learned during construction and other confirmatory tests performed to ensure the continued understanding of and confidence in the safety basis. Typically, a safety case is compiled and presented at certain stages of a stepwise repository development programme with an aim to inform decision makers whether adequate information is available so that decisions to proceed to the next step can be made. Such decisions, depending on the developmental stage and specificity of the programme, may concern areas such as policy, legislation, licensing or other internal programme details of a waste management organisation.

As a repository development programme continues to advance, the safety case provides an important basis for repository development activities including research and development (R&D).

The primary aim of this document is to define the purpose, scope and content of safety cases for geological repositories for long-lived radioactive waste. It is intended to provide both a point of reference for those involved in the development of safety cases, and for those with responsibility for, or interest in, decision making in radioactive waste management. This document focuses on addressing the long-term safety, i.e. the facility's safety during the post-closure phase. It is the primary purpose of a repository to provide such long-term safety. Addressing the post-closure phase is a particular challenge due to its long timescale (i.e. of the order of hundreds of thousands of years), which raises subsequent issues of how to demonstrate safe performance of the repository with adequate confidence based on present analyses and data. The safety case has to show that the possible evolutions and performance of a well-chosen geological site and host rock and a well-designed engineered system can be bounded with reasonable confidence into the future.

Preparing a safety case is a multi-faceted activity. The following summarise the components of this activity that are described in greater detail later in this document.

The safety case context

A clear statement of purpose is required to set the safety case in its decision context. This requires describing the decision being supported. In addition, it requires recognising that format and content should be adapted to the decision context of each safety case.

The safety strategy

The safety strategy is the high-level approach adopted for achieving safe disposal, and includes an overall management strategy, a siting and design strategy and an assessment strategy. This includes maintaining sufficient flexibility within a stepwise planning and implementation process to cope with unexpected site features or technical difficulties and uncertainties that may be encountered, as well as to take advantage of advances in scientific understanding and engineering techniques. The siting and design strategy is generally based on principles that favour robustness and minimise uncertainty, including the use of the multi-barrier concept. The assessment strategy must ensure that safety assessments capture, describe and analyse uncertainties that are relevant to safety, and investigate their effects.

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 system safety, and the assessment methods, models, computer codes and databases for analysing system performance. The quality and reliability of a safety assessment depend on the quality and reliability of the assessment basis. A discussion of the assessment basis in any detailed presentation of the safety case should include evidence and arguments to support the quality and reliability of its components.

The safety assessment

The evaluation of system safety requires a methodological approach to the numerous processes, features and other technical issues that need to be systematically evaluated. Planning needs to consider the complexity of necessary analyses, the time and resources needed to prepare the tools to perform these analyses, as well as the sequencing and integration of the analyses. Advance planning is also needed to make sure the resources are available to support the required analyses. Resources include having the correct skill mixes in the investigative, design and analytical organisations to make the overall effort scientifically and technically credible. Decisions need to be made, and documented, regarding how importance analyses and uncertainty analyses are to be performed, and for what aspects deterministic sets of analyses, or probabilistic analyses, or both, are to be used.

Most national regulations give safety criteria in terms of dose and/or risk and require an evaluation of these indicators, using either mathematical analyses or more qualitative arguments, under a range of evolution scenarios for the disposal system. Robustness of the safety case is strengthened by the use of multiple lines of evidence leading to complementary safety arguments that can compensate for shortcomings in any single argument. One approach to creating a basis for a conceptual understanding of a geological system and its important operative processes is to collect data into a "geosynthesis" – a data model that illustrates data as distributed over the entire geological

system in three dimensions and which is used to populate the data used in process models. More generally, the conceptual understanding of a repository system may also be established through a series of process reports which present the thermal, hydraulic, mechanical and chemical process information of the engineered and geological components of the repository system over the time frame of concern. This gives both an indication of how well the system has been characterised, and illustrates the integration of the science, the design and the modelling that simulates system evolution with time.

Statement of confidence

To justify a positive decision to proceed to the next stage of planning or implementation, there needs to be confidence in the possibility of achieving a safe repository. This requires a *statement of confidence* on the part of the authors of the safety case, and it is based on the analyses and arguments developed and the supporting evidence gathered. The statement of confidence recognises the existence of open issues and uncertainties, and perspectives about how they can be addressed in the next step(s). The audience of the safety case must decide whether it believes the reasoning that is presented is adequate, and on that basis whether, or to which extent, it shares the confidence of the safety case author.

General considerations to establish credibility

In order to be credible, the safety case documentation must be broadly auditable from a number of audiences including, but also beyond, the technical regulator. A number of additional considerations must be taken into account when preparing the safety case. These include:

- *Transparency*. A safety case should be both clear and understandable to the intended audience(s); the objective is to inform the audience's decisions regarding safety.
- *Traceability*. For more technical audiences, it must be possible to trace all key assumptions, data and their bases, either in the main safety case documents or in readily available supporting records.
- *Openness*. Remaining uncertainties and open technical questions that may affect safety or confidence in safety should be discussed in documentation.
- *Peer review*. Both internal and external peer review is a valuable tool for enhancing confidence in a safety case on the part of its author, and also the wider scientific and technical community

1. Introduction

Radioactive waste is generated in all phases of the nuclear fuel cycle and as a consequence of the use of radioactive materials in industrial, medical, military and research applications. All such waste must be managed safely. The most hazardous and long-lived waste, such as spent nuclear fuel and high-level waste from fuel reprocessing, must be contained and isolated from humans and the environment for hundreds of thousands of years. Geological disposal is the currently favoured radioactive waste management end-point, providing security and safety in a manner that does not require active monitoring, maintenance and institutional controls (NEA, 1999b, 2008a). Engineered geological disposal has been judged to be technically feasible in principle (NEA, 1999b); it has also been judged to be acceptable from an ethical and environmental viewpoint (NEA, 1995, 2008a); and it is also accepted from an international legal perspective in Europe (EU, 2011; EC, forthcoming). Disposal of long-lived radioactive waste in engineered facilities, or repositories, located deep underground in suitable geological formations, which are closed and sealed following waste emplacement, is thus being investigated and developed world wide in order to protect humans and the environment both now and in the future. In some countries very deep borehole disposal is currently being considered at a conceptual level, which would require appropriate security controls and passive safety measures to be applied.

A repository will be a licensed nuclear facility the safety of which has to be demonstrated for an unprecedented long life cycle. The process for licensing a repository for construction, operation and closure is facilitated if regulators and stakeholders have a common understanding of the safety bases for the repository over its intended lifetime. Different challenges will arise when considering various stages of the repository life span as the repository system components (e.g. waste packages, engineered and natural barriers) evolve.

The present document is concerned with safety in the post-closure period. Licensing will, however, also require due consideration of potential impacts and risks during the operation of the repository and prior to its closure. These include:

- security of the waste against unauthorised interference or recovery;
- the radiological and occupational safety of workers both during normal operations and in the event of accidents;
- the protection of the public from potential radiological exposures, e.g. due to accidents during transport and at the facility;
- the radiological protection of the wider environment in which the repository is located.

In addition, the conventional (non-radiological) environmental, social and economic impacts of the development, operation and closure of the facility will have been assessed and, in most countries, presented in an environmental impact assessment (EIA) as a necessary step to gaining approval for geological repository development.

The process of analysing the long-term performance of a repository and showing, with an appropriate degree of confidence, that it will remain safe over a prolonged period, beyond the time when active control of the facility can be relied on, is termed "post-closure safety assessment". The task involves developing an understanding of how the disposal system will perform its functions including long-term confinement of the hazardous substances contained in the waste, and under what circumstances radionuclides or other hazardous substances might be released from the repository, how likely such releases are, how they are prevented, limited or mitigated, and what the radiological or other consequences of such releases could be to humans and the environment.

Importantly, it is necessary to understand how the geological characteristics of the site and the components of the design function to prevent, lower the likelihood of, or attenuate such releases. This in turn involves collating data, developing models and performing analyses related to evaluating safety. In addition to such analyses, the scope of the safety assessments has broadened to include the collation of a broad range of evidence and arguments that complement and support the reliability of the results of the assessment's quantitative analyses (NEA, 2012). This larger scope is referred to as the "safety case".

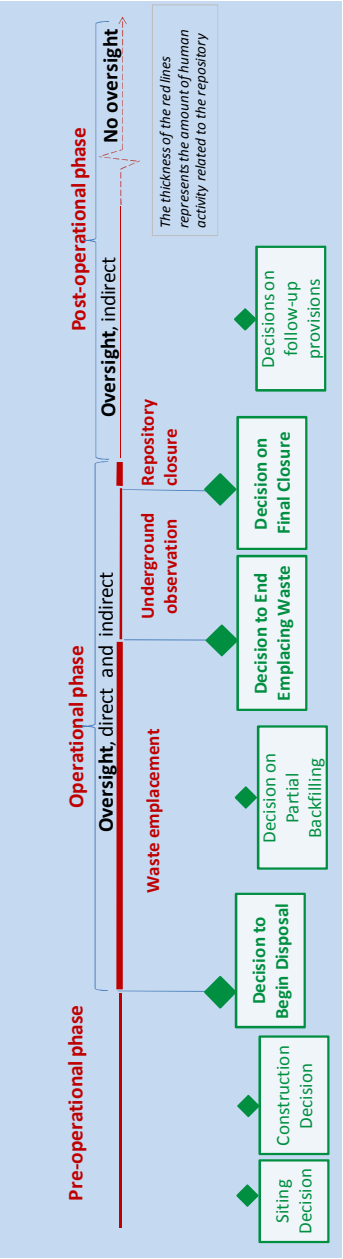
A safety case is a formal compilation of evidence, analyses and arguments that quantify and substantiate a claim that the repository will be safe. An initial safety case can be established early in the course of a repository project. Such a preliminary safety case then evolves into a more comprehensive safety case as a result of work carried out, incorporating experience gained and information obtained throughout the stepwise evolution of the project (Figure 1.1). For example, early safety cases (e.g. safety cases used to assist early site characterisation efforts) might rely on rather generic assumptions about the properties of a host rock and the layout of a repository, whereas the safety case for authorisation of construction of the repository would need sufficient factual basis and detail to provide the necessary confidence for the regulator to determine that the repository would be safe.

Generally, safety case updates after construction is authorised would incorporate information learned during construction and other confirmatory tests performed to ensure the continued understanding of and confidence in the safety basis. Typically, a safety case is compiled and presented at certain stages of a stepwise repository development programme with an aim to inform decision makers whether adequate information is available so that decisions to proceed to the next step can be made. Such decisions, depending on the developmental stage and specificity of the programme, may concern areas such as policy, legislation, licensing or other internal programme details of a waste management organisation. As a repository development programme continues to advance, the safety case provides an important basis for repository development activities including research and development (R&D). The development of a safety case is recognised as a good practice as described in the recent IAEA safety standard SSR-5 (Box 1.1) (IAEA, 2011).

The primary aim of the present document[1] is to define and to discuss the purpose, scope and content of safety cases for geological repositories for long-lived radioactive waste. It is intended to provide both a point of reference for those involved in the development of safety cases, and for those with responsibility for, or interest in, decision making in radioactive waste management.

1. The present document is intended to replace its predecessor, *Post-closure Safety Case for Geological Repositories, Nature and Purpose* (NEA, 2004a).

Figure 1.1: Different phases of a geological disposal system (Weiss, 2012)



The document presents some general considerations and some specific illustrative examples, but is not intended to be prescriptive. This is because, although the presentation of a safety case is a legal requirement for certain decisions in most countries, the form of this legal requirement can vary considerably and the form of the safety case and its presentation must be adjusted accordingly. The chapters in this document present the following:

- Chapter 2 describes the role and elements of a safety case and considerations for its presentation.
- Chapter 3 describes the safety strategy; i.e. the high-level integrated approach to achieving safe disposal.
- Chapter 4 describes the assessment basis, i.e. the scientific and technical information on which the safety case is built as well as the analysis methods and tools used in the assessment.
- Chapter 5 describes the process of compiling the safety case.
- Chapter 6 describes how evidence, analyses and arguments are synthesised.
- Chapter 7 provides summarising conclusions.

Box 1.1: Descriptions of safety assessment and safety case

4.6. The development of a safety case and supporting safety assessment for review by the regulatory body and interested parties is central to the development, operation and closure of a disposal facility for radioactive waste. The safety case substantiates the safety of the disposal facility and contributes to confidence in its safety. The safety case is an essential input to all important decisions concerning the disposal facility. It has to provide the basis for understanding the disposal system and how it will behave over time. It has to address site aspects and engineering aspects, providing the logic and rationale for the design, and has to be supported by safety assessment. It also has to address the management system put in place to ensure quality for all aspects important to safety.

4.7. At any step in the development of a disposal facility, the safety case also has to identify and acknowledge the unresolved uncertainties that exist at that stage and their safety significance, and approaches for their management.

4.8. The safety case has to include the output of the safety assessment (see paragraphs 4.9-4.11), together with additional information, including supporting evidence and reasoning on the robustness and reliability of the facility, its design, the logic of the design, and the quality of safety assessment and underlying assumptions.

4.9. The safety case may also include more general arguments relating to the disposal of radioactive waste and information to put the results of safety assessment into perspective. Any unresolved issues at any step in the development or in the operation or closure of the facility have to be acknowledged in the safety case and guidance has to be provided for work to resolve these issues.

4.10. Safety assessment is the process of systematically analysing the hazards associated with a disposal facility and assessing the ability of the site and the design of the facility to provide for the fulfilment of safety functions and to meet technical requirements. Safety assessment has to include quantification of the overall level of performance, analysis of the associated uncertainties and comparison with the relevant design requirements and safety standards. The assessments have to be site specific since the host environment of a disposal system, in contrast to engineered systems, cannot be standardised.

4.11. As site investigations and design studies progress, safety assessment will become increasingly refined and specific to the site. At the end of a site investigation, sufficient data have to be available for a complete assessment. Any significant deficiencies in scientific understanding, data or analysis that might affect the results presented also have to be identified in the safety assessment. Depending on the stage of development of the facility, safety assessment may be used in focusing research, and its results may be used to assess compliance with the safety objective and safety criteria.

Source: (IAEA, 2011), pp. 30-31.

2. The Safety Case and Its Presentation

The role of the post-closure safety case in repository planning and implementation

The development of a repository is a significant national effort requiring several decades to complete. Planning and implementation typically proceed in a stepwise manner, punctuated by decision points. Significant decision points early in a disposal programme may include the definition of the types and amount of waste to be disposed of, the choice of host rock and associated engineering concept, general R&D requirements, and the choice of sites for investigation.

Once a site is identified and an initial engineering concept defined, the decisions may involve more detailed planning of the scope of above- and below-ground investigations, including demonstrations of the engineering feasibility of key elements, choices between design variants and the optimisation of the underground layout. A more mature programme will also be focused on obtaining any necessary legal or regulatory approvals for construction, operation and eventually closure. A safety case and ensuing license for operation (i.e. waste emplacement) plays a particular role since the facility will enter a nuclear regime when the first package or container is being emplaced.

The presentation of a safety case in the form of a structured set of documents is typically required at major decision points in repository planning, implementation and operation, including decisions that require the granting of licenses or permits. A license or permit to operate, close and, in most cases, even to begin construction of a facility will be granted only on the condition that the developer has produced a safety case that is accepted by the regulator as demonstrating compliance with applicable standards and requirements.

Technical dialogue between the implementer and the regulator early in the process in an open and transparent manner might help to assure: *i)* that the regulator fully understands the technical content of the license application when it is delivered for formal review and has the requisite expertise at hand; *ii)* that the implementer has correctly interpreted applicable regulations and is given the opportunity to request clarifications if required. It is however crucial not to compromise the independence of either party in such a dialogue. There may also be other stakeholders[2] who need to approve of the safety case before formal regulatory review in some situations. Examples of such other stakeholders might be an independent technical oversight organisation or an independent peer review group.

Building a safety case that is adequate for repository licensing is a complex task that requires focus, resources and long-term commitment by several categories of stakeholders. Crucially, the discipline of preparing a safety case, and presenting the case for scientific and technical review, regulatory review or wider non-technical reviews, ensures that post-closure safety is explicitly considered at each project stage.

2. The word "stakeholder" is used here to mean any actor, institution, group or individual involved in the repository decision-making process.

If, at a given stage, the decision makers concur with the findings of the safety case – i.e. they agree that a sufficient level of confidence in safety has been reached to justify a positive decision to proceed from one planning and development stage to the next – then permission may be given to proceed. Otherwise, a review may be needed to establish what modifications are required or where improvement in confidence can be found. Options include postponing a decision pending further studies to address uncertainties; taking additional actions to gain social, legal or political approval; or, if necessary, stepping back, e.g. looking again at alternatives, such as new design concepts, alternative sites or even retrieving emplaced waste in cases where developments after emplacement and before final closure show the safety case to have not taken important safety-relevant conditions properly into account.

The background to major decisions generally needs to be explained to, and discussed with, diverse audiences, such as the national regulator, political and legal decision makers, or other stakeholders. A key function of the safety case is to provide a platform for informed discussion whereby interested parties can assess their own levels of confidence in a project, and identify the issues that may be a cause for concern or on which further work may be performed with a likelihood of providing meaningful information.

The scope, level of detail and style of presentation of a safety case will vary depending on the intended audience, the decision under consideration, and any national legal and regulatory requirements relating to that decision. Often, producing documentation that is structured hierarchically (from general summaries to detailed technical reports) will help to inform different audiences. A comprehensively documented safety case can be viewed as a starting point for dedicated presentations, brochures, etc., tailored to the needs, technical expertise and expectations of different stakeholders. It has to be ensured that the messages conveyed in these documents are consistent, i.e. there is only one factual basis of the safety case even if it is presented in different ways. Its foundation should always be consistently based on sound scientific evidence and arguments.

The factual basis, scope, content and level of detail of a safety case will evolve over time together with the stepwise development of a repository programme (Figure 1.1) (Weiss, 2012). For example, early safety cases (e.g. safety cases used to assist early site characterisation efforts) might rely on rather generic assumptions about the properties of a host rock, its geological environment, and the layout of a repository, whereas the safety case for authorisation of construction of the repository would need sufficient factual basis and detail to provide the necessary confidence for the regulator to determine that the repository would be safe. Generally, safety case updates after construction is authorised would incorporate information learned during construction and other confirmatory tests performed to ensure the continued understanding of and confidence in the safety basis.

As a repository operates, a "nuclear safety culture" will be part of the operating philosophy, which means having workers exercise an open and questioning attitude in performing their work. This will likely mean the suggestion of changes in operations or even in design. Such changes need to be evaluated in terms of potential impacts on the safety bases.

Optimisation of protection, as defined by the ICRP, is regarded as a process to keep the magnitude of individual doses, the number of people exposed and the likelihood of potential exposure as low as reasonably achievable with economic and social factors being taken into account. By comparison, system design and operational optimisation can be seen as a way of increasing the technical quality and robustness of the whole waste management process and system. An optimal solution means balancing the political and acceptance issues and any other boundary conditions imposed by society, with the need to use resources efficiently. It is therefore a learning process, and as such can contribute to building confidence in the safety case by the demonstration of ongoing learning across the organisation. Optimisation occurs at each stage of the disposal facility development programme, and is therefore forward looking rather than focused on re-examining past decisions. It

should be about the right way forward at each stage, making the best decisions to move forward from the present situation based on current knowledge and understanding.

Safety objectives of a repository

Repositories are designed with the primary aim of containing and isolating the waste. Containment means to confine the radionuclides within the waste matrix, the packaging and the disposal facility. Isolation means keeping the waste and its associated hazard away from the biosphere,[3] with no intent for retrieval, making deliberate human intrusion to the waste difficult without special technical capabilities if practicable. Since complete containment cannot be guaranteed for the whole period that the waste presents a potential hazard, a further aim of a repository is to ensure that potential releases do not present an unacceptable risk. Safety after closure of the repository is provided by the passive safety functions of the geological environment and the engineered barriers placed around the waste, as well as the stability of the waste form itself. Over an appropriately long time scale to assure system safety, the possible evolution and performance of a well-chosen geological site and host rock and a well-designed engineered system can be bounded with reasonable confidence.

Box 2.1 presents standards that have been internationally suggested for geological disposal systems. National regulators may use these international recommendations in writing their regulations for radioactive waste disposal systems.

Although some post-closure monitoring and controls may be implemented to assure societal acceptance, such actions should not be relied upon in making the case for system safety since future societies may have no interest in maintaining them, or may lack the capability to do so. Indeed, the closure of a repository may be defined as the administrative and technical actions whose purpose is to negate the need for continued active control, so minimising the burden of care on future generations. This is not to say that such future societal activities should be discouraged, it is only to say that the safety case should not need to rely on such future actions to assure safety.

Similarly, multiple approaches to preserve records, knowledge and memory are being considered in most nations. They may consist of national archives, land registry restrictions, monuments, markers with different levels of messages and including symbols, e.g. warning future generations not to drill in the repository domain or close to it. The basic philosophy is to maximise the sources of information, the durability of the information and its ability to be understood. International efforts are now (autumn 2012) under way in this area. From a safety case point of view, long-term performance must not assume their existence or their effectiveness in preventing intrusions for more than a few centuries.

Thus, post-closure safety and security must rest on the main protective functions of waste isolation, and of confinement, limitation and retardation of radionuclide releases. These functions are to be passively assured by the waste form itself, the engineered barriers placed around the waste and the geological environment. Safety functions are discussed in more detail in Chapter 4.

Elements in a safety case documentation

A number of elements contribute to the safety case, and must be described in any detailed documentation of the safety case. The relationships between these elements are illustrated in Figure 2.1. While all elements are expected to be presented in a mature safety case, the way they are

3. In this document, "biosphere" refers to that part of the environment normally inhabited by or accessible to humans, or used by humans, including groundwater, surface water, the atmosphere and marine resources.

structured may vary considerably between cases. This is largely due to the fact that accounts of safety given in national programmes are structured so as to comply primarily with the requirements laid out in national regulations. However, as explained above, it is good practice to establish a hierarchical reporting structure.

The context and purpose of the safety case should be made clear. This includes the role to be played by the repository in the overall waste management strategy and an outline of the programme and the current step or decision point within the programme against which the safety case is presented. This will set the context in which the current strength of the safety case and the importance of remaining uncertainties can be judged.

Box 2.1: Radiation protection in the post-closure period

Geological disposal of long-lived solid radioactive waste poses a number of challenges related to radiological protection over extended periods of time, e.g. the nature and role of optimisation of protection during the various phases of the development and implementation of the disposal facility and the applicability of dose and risk in the far future for decision aiding.

In application of the radiological protection optimisation principle, the recommended ICRP reference radiological impact criterion for the design of a waste disposal facility is an annual dose constraint for the population of 0.3 mSv in a year (ICRP 103) (2007), without any weighting of doses in the far future, for design basis evolution scenarios. For less likely events within the design basis resulting in exposures and for doses in the future – both categorised as potential exposures by the ICRP – the Commission recommends a radiological risk constraint for the population of 1×10^{-5} per year.

Significant exposure to people and the environment may ensue from non-design basis evolutions that include very unlikely or extreme events. In these cases, the potential radiological impact is typically evaluated at the planning stage using stylised or simplified scenarios. The results of those analyses can be used as indicators of system robustness by comparing them with numerical values. If this approach is taken, the ICRP recommends the application of the reference levels defined for emergency and/or existing exposure situations. It should be accepted that a fully optimised system may result in a distribution of doses where some are above the reference level (ICRP 109, p. 37) (2009). For the specific case of inadvertent human intrusion in geological disposal the ICRP recommends the same radiological treatment as for non-design basis events, although protection from exposures associated with human intrusion is best accomplished by efforts to reduce the possibility of such events.

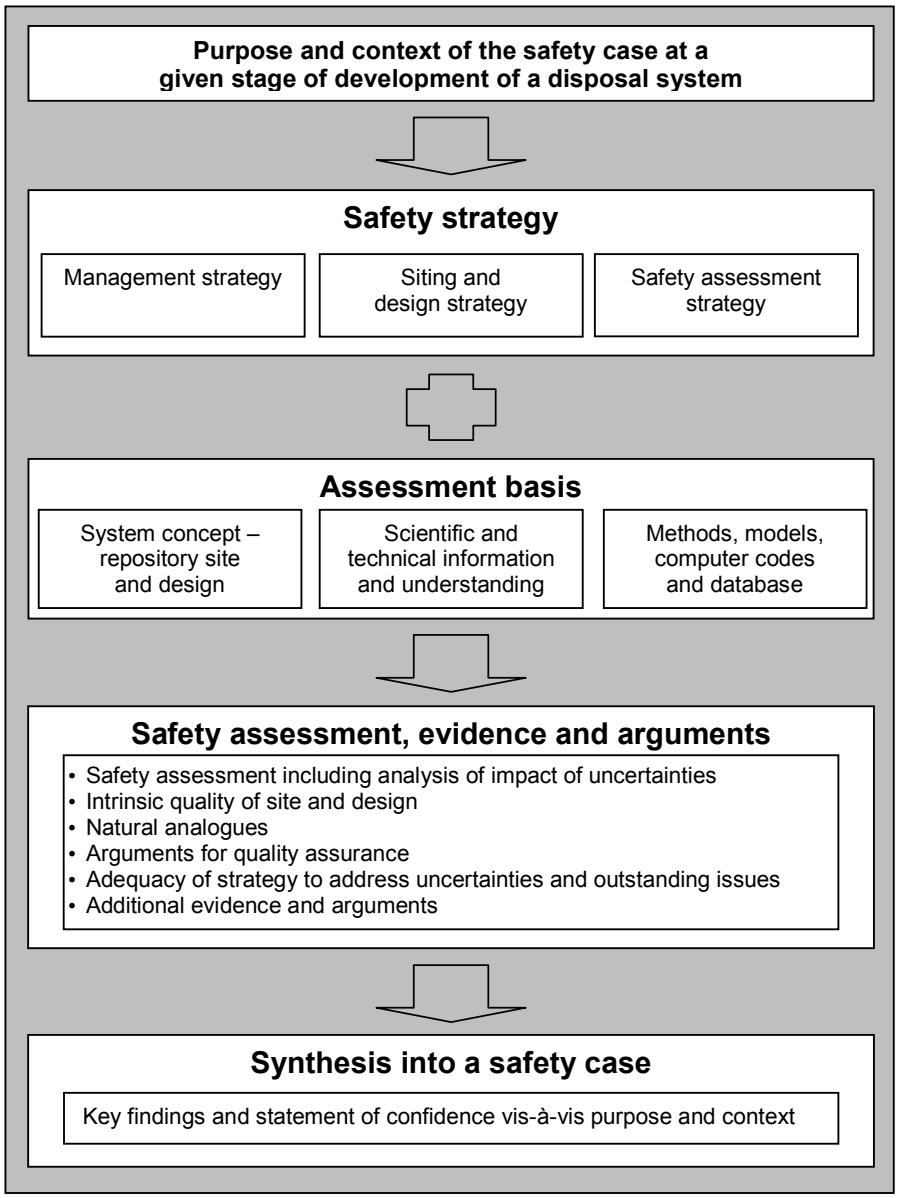
It is to be noted as well that, according to ICRP Publication 103 (2007), effective dose loses its direct connection to health detriment after the time span of a few generations, given the evolution of society, human habits and characteristics. Furthermore, in the distant future, the geosphere and the engineered system and, even more, the biosphere will evolve in a less predictable way. The scientific basis for assessments of detriment to health at very long times into the future then becomes questionable and the strict application of numerical criteria may be inappropriate. Hence, the dose and risk criteria are to be used for the sake of comparison of options rather than as means of assessing health detriment.

The IAEA requirements of SSR-5 (2011) that apply to all types of disposal facilities are broadly compatible with the above ICRP recommendations for geological repositories. In particular they specify values for dose reference levels for inadvertent human intrusion scenarios.

Source: Summary of radiological protection considerations from draft ICRP recommendations specific to geological disposal [update of ICRP 81, see (ICRP, 1998) and (Weiss, 2012)].

Figure 2.1: An overview of the relationship between the different elements of a safety case

Modified from Figure 1 of (NEA, 2004a)



The safety strategy, which is the high-level approach adopted for achieving safe disposal, should also be described. This includes the strategies: *i)* for the overall management of the various activities required for repository planning and implementation including QA procedures: *ii)* for siting and design; *iii)* for performing safety assessments (see Chapter 3, *Definition and Components*). The safety strategy should be shown to be well suited to the requirements of the project and capable of achieving project goals and tackling future decisions.

The information and analysis tools for safety assessment must be described. These are collectively termed "the assessment basis", and include:

- the system concept, which is a description of the repository site and design including the engineered barriers,[4] and of how both engineered and natural barriers are expected to provide safety;
- the scientific and technical information and understanding, including assessments of the uncertainties in scientific understanding;
- the methods of analysis, computer codes and models, and databases that are currently available to support the numerical modelling of the disposal system, its evolution and the quantification of its performance.

The adequacy and reliability of the assessment basis for carrying out safety assessments must be addressed as part of the safety case. This information is important to allowing a reader/reviewer to determine his/her level of confidence in what is being presented. At the technical level, this implies that traceability of data and information used in assessments or to support other lines of evidence of key assumptions and their bases is indispensable.

The safety assessment analyses repository performance and provides a quantitative estimate of potential radiological consequences associated with a range of possible analysed evolutions of the system over time, i.e. for a range of scenarios. It also serves to identify uncertainties that affect the assessed level of safety. Other evidence and arguments (in some programmes described as being a qualitative part of the safety assessment) include the intrinsic quality of the site and the design, the use of natural analogues, an account of measures taken to assure the quality of the safety assessment, and a strategy to address residual uncertainties and outstanding issues.

Finally, a synthesis must be made that draws together key findings that quantify and substantiate a claim that the repository is safe, including an evaluation of uncertainty and of perspectives of addressing them. This judgement should be accompanied by a statement of confidence in the potential safety of the disposal system in the context of the assessment basis available at the current stage of the repository programme as a basis for a decision to move to the next stage.

The safety strategy, the safety assessment and its basis, the types of evidence, the analyses and arguments that are available and their synthesis within a safety case are described in subsequent chapters.

4. The engineered barrier systems (EBS) consist of the materials placed within a repository, including the waste form itself, waste canisters, buffer materials, backfill, seals and plugs (EC/NEA, 2010).

3. The Safety Strategy

Definition and components

Every organisation with responsibility for permanently disposing of radioactive waste requiring geological disposal has a safety strategy, whether it is published under such a title or not. The safety strategy starts by determining the waste types on hand or in production, and the required capacity and functions of a disposal system. The safety requirements imposed internally by the waste management organisation and externally by the regulator(s) come into play. Assuring that safety requirements will be met entails the organisation to select a site located in a region that is sufficiently stable, geologically, to allow a safe system to be built. The type of host rock selected is also important, since it determines, in large part, what engineered system is needed to assure long-term safety in this specific setting.

Typically, these types of background and preliminary decision-making considerations are made part of the safety case's introductory sections.

The safety strategy should include providing safety through use of an appropriate engineered system placed into a suitable site. Selection of an ideal or perfect site ought not to be a requirement as sites can appear to be perfect until a thorough site characterisation is completed, dispelling notions of perfection. Societal acceptance is likely to be an important criterion and thus a site with a volunteer host community is likely to be seen as an important advantage.

The safety strategy is the high-level integrated approach to achieving safe disposal. This includes several sub-strategies for:

- the management of the various technical and communication work activities;
- the repository siting and design decision-making process;
- the performance of safety assessments;
- the development of a safety case.

Making a case for the adequacy of the safety strategy for achieving project safety goals is a part of the safety case. Whether the safety strategy is published and updated separately or as part of each safety case is an option to be selected by implementing organisations. Typically, however, a safety strategy becomes the basis for communications with stakeholders. Feedback from stakeholders on issues needing to be addressed may help more fully form the safety strategy.

A safety strategy involves making siting and design/layout decisions, defining high-level safety functions and the ways that they will be achieved, setting up a management capable of guiding a complex programme of work to achieve a predefined endpoint over many years, and designing a required safety assessment.

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, development and operation, including decisions that require the granting of licences.

The following sections discuss aspects of repository performance that ought to be addressed as part of the overall safety strategy.

Informing principles

The protection and precautionary principles

The safety strategy should be specifically written to address the types and amounts of waste to be disposed, the potential host rocks and geological environments that are available, as well as various national preferences and societal choices. Any repository programme should, however, aim at strategies that accord with good management, siting, and engineering principles and practices, including the "protection principle" which implies:

- A siting and design strategy should be adopted that aims at developing a reliable and robust system. Robust systems are characterised by a lack of complex, poorly understood or difficult to characterise features and phenomena, demonstrated quality control, and an absence of, or relative insensitivity to, detrimental phenomena arising either internally within the repository and host rock, or externally in the form of geological and climatic phenomena that introduce processes with the potential to compromise safety.
- An assessment strategy should preferably be adopted that provides a range of arguments and analyses for the safety case that are well-founded, and supported, where possible, by multiple lines of evidence. There must be an adequate treatment of uncertainty – the safety case may, for example, take into account all processes that may affect system performance, but in documenting the safety case, emphasis may be placed on a limited number of processes or features relevant to the safety functions of the repository and its environment. Processes relevant to safety ought to be well-understood and reliably modelled, such as long-lived corrosion resistant canisters and stable properties of the host rock. On the other hand, potentially detrimental processes or features or events should be disclosed and directly taken into account in the safety assessment, if their probability warrants it.

A related principle is the "principle of precaution" which is understood to mean "erring on the side of conservatism in the face of uncertainty".

The need for flexibility

A degree of flexibility should be built into the planning and implementation of a repository. This is in order to cope with unexpected site features or technical difficulties and uncertainties that may be encountered, as well as to take advantage of advances in scientific understanding and engineering techniques. Experience gained in collaborative projects in national and international above- and below-ground test facilities is particularly valuable in this respect (IAEA, 2001).

Flexibility is particularly important given the long time scales over which repositories are planned and developed, and the scarcity of data, particularly on the geological environment, in the initial stages of a project. Some uncertainties may only be resolved by investigation methods applied during construction and even during operation of the repository. It may also be necessary to respond to possible changes in the social and political environment during the course of a project. Thus, site selection, the development of a suitable design for a selected site, site characterisation and other R&D activities are carried out concurrently in an iterative, stepwise manner, providing a framework for:

- comprehensive[5] scientific and technical investigations and analysis, including safety assessment and an evaluation of uncertainty, in the course of each stage by the developer;
- thorough scientific and technical review and development of guidance and requirements by the regulator;
- opportunities for political and social consultation and other societal involvement.

The need for flexibility in repository development has an impact on waste management steps prior to disposal, e.g. it might be necessary to balance the need for durable waste forms which allow safe storage on one hand and the need to retain flexibility in waste form so as to avoid prejudicing the choice of eventual disposal options on the other.

Flexibility may contribute to societal acceptance, since step-by-step implementation allows time during which confirmatory studies and outreach activities may be undertaken. When giving consideration to the merits of alternative options, a decision point should be defined as to whether to stay with the current option or to make changes. If the adoption of some new alternative is proposed, however, it is important to consider the resources that might be required to bring that alternative to a similar state of development as the main options in hand. That is, a well-developed option should not lightly be abandoned in favour of a less well-developed option that might have drawbacks that are, as yet, unrecognised. This does not reflect a lack of objectivity, but rather inserts realism into the decision process.

Robustness and the multi-barrier principle

Repositories are typically sited in stable geological environments that offer favourable conditions in which the waste and engineered barriers are protected, and this protection can be relied upon over a long time period. In practice, this means that key characteristics that provide safety, such as mechanical stability, low groundwater flux (or the absence of groundwater) and favourable geochemical conditions, should be unlikely to change significantly over relevant time scales. Environments are thus generally chosen that are:

- unlikely to be affected by major tectonic movements, volcanic events or other geological phenomena that could give rise to rapid or sudden changes in geological or geochemical conditions;
- largely decoupled from events and processes occurring near the surface, including the effects of climate change;
- lacking in scarce natural resources that may attract exploratory drilling,[6] thus minimising the possibility of inadvertent human intrusion in the future, when the location of the repository may no longer be known.

Repository designs are tailored to take advantage of the beneficial characteristics of the selected site and the nature of the waste forms and inventories to be disposed. To this end, repositories employ materials for their engineered barrier systems that are, in general, well understood, tested, well characterised, and resistant to physical and chemical degradation under the conditions that are expected in the geological environment for as long as necessary to assure long-term safety. There are

5. The word "comprehensive", when used in the context of describing the work required to create a safety case, is being used in the sense of being sufficiently inclusive to allow a credible case for safety to be made.
6. This principle ought not to be taken as an absolute requirement since the nature and value of future resources is not known, plus in some instances a resource may be sufficiently common that there is still a low likelihood that the relatively small footprint of a deep repository will be inadvertently intruded.

advantages in using engineered materials that have already been used in comparable applications, if such industrial analogues are available. Waste forms are subject to specifications that the producers of the waste have to meet in order for the waste to be accepted for disposal in a geological repository. More generally, there are quality assurance (QA) procedures that require standard tests to ensure that the engineered components of a disposal system meet design specifications. Any potential interactions of engineered components with each other or with the geological environment that could give rise to safety concerns are to be investigated and mitigated if necessary by modifying the design.

Engineered components can also be designed to minimise the consequences of uncertainties so that the required performance is demonstrable. For example, the performance of canisters durable for several hundred to some thousand years, which are envisaged for most high-level waste repositories, can mitigate the effects of uncertainties associated with the complex and coupled thermal, hydraulic, mechanical and chemical processes that could occur during an initial transient phase following repository closure. To evaluate whether or not the canisters remain intact through this initial phase, the impact of these processes on canister behaviour must be addressed to an appropriate extent. However, if the canisters remain intact throughout this initial phase, then, provided understanding of the process is adequate to allow estimation of the characteristics of the system at the end of this phase, the uncertainties associated with the coupled, transient processes are no longer relevant to safety.

Robustness is favoured by the multi-barrier concept, i.e. the concept of multiple components that operate in concert to isolate the waste, and prevent, delay and attenuate potential radionuclide release to the biosphere. The barriers should be complementary, with diverse physical and chemical components and processes contributing to safety,[7] so that uncertainties in the performance of one or more components or processes can be compensated for by the performance of others to a significant extent. A system based on the multi-barrier concept typically comprises the natural barrier provided by the repository host rock and its geological environment, and the engineered barrier system. At an early stage of repository development, some engineered components may, to some extent, be "over-designed" to avoid or mitigate the effects of early uncertainties.

As conditions in the repository and its environment evolve over the course of time, some barriers or components can become less effective or cease to perform certain functions and new functions come into operation that to some extent take their place. This means that many uncertainties in the evolution of the repository and its environment have only limited implications for the overall safety of the system. For example, canisters containing the waste may eventually be breached, following which the safety of the repository may depend on geochemical immobilisation and retardation processes and the slow rate of groundwater movement within and around the repository. Although not necessarily emphasised in a safety case, these latter processes also provide the basis for additional assurance of safety at times when the canisters are expected to be intact, i.e. even if the longevity of the containers or canisters is less than expected, other mechanisms exist that nevertheless ensure adequate levels of safety. Confinement in intact canisters, geochemical immobilisation and retardation, and the reduction of the rate of groundwater movement by a backfill are examples of complementary engineered system safety functions.

Characterising and addressing uncertainties

A key output from safety assessment and safety case compilation is the identification of uncertainties that have the potential to undermine the understanding of the degree of safety the system offers. Based on this information, a strategy for addressing uncertainties and open issues must be

7. So-called safety functions, see Chapter 4.

developed and a decision made about whether and how to move forward to the next step in a repository programme.

Some uncertainties can be reduced by methods including additional 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 increase confidence in system safety. For example, *in situ* experiments of radionuclide migration may improve confidence in the migration models or allow their improvement. In some cases, uncertainty can be managed by seeking multiple lines of evidence for particular assessment assumptions or parameters, including, for example, evidence from natural analogues to support the longevity of engineered materials.

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 (cf. the discussion of robustness in the previous chapter).

Ideally, more scientific (or engineering design) work will both narrow a range of uncertainty and give confidence that it is well understood. However, there will also be cases in which scientific work leads to the identification of uncertainties of which the developer previously was not aware. Uncertainty descriptions of an outcome of a model help a decision maker put the numerical result(s) into a risk context. No matter how much work is done, there will be uncertainty in long-term safety assessments. Uncertainties need to be identified and their relevance for safety needs to be assessed in the safety case. Often, this identification and assessment is the most important basis for defining priorities for further R&D work in the next stage of repository development.

Methods for handling uncertainty are developed, tested and applied in many industrial and other applications. The challenges for application to post-closure performance are different in that they must address potential futures that are simply not applicable to shorter-term industrial concerns. These uncertainties are addressed by defining and analysing the possible scenarios that describe the potential evolution of a geological disposal system.

The potential human-intrusion scenario

Ideally, potential future evolution scenarios can be quantitatively described given a scientific or technological basis for determining their likelihood over time. But there is one scenario for which this is usually not possible: future human action that leads to an inadvertent intrusion into the deep repository.

Although the emplacement of the waste in deep geological formations in itself can be seen as a powerful countermeasure against potential human intrusion, it is generally accepted that human actions have to be taken into account when assessing the safety of the disposal system. Attempts at predicting human intrusion activity over an extensive period will be speculative, though, owing to the inability to discern the likely evolution of current technology, society and future human behaviour in general. No amount of modelling or testing is going to provide such information. Therefore, regulatory guidance is necessary for dealing with this specific scenario. In most existing national regulations, stylisation of human intrusion scenarios is seen as the most appropriate way to address their potential consequences for the intruder and/or the public within the repository domain

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4. The Assessment Basis

Components of the assessment basis

The assessment basis is the essential content on which the safety assessment is based. It includes as key components (see Figure 2.1):

- *System concept – the repository site and design*. This typically includes the main geological, hydrogeological, geochemical, mechanical and other features of the repository site [often compiled in a so-called geosynthesis or site-descriptive model (NEA, 2010)], 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 for repository closure. The system concept should also describe how both engineered and natural barriers are expected to provide safety. Such a description is often based on the assignment of safety functions to the safety bearing components of the system. It may also include a description of possible deviations in the implementation of the system.
- *Scientific and technical information and understanding*. 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 multidisciplinary information collected by science and technology.
- *Methods of analysis, computer codes, models and databases*. These methods and tools are currently available to support the numerical modelling of the disposal system, its evolution and the quantification of its performance. Methods for building confidence in modelling and for determining and evaluating uncertainties should also be described.

The quality and reliability of a safety assessment is contingent on the quality and reliability of the assessment basis. A discussion of the assessment basis and the presentation of evidence and arguments to support the quality and reliability of its components is thus a key element of the safety case. At earlier stages of a repository programme the assessment basis, and probably even the assessment tools, will be different from those as a programme matures.

Presentation of the assessment basis and support for its quality and reliability

System component functions and the basis for evaluating performance

The system components that are described include the waste inventory, the engineered barriers and particular features of the repository layout or design with implications for post-closure safety, e.g. the arrangement of seals, the host rock and surrounding geological environment and the surface site. The description of each should include:

- its geometry and constituents and their physico-chemical characteristics;

- its safety functions, for example, to delay the arrival of the water and the start of degradation of the waste form or maintain favourable groundwater chemistry.

In some programmes, it also includes a general description of expected future evolution and performance, that is, for example, the period over which it is expected to fulfil its safety function. In other programmes an election is made to include such detailed description in the safety assessment itself.

Of these components of the system description, over the last few years there has been much activity addressing the uses that can and ought to be made of safety functions. Recent safety assessments have defined and addressed safety functions as a way to provide a more in-depth explanation of the functioning of the repository system and a means for linking safety assessment to repository design and engineering.

Scientific and technical information and understanding

The presentation of scientific data and understanding in a safety case should highlight evidence that the information base is consistent, well founded and adequate for the purposes of the current safety assessment. Adequacy would change with time and the importance of the pending decision for which system safety is being evaluated. Any relevant uncertainties should, where possible, be quantified or bounded, and in either approach evaluated. Expected features, events and processes (FEP) that are potentially important for the safety of a system, as well as those FEP that are unexpected but still plausible, should both be considered.

With respect to the quality and reliability of the scientific and technical understanding and data, the presentation should show, consistent with the degree of maturity of the repository programme, that:

- a sufficiently comprehensive research and site investigation programme has been implemented;
- diverse sources of information (and methods of acquisition) have been combined to form a consistent picture of the characteristics and history of a site, based on which a prognosis of future evolution can be made;
- engineered features have been evaluated in terms of ease of construction, and performance over requisite ranges of conditions representing time periods of interest.

Research results and other information must be described in traceable documentation that presents all data and provides clear records of their use as part of a formal quality assurance system to ensure the reliability of data and their application. Scientific information and knowledge are often compiled in extensive process reports which constitute a major portion of the safety case. Other means for compiling and documenting scientific evidence include the use of: *i)* "geosynthesis" and "site-descriptive models" as described in the NEA AMIGO Project Report (NEA, 2010); *ii)* tools used to describe the various thermal, hydraulic, mechanical and chemical phenomena of the repository taking into account discretisation of space and time (see Figure 5.1); *iii)* computer-based tools or methods to address the interactions of various phenomena and to identify uncertainties related to the safety of the repository system.

Assessment methods, models, computer codes and databases

The assessment methods (methods for deriving scenarios, defining conceptual models, for writing the computer codes that implement mathematical models, for assuring the usability of data from controlled databases, etc.) must be clearly and logically presented. Besides appropriate quality

assurance and quality management (cf. next paragraph), arguments for their reliability include being able to demonstrate that:

- Effective communication has taken place between those engaged in natural and engineered system research and safety assessors, to ensure that safety assessors are informed of all relevant information, and its limitations, as it is prepared for use in modelling.
- Sensitivity analyses have been carried out to ensure scenarios and their relevant calculations address key FEP that are affecting the performance of the disposal system.
- Suitable criteria were developed and properly applied for the exclusion or inclusion of features, events and processes from scenarios for evaluation.
- Evidence supporting the choice of scenarios, models and data comes from a wide range of sources, including field, laboratory and theoretical studies, and multiple lines of argument are, where possible, used to support the choice of particular scenarios, model assumptions and parameter values.
- Mathematical models are based on well-established physical and chemical principles, or on empirical relationships with an experimental basis that supports their applicability in conditions (e.g. scales of space and time) relevant to the assessment.
- A clear strategy and method exists for the evaluation and management of uncertainties.

Quality assurance and quality management

Current plans for and uses of quality assurance (QA) are to be addressed in the safety case, along with the principles of the organisation's quality management (QM) system. The QA plan should not only address basic data quality and their management, but also the manufacturing process of the engineered barriers and the excavation processes of the host rock and its stabilisation. Evidence has to be provided that the safety-relevant features of engineered components "as built" (e.g. the permeabilities of seals) will be consistent with what has been specified in the safety concept and described in the assessment basis. In the end there must be a sense of industrial feasibility. Although in the beginning of repository development QA/QM plans may be limited, it is accepted that they will be adapted as the repository project advances to more advanced stages.

Building a credible case for system safety requires that quality be managed and verified through a competent quality assurance programme. Quality management involves assuring that:

- The approach to demonstrating safety is logical, clear and systematic.
- The safety assessment is conducted within an auditable framework.
- The approach has been continually improved through an iterative process.
- The approach and its key components have been subjected to independent peer review.

Assuring that there is an auditable framework involves making sure that computer codes are developed in the framework of a QA procedure, and verified, for example by comparison with analytical solutions, laboratory tests or field tests or observations and alternative codes. Evaluations of adequacy may be helped through simulating experiments and processes observed in natural settings.

All of this information, and all of the analyses discussed, are used to compile a safety case, as discussed in the next chapter.

5. Safety Assessment and the Compilation of the Safety Case

Safety case development process

While the overview of the building blocks of the safety case are presented in Chapter 2 (in particular by Figure 2.1), the intent of the present chapter is to describe the process defined by the assessment strategy that leads to assembling a safety case. The assessment strategy involves the selection of codes and models and data, and the specification of the analyses that are to be performed in order to evaluate system performance and its uncertainties.

Many safety reports clarify the assessment strategy process by means of flowcharts. Based on a review of common elements and differences of assessment strategy flowcharts presented by a range of national and international organisations, as well as trends in such flowcharts that are apparent over time, in the NEA MeSA project (2012) a generic assessment strategy flowchart was developed. The MeSA flowchart was consulted for use in this document as Figure 5.1, but simplified for the purpose of illustrating the role of technical aspects of a repository programme, in concert with programme management, to lead to a decision supported by a safety case. Figure 5.1 also illustrates how a safety case evolves over time and which iterative mechanisms contribute to this evolution.

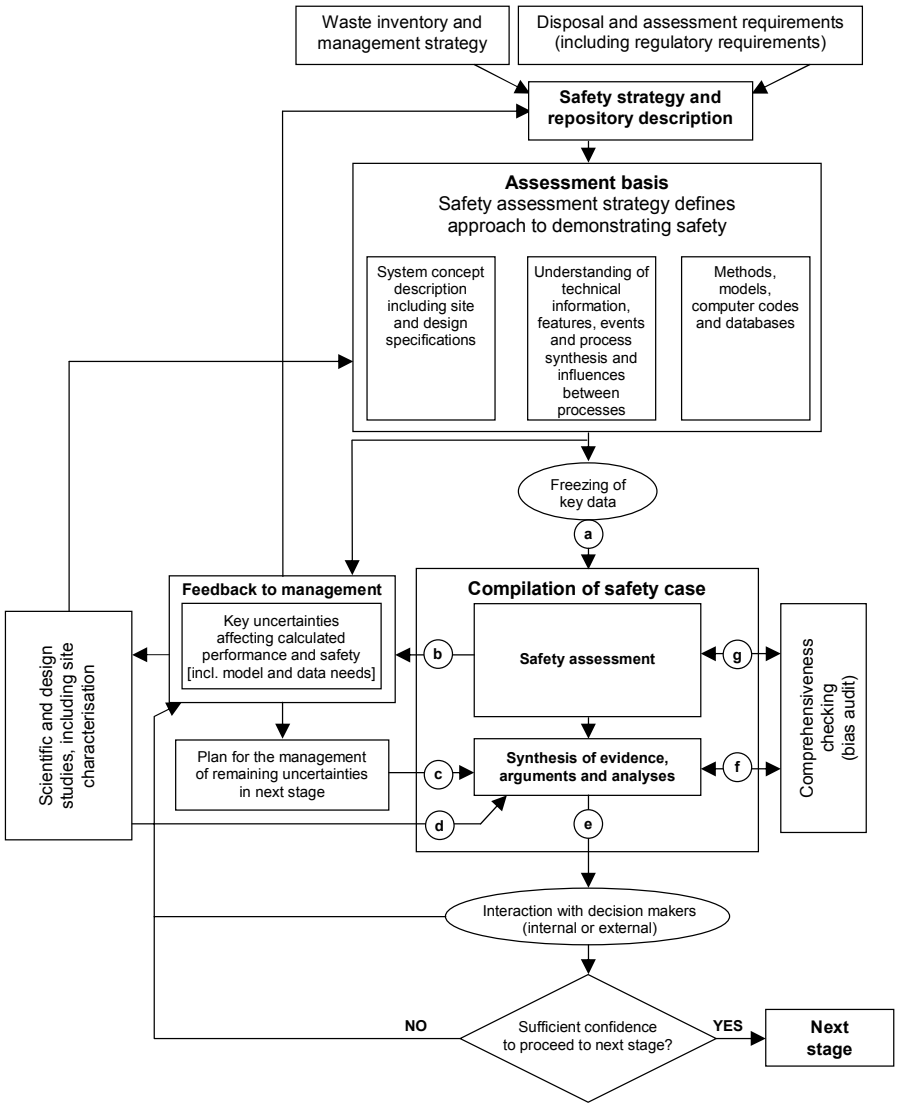
In Figure 5.1 the *assessment context*, the *safety strategy* and the *assessment basis* form the starting points of a given stage of the development of the safety case. These basic elements were discussed in the previous chapters. An important additional element in the development of the safety case explicitly indicated in the MeSA flowchart is the existence of an adequate programme of *scientific and design studies* (leftmost box in Figure 5.1) to provide preliminary data in earlier stages and to resolve remaining safety-relevant issues in later stages. These studies include site characterisation, modelling and laboratory studies of key processes, natural analogue studies, design studies and demonstration of technologies. The results of this work contribute to the physical and operational optimisation of the system and provide direct input to the assessment basis. They also provide supporting evidence for the compilation of the safety case that complements quantitative analyses of radiological consequences from the safety assessment.

As part of the safety concept developed as an outcome of the safety strategy, broad safety functions, i.e. isolation by the geological environment from the surface environment and confinement by engineered and/or geological components, will be defined and detailed aspects will be made part of the system description. However, 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 once such a buffer has been decided upon. At earlier times, however, only the functions required by a buffer may be specified, and qualitatively addressed. The point being that the details of the system description and the safety concept are developed to some extent iteratively and in parallel, and may change with time. As has been previously noted, flexibility is important in carrying out a waste management programme.

The remainder of this section will discuss: *i)* some of the core content of the safety assessment; *ii)* the nature of the safety assessment outcome; *iii)* the treatment of uncertainties.

Figure 5.1: A high-level generic flowchart, showing the common elements and linkages involved in producing a safety case

Modified from (NEA, 2011)



Building blocks of the safety assessment

Safety assessment, e.g. an iterative procedure for evaluating the performance of a repository system and its potential impact, aims to provide reasonable assurance that the repository system will achieve sufficient safety and meet the relevant requirements for the protection of humans and the environment over a prolonged period. While there is no standardised approach for structuring the assessment, a typical safety assessment consists of building blocks as described in the following sections.

The role of a safety assessment, in a safety case, is to quantify the repository system performance for all selected situations and to evaluate the level of confidence (taking into account of the identified uncertainties) in the estimated performance of the system. Due to uncertainties in predicting future events, reasonable assurance needs to be provided that the repository system will perform as it is designed and that compliance with safety criteria will be achieved. The results of the safety assessment provide the necessary technical input to support decision making and essentially, the supporting safety assessments form a central part of the safety case.

System concept description

The system concept description (see Figure 2.1) provides an important link between the assessment basis and the 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. It includes extensive lists and descriptions of data and phenomena concerning the characteristics of the repository constituent parts primarily reflecting:

- 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.

The radionuclide and chemotoxic component inventory, the physico-chemical characteristics of the waste, and its long-term behaviour under disposal conditions, are input for designing and dimensioning the disposal system. Main characteristics of the waste are typically compiled 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.

The characterisation of the host rock and its geological 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; *ii)* characterising its long-term behaviour under the effect of the disturbances caused by the repository itself and by natural and human-induced processes and events. Nowadays, most organisations compile and assess the geoscientific information into a site geosphere model in order to ensure interdisciplinary consistency as well as to focus this model-based geosynthesis on the needs of the safety assessment (NEA, 2010).

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 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 to be characterised and will behave under certain circumstances and on what the relevant FEP and uncertainties influencing the evolution of the disposal system and the safety functions are. It requires:

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

There are several methods to analyse and integrate data and illustrate process understanding. Many approaches consider the identification of FEP with their interactions, their analyses and their conceptualisation by fractioning 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 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 evolutions). Dedicated tools may also be used to structure the available scientific information in order to illustrate the system evolution over space and time. The two "story boards" shown in Figure 5.2 illustrate how the various processes may influence the repository system in different phases of repository development.

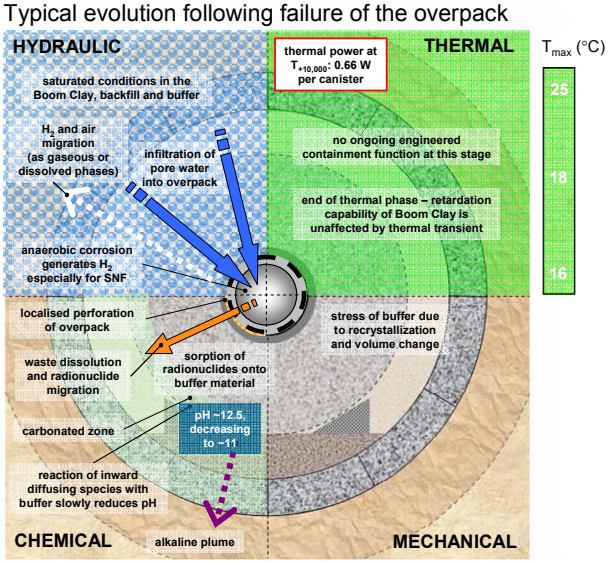
The overall time frame for analyses and integration may be defined/ recommended by regulation, notably to account for some specific FEP such as climatic and geological evolution. More specific time windows are then usually defined based upon the major thermal, hydraulic, mechanical and chemical processes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

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 FEP 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. The compilation of scientific information to support the safety assessment was discussed in Chapter 4.

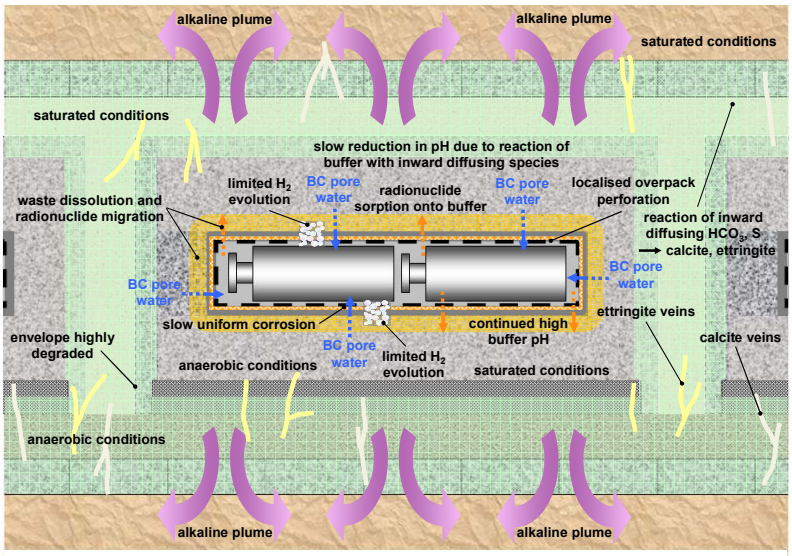
Figure 5.2: A storyboard example of the transverse (above) and longitudinal (below) cross-section of a cementitious-based disposal tunnel for VHLW in clay, showing key processes occurring in the post-closure phase

Reproduced with permission from ONDRAF/NIRAS (2008, 2009)

Typical evolution following failure of the overpack



Typical evolution following failure of the overpack



HLW Glass

Scenarios in safety assessment

A "scenario" is understood as a simplified description of a potential evolution of the repository system from a given initial state. Scenarios are a fundamental basis for the assessment of post closure safety which includes assessing the potential consequences on humans and the environment.

As a prerequisite for scientific modelling in the context of the safety assessment, it is necessary that FEP are developed and combined into logically consistent and, to the extent achievable, independent descriptions of potential system evolutions, i.e. *scenarios* or *scenario classes*. Scenarios, or related classes of scenarios, are then conceptually described, creating conceptual models. Conceptual models are then developed into mathematical models embodying the proper physics and chemistry to allow the modelling of the development of the repository system or component future states given these scenarios, always in the contexts of their supporting scientific bases.

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 complete characterisation for geological processes over large spatial scales and long times, and the limited possibility to forecast human habits, imply a broad range in the possible evolution of the system. However, the robustness of the safety concept allows limiting the modelling of the broad possible evolutions of the system to a handful of likely scenarios in the safety case (e.g. undisturbed performance, climate evolution impacts, human intrusion consequences, early canister failure). A way to reduce the number of possible scenarios to only those that are safety-relevant is to apply them to address component safety functions over the time scales that these functions are relied upon. For example, the French *Dossier 2005 Argile* (ANDRA, 2005) addresses the following scenarios in connection to the safety functions:

- If the system functions as expected and designed (reference scenario), safety is achieved by three general safety functions, namely limiting water circulation, limiting the release of radionuclides and immobilising them in the repository during the early phase after repository closure, and delaying and attenuating radionuclide migration. The system evolution is dominated by slow diffusive and chemically-retarded nuclide migration.
- By postulating a failure of the seals, a scenario is considered in which the water circulation is much less limited than expected.
- Postulating an early failure of the waste containers leads to a scenario in which limiting the release of radionuclides and immobilising them in the repository is no longer ensured.
- Postulating an intrusive borehole leads to considering a scenario in which radionuclide migration is much less delayed and attenuated than desired.
- Finally, a scenario is postulated in which all three safety functions are failing to some extent.

There are several methods to derive and develop scenarios. They comprise the compilation and arrangement of safety-relevant FEP as well as mapping them to the system safety concept and component safety functions, taking into account safety-relevant phenomena and uncertainties. All these methods have in common that they aim at logic, consistency, clarity, traceable documentation of decisions, comprehensiveness, flexibility within an iterative assessment, and involvement of multiple disciplines. It is necessary to perform a thorough examination of what scenarios could "endanger" safety functions over the time period on which they are required to be effective.

This topic is described in some detail on p. 35 and pp. 129-131 of the NEA MeSA report:

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 focusing 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. (NEA, 2012a)

Since one of the purposes of scenario development is to explore potential system evolution, it may be desirable to assign qualitative or quantitative statements about the probability or likelihood of occurrence of the identified scenarios. 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 "unlikely"). 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 communicating the considerations that have gone into crafting the safety assessment and 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 effective safety functions are (much) less likely.

Formal expert elicitation methods are sometimes used to give ranges of probabilities for unlikely scenarios, but more often bounding assumptions concerning scenario probabilities are made. As long as consequences are sufficiently low, numerical compliance with regulatory requirements can still be ensured without making the sizable investment involved in more formally weighing potentially high consequences against very low probabilities.

Safety assessment and modelling

The system description and the derived scenarios are used to describe the potential evolution of system components and of the system as a whole. This evolution is simulated by means of numerical models. The aim of modelling is twofold:

- Models help to better understand individual processes and their relevance for safety, as well as the interactions between these processes in the system, i.e. potential system evolution and safety performance. Thus, there is an iterative connection of modelling activities with system design and description, and with scenario development.
- Modelling is used for demonstrating compliance with regulatory or other requirements.

Modelling is typically done at several levels; *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* which form a central part of any safety assessment.

Process-level models are increasingly being applied to consider coupled THMC processes such as mechanical stresses coupled with hydraulic regimes or the impact of hydraulics and temperature on the chemical milieu, although typically models at this point in time do not consider all of these processes simultaneously The integrated or system-level model is used to better understand the interplay of the system components and the performance of the disposal system as a whole.

System-level modelling is also used to provide a quantitative estimate of potential impact on humans and the environment over the assessment time frame. Simplifications are unavoidable when reducing nature to mathematical expressions in both types of models, but especially for system-level models. Models cannot provide exact predictions of repository evolution or radiological impact; rather, modelling results illustrate possible ranges of repository performance and are usefully supported by other lines of evidence used in a safety case.

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 fixed, single-valued parameters (sometimes called deterministic calculations). Alternatively, large numbers of calculations may be performed probabilistically using parameter values sampled at random from probability density functions (PDF). Models, computer codes and data (individual parameter values or PDF) are selected by the safety assessment team, based on the synthesis of scientific understanding in the assessment basis. A bias audit (the right side box in Figure 5.1) gives technical confirmation of the selected data being appropriate for the purpose of the analysis.

The use of deterministic (single value) or probabilistic (sampling from ranges of values) calculation is not an either/or choice. Often the two approaches are used side by side. When an important contributing aspect of system performance needs to be understood in terms of sensitivity to selection of data from available data ranges, for example, a probabilistic analysis may be used to inform the choice of data values for deterministic calculations.

The nature of the safety assessment outcome

The results of the analyses of scenarios include numerical results for specific safety indicators, e.g. potential annual effective dose or annual risk to humans, statements concerning uncertainty and sensitivities in the results from the calculations, and discussions of the contributions the results are making to system understanding. In building the safety case, these results are given a context with arguments, for example, based on 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. The results are also discussed in the context of any independent supporting evidence (e.g. the existence of relevant natural analogues for the repository). This work creates the synthesis of evidence, analyses and arguments that quantify and support the results of the safety evaluation and constitute the safety case.

Most national regulations relating to repositories for nuclear waste give, amongst other requirements, quantitative safety criteria in terms of annual dose and/or risk, and these indicators are evaluated for a range of evolution scenarios for the disposal system using numerical modelling. Output can take the form of a single number, like a maximum annual dose over the time frame of interest to a defined individual in a defined location with a defined biosphere with defined habits. It can also take the form of the graphic output of a dose for a predefined individual at a given location, over the time frame of interest. However, the individual human behaviours 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 time scales (NEA, 2004, 2012a). Calculated doses and risks are therefore indicators for repository performance rather than predictions of future radiological effects.

The possible evolutions and performance of a well-chosen geological site and host rock and a well-designed engineered system can be bounded with reasonable confidence over sufficiently long time scales to assure adequate system safety. Supporting evidence of such bounding can be evidence concerning the stability of geologic formations in general, natural analogues, or natural tracer profiles. Since spent fuel has a large content of extremely long-lived ^{238}U with its continuous generation of hazardous uranium daughter nuclides, it might strengthen the safety case to include a *qualitative* description of the evolution of the spent fuel over long times for comparison with other similar hazards (e.g. natural background levels of radon resulting from ^{238}U in soils and rock). The potential dose or risk 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 include complementary (also qualitative) safety arguments that avoid over-reliance on any single argument. One type of evidence and argument in support of a safety case is the use of indicators complementary to dose and/or risk (IAEA, 2003; NEA, 2012, 2012a). These additional, complementary indicators of performance can be useful for showing more clearly a repository´s intrinsic performance without requiring assumptions about the future surface environment and the biosphere.

The example below shows how a primary indicator (annual effective dose) can be complemented by two additional safety indicators:

- *Annual effective dose [Sv/a]*. The goal for this indicator is to be able to show that human health is not jeopardised by radionuclides released from the repository, i.e. all biological effects to a human individual remain so small that they have no significant health impacts.
- *Radiotoxicity concentration in the biosphere water [Sv/m^3]*. The goal for this indicator is to show that radiological hazard from the ingestion of the biosphere water that contains trace amounts of radionuclides from the repository is comparable to average regional drinking water or to drinking water standards, as may be considered appropriate. (Note that the average drinking water in the region is consumed by a regional population, whereas any release to the groundwater from the repository would be consumed by fewer individuals.)
- *Radiotoxicity flux from the geosphere [Bq/m^2/a]*. The goal for this indicator is to show that radiotoxicity flux from the geosphere containing the repository to the groundwater is comparable to the natural radiotoxicity flux in the regional groundwater.

A goal was expressed for each of the three indicators described above. Typically the regulator will prescribe a numerical value not to be exceeded for the primary safety indicator. Some "reference values," or numerical targets, for the complementary indicators have also been suggested. A reference value is a yardstick against which an indicator can be compared and repository safety and performance evaluated (IAEA, 2011; NEA, 2002).

The need for reference values depends, to a large extent, on the purpose of the indicator and the assessment context. If, as suggested above, the value obtained is to be compared with a natural value for the region, then that regional value becomes the reference value. It is not clear that specifying reference values is useful without a regional context for indicators that refer to natural radioactivity. It may be helpful, if a complementary safety indicator addresses subsystem performance, for example, to have a reference value based on that subsystem's role in assuring system performance (the primary safety indicator).

One reason for using complementary indicators is 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 very long assessment time periods. This time-scale-dependent approach is not often reflected in regulatory guidance documents.

Primarily, the growing interest in using complementary indicators is moving to evaluating sub-system performance and the evolving status of barriers over time (expressed as performance indicators or safety function indicators, e.g. the thickness of a barrier susceptible to corrosion, the evolution of the radiotoxicity inventory in compartments of the repository system, etc.). This adds understanding to the assessment of system safety at all time periods.

Handling of uncertainty

The process of carrying out a safety assessment can reveal issues and uncertainties that need to be addressed. Some of them may have implications for the assessment context, others may need to be addressed by further scientific and/or design studies. These types of feedback to scientific and design studies are illustrated by the arrows leading to the leftmost box "scientific and design studies" in Figure 5.1. Since in any case these issues have to be addressed in the next stage of safety case development, they will be identified and discussed in the safety case report.

Assessment results are necessarily associated with uncertainties. 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 to arrive eventually at a safety case that is adequate for licensing. Uncertainties can partly be reduced by collecting additional and more accurate data, by design changes, by further research or by additional model development. However, uncertainties will persist. Uncertainties reflect limits in understanding long-term system evolution. Often, statistical methods are employed in evaluating the impact of uncertainties on safety statements.

Internationally, there is a high level of consensus on the types or sources 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* are associated with significant changes that may occur within the engineered and natural systems over time, and the uncertainties concerning physical and chemical processes accompanying those changes.
- *Model 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 simplified models and computer codes.

- *Data and parameter uncertainties* are associated with the parameter values used in the implemented assessment models, since data may be incomplete, cannot be measured accurately or are not available.

This classification system essentially arises from the way safety assessment is implemented. Actually, all three uncertainty classes are related to each other, and some uncertainties can be handled in different ways, such that they might be dealt with in one class or another.

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 event or process being uncertain*, for example ruling out uncertain events on the basis of very low probability or very low consequence.
- 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 man" 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 need to be reduced most 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, development and site characterisation programmes is an important aspect of developing overall confidence in the safety case. Statements about uncertainties, their relevance for safety and about means to address them in the future are a central output of a safety case at a certain step of repository development

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6. Synthesis of Evidence, Analyses and Arguments and Statement of Confidence

Types of evidence, arguments and analyses

Most national regulations give safety criteria in terms of dose and/or risk, and the evaluation of these and other indicators (cf. Chapter 5), using either mathematical analyses or more qualitative arguments, for a range of system evolution scenarios, generally appears prominently in safety cases that are intended for regulatory review. There are, however, complementary types of evidence and argument that potentially increase the robustness of the safety case. These include: *i)* evidence for the intrinsic quality of the site and design; *ii)* arguments for the adequacy of the strategy to manage uncertainties and open questions.

Evidence for the intrinsic quality of the site and design

The safety of any repository depends primarily on the favourable characteristics or intrinsic properties of the host rock in its geological environment and the engineered barrier system. Important characteristics include their robustness and reliability over prolonged periods. These characteristics need to be stressed in any safety case. Principles that favour the robustness and reliability of a repository and its environment are described in Chapter 3 in the context of the siting and design strategy. By showing how, or by giving evidence that, the site and design conform to these principles, arguments for the intrinsic quality of a specific site and design can be made. For example, evidence for stability and other favourable characteristics of the host rock and geological environment can often be obtained from *in situ* observations and measurements (Box 6.1). It is important to demonstrate that, and how, the relevant site and design information has been appropriately used in the safety assessment.

Arguments for the adequacy of the strategy to manage uncertainties and open questions

Some types of uncertainty can be considered to be of no relevance to the decision in hand. For example, uncertainties regarding, say, human diet in the far future may be of limited relevance. Some uncertainties also exist concerning the relationship between radiation dose and the risk of cancer. This is not, however, relevant to deciding whether radiological risk evaluated using this relationship meets a regulatory risk target, because the target represents a currently acceptable radiological risk that has been defined, already taking into account the uncertainty in the dose-risk relationship (NEA, 2009). Other uncertainties can be shown by safety assessment to be unlikely to compromise safety. A safety case should highlight uncertainties that appear to call into question the robustness of the disposal concept and discuss how they are being addressed through, perhaps, further studies or the pursuit of design options. The point should be made that the uncertainty source in question can be adequately dealt with in future project stages via an appropriate research programme and management strategy.

Box 6.1: Arguments derived from *in situ* observation providing evidence for the long-term integrity of a salt dome considered as host formation for a geological repository [from (NEA 2008)]

One main line of evidence shows that the inner rock salt of the dome has not interacted with external water for more than 2×10^8 years (the time of deposition), and that peripheral salt dissolution is limited to a few tens of metres of soluble potash seams. These results are based on investigations in the Gorleben salt dome and other salt formations such as the study of brine and gas inclusions and bromine concentration profiles.

The second main line of evidence is based on observations of very low water content and the plastic behaviour of the salt rock. This last characteristic means that any voids and fissures will be reduced and closed, and is based on results of several laboratory and *in situ* studies and the investigation of the self-sealing process in the excavation disturbed zone of a 90-year old drift in a salt mine.

Other observations, such as basaltic intrusion into a salt formation, show that high temperatures have low impact on the rock salt stability. Furthermore, subrosion rates of the Gorleben salt dome are less than 40 m in 10^6 years. Even under the conditions of a strong subglacial erosion event, only a very minor part of the salt dome was affected and, by far, the major part of the salt dome retains the integrity needed to provide barrier functions.

In general, any argument for safety is based on a number of claims that must themselves be based on evidence. For example, in order to test compliance with regulatory safety criteria, the scenarios for the evolution of the repository and its environment and the safety functions that they provide are derived, and their radiological consequences evaluated using quantitative models. A claim that compliance has been demonstrated must be supported by evidence for the reliability of the analyses and the adequate treatment of uncertainty. Thus, it needs to be supported by a detailed discussion of:

- the handling of uncertainty in the safety assessment;
- the quality and reliability of the science and design work that is the assessment basis, including the development of the scenarios, the adequacy of the range of scenarios considered, their likelihood, and the adequacy or quality of the methods, models, computer codes and databases used to analyse them;
- quality management requirements for performing safety assessment calculations.

Due to the use of pessimistic parameter values and conservative assumptions in handling uncertainty at many levels in the analyses, the actual performance of the repository is likely to be more favourable than that indicated by the safety assessments. Conservatism of the analyses constitutes an additional qualitative argument for safety, although conservatism in and of itself may also be interpreted as a lack of knowledge, and may thus detract from confidence. Conservatism is inevitable, but should be used and managed judiciously.

Emphasis placed on different lines of evidence, arguments and analyses when presenting a safety case

In general, a safety case will include all the different lines of evidence, arguments and analyses that are available to support the quality and performance of the disposal system at a given stage of repository planning and development, as described in the previous sections. Any lines of evidence that are not supportive of the safety case should also be discussed and analysed. The emphasis placed

on different lines of arguments and analyses when presenting a safety case can vary, however, depending on:

- the concerns and requirements of the intended audience;
- the time scale over which safety is being discussed and the variation of hazard with time;
- the stage of project development and level of confidence that has been established in performance of different aspects of the system to date;
- the expected evolution of the system, and associated uncertainties, and their implications for performance.

Overall, a safety case has to make the best use of the arguments for safety that are available and these may vary between projects.

Box 6.2 presents a list of arguments for system robustness that is applicable to several proposed repositories in several geological settings.

Box 6.2: Examples of the types evidence that can be used to support arguments for the robustness and other favourable characteristics of the repository and its environment when applicable

From (NEA, 2008), see also (EC, 2011)

Types of argument	Examples of application
The existence of natural uranium deposits, and other natural analogues of a repository system or one or more of its components	Long-term stability of formation, bentonite, used as a buffer material in many repository designs (also the feasibility, in principle, of geological disposal)
Thermodynamic arguments	Stability of copper, which is used as a canister material in some designs, in deep groundwaters
Kinetic arguments	Corrosion rate of iron, which is a canister material in some designs
Mass-balance arguments (showing that there is only a limited amount of reactant so that the extent of a detrimental reaction must be limited)	Limited chemical alteration (illitisation) of bentonite; the slow rate of copper corrosion
Natural isotope profiles in some argillaceous rocks, groundwater ages and palaeohydrogeological information in general	Slow groundwater movement and long-term stability of the geosphere
Long-term extrapolation of short-term experiments and observations	Corrosion processes; radioactive decay
Detailed modelling studies	Slow groundwater flow and radionuclide transport; low likelihood and consequences of earthquakes

In presenting a safety case, emphasis is placed on those safety functions that are expected to be most important, and on those arguments that are considered the most convincing at any given time in the evolution of the repository and its environment. Weaknesses in the arguments being made should be readily acknowledged and placed into an overall safety context. For example, canisters may initially be confidently expected to provide complete confinement of the wastes and safety arguments may emphasise evidence supporting the integrity of the canisters over a certain period. In discussing the basis for this confidence, however, it is necessary to discuss processes and events with the potential to degrade the confinement function.

At later times, when waste packages may have been breached, arguments based, e.g. on the stability of the waste forms, geochemical immobilisation, the slow rate of groundwater movement and the stability of the geological environment, are used to show that releases to the human environment are nevertheless small, even given uncertainties in scenarios, data and models. At still later times, arguments based on radioactive decay and the resulting decreased hazard potential of the waste are likely to receive more prominence. In some safety assessments, and in some regulations, discrete periods or "time frames" are defined in which different lines of argument are available, or in which a different emphasis or weighting of arguments is appropriate. Time frames can provide a useful framework for internal discussions among experts within an implementing organisation, between implementers and regulators as well as between implementers, regulators and the public, as discussed in (NEA, 2012a).

Statement of confidence

In general, a safety case will conclude that there is adequate confidence in achieving a safe repository which then justifies a positive decision to proceed to the next stage of planning or implementation. This is a *statement of confidence* on the part of the author(s) of the safety case based on the analyses and arguments developed and the evidence gathered. If the evidence, arguments and analyses do not give the developer sufficient confidence to support a positive decision, then the assessment may need to be revised (e.g. enhancing the information used in the assessment basis), the design may need to be revised, or even the site itself reconsidered, before presenting a safety case for the decision at hand (NEA, 1999).

A synthesis of the available evidence, arguments and analyses should thus be made. The synthesis should show how all relevant data and information have been considered, all models have been tested adequately, and a rational assessment procedure has been followed. It should also consider the limitations of the presented evidence, arguments and analyses, and highlight the principal grounds on which the author of the safety case has come to a judgement that the planning and development of the disposal system should nevertheless continue. This includes the strategy by which any open questions and uncertainties with the potential to undermine safety will be addressed and managed. At the early stages of a programme, there may be many such open questions and uncertainties, and the safety case should make clear the view of the developer that there are good prospects for dealing with these in the course of future stages, e.g. by site characterisation and optimisation of system design, and set out the strategy by which this will be achieved.

The safety case is a basis for decision making and must be presented to the relevant decision makers for their consideration and review. The statement of confidence can make no presumptions about the confidence of the audience, which may include regulators, the general public or other stakeholders. The audience member will decide whether (s)he believes the reasoning presented is adequate and comprehensive, and whether (s)he shares the confidence of the author. The confidence of the audience in the findings of a safety case can, however, be promoted by presenting key arguments in a manner that is transparent and convincing, and by fully disclosing all relevant results,

and subjecting them to QA and review procedures. At the later stages of a programme, and certainly by the time a safety case is presented as part of a license application, uncertainties and open questions with a potential to undermine safety should have been addressed in a manner appropriate for the decision at hand, and this will be reflected in the statement of confidence. Uncertainties will inevitably remain (a host rock, for example, can never be fully characterised without, in the process, perturbing its favourable characteristics), but the safety case should indicate the reasons why these uncertainties do not undermine primary arguments for safety.

7. Conclusions

Disposal of long-lived radioactive waste in an engineered repository located deep in a suitable geological formation is being investigated world wide. With its ultimate goal of protecting humans and the environment both now and in the future, a repository is considered to be safe, from a technical point of view, if it meets relevant safety standards specified by the responsible host nation regulator, which take into account international safety standards.

Repository development involves a number of stages punctuated by interdependent decisions on whether and how to move to the next stage. These decisions require a clear and traceable presentation of technical arguments, a safety case that will help to gain confidence in the safety of a proposed concept, or of a proposed new stage in the development of that concept. A safety case is developed stepwise, keeping pace with the collection of additional information and aiding in the identification of desirable new or additional information. In the context of the decision making at each stage, the safety case can serve as a platform for dialogue amongst the involved stakeholders, including the responsible national regulatory authority.

The safety case concept was developed over a period of several decades. The NEA IPAG-1 exercise (1997) and the NEA Confidence Study (1999) both in the 1990s provided the early impetus. The concept was then documented in (NEA, 2004a) and in several IAEA safety standards. Since then, several safety cases supporting national programme decisions have been developed. Considerable evolution with regard to methodology and tools has taken place, which has also been mirrored in a number of international projects. The present brochure – being an update of (NEA, 2004a) – is meant to reflect that evolution. Namely, in the past decade there has been progress in terms of: *i)* scientific understanding, particularly advances in understanding and modelling coupled processes; *ii)* advances in computer and hence modelling capability; iii) experience in writing competent cases for the safety of specific proposed repositories. The role of modelling in support of the safety assessment has generally become more balanced with other lines of evidence. There has been some evolution concerning the definition of safety functions and the means for using them to more transparently describe system evolution over time. Uncertainties are being addressed more effectively and there have also been developments concerning the use of alternative safety indicators.

There is no universal format or plan for achieving and documenting a safety case, but there is nowadays an international consensus on the main elements of such a safety case. It is widely agreed that the documentation should include a clear presentation of the safety concept and a complete compilation of the technical data and analyses. A short, higher-level document with only a minimum of technical details is desirable for the less technically-oriented stakeholders.

A safety case should be forward-looking. It should point ahead to the nature, type and general schedule of the continuing work, and should describe how the new work will be evaluated in terms of confirming or challenging the current safety estimates. Other general considerations to establish credibility in developing a safety case include the following:

- *transparency*, i.e. providing the audience with clear and easy to understand information regarding system safety so that decisions can be made;

- *traceability*, i.e. all key assumptions, particularly the scientific and technical data and their bases, should be clearly documented in the safety case or its supporting documents;
- *openness*, i.e. uncertainties and outstanding issues which may affect the system safety or confidence should be discussed.

Information exchange and peer review in international fora can play a key role in addressing the credibility of a safety case. In recent times, international peer reviews have provided valuable guidance to repository development projects as well as offered substantial support to national regulatory processes.

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