Radioactive Waste Management

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POST-CLOSURE SAFETY CASE FOR GEOLOGICAL REPOSITORIES

NATURE AND PURPOSE

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NUCLEAR ENERGY AGENCY
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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NUCLEAR ENERGY AGENCY

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The mission of the NEA is:

- to assist its member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purposes, as well as
- to provide authoritative assessments and to forge common understandings on key issues, as input to government decisions on nuclear energy policy and to broader OECD policy analyses in areas such as energy and sustainable development.

Specific areas of competence of the NEA include safety and regulation of nuclear activities, radioactive waste management, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information. The NEA Data Bank provides nuclear data and computer program services for participating countries.

In these and related tasks, the NEA works in close collaboration with the International Atomic Energy Agency in Vienna, with which it has a Co-operation Agreement, as well as with other international organisations in the nuclear field.

FOREWORD

Disposal of long-lived radioactive waste in engineered facilities, or repositories, located deep underground in suitable geological formations, is being widely investigated world wide in order to protect humans and the environment both now and in the future. A repository is said to be safe, from a technical point of view, if it meets the relevant safety standards, that are internationally recommended or specified by the national regulator. The process of analysing the 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 guaranteed, is termed post-closure safety assessment. In recent years the scope of the safety assessment has broadened to include the collation of a broad range of evidence and arguments that complement and support the reliability of the results of quantitative analyses and the broader term "post-closure safety case", or simply "safety case"[1], is used to refer to these studies. It has also become obvious that repository development will involve 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 that will help in gaining confidence in the feasibility and safety of a proposed concept. The depth of understanding and technical information available to support decisions will increase from step to step. The safety case is a key input to support the decision to move to the next stage in repository development. It reflects the state and results of research and development (R&D) undertaken at a certain stage, and informs decisions concerning future R&D efforts.

This report defines and discusses the purpose, and general contents, of safety cases for geological repositories for long-lived radioactive waste. The aim is to provide 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. In addition, it gives an explanation of the particular nature of such cases for safety experts in other fields and for interested individuals with knowledge of relevant fields of science and

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[1] In this report, the term "safety case" is taken to refer to the safety case of the post-closure period.

engineering. It draws on the experience of experts in radioactive waste management and geological disposal safety studies as assembled in the OECD/NEA Radioactive Waste Management Committee (RWMC) and the Integration Group for the Safety Case (IGSC), which supports the former committee. The IGSC has membership from NEA member country organisations involved in the practice, regulation of radioactive waste disposal and related research and development, as well as representatives from international organisations such as the International Atomic Energy Agency (IAEA) and the European Commission (EC).

The report builds on work carried out by the RWMC Integrated Performance Assessment Group (IPAG), which during three phases of work over six years in the 1990s examined the practice of safety assessments, the regulatory review of assessments, and the development and communication of confidence in safety assessments. It also draws on the technical report *Confidence in the Long-term Safety of Deep Geological Repositories* produced by the RWMC, on the basis of experience accrued within the IGSC, and on the results of recent international peer reviews organised or co-organised by the NEA of major safety studies related to geological disposal programmes in several countries.

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EXECUTIVE SUMMARY

Long-lived radioactive waste, such as spent nuclear fuel and waste from fuel reprocessing, must be contained and isolated from humans and the environment for many thousands of years. Engineered geological disposal is the currently favoured radioactive waste management end-point providing long-term security and safety in a manner that does not require active monitoring, maintenance and institutional control. Isolation of the waste rests on radionuclide containment, on the retardation of potential releases and attenuation of these releases to levels that are in accordance with acceptable standards of safety.

Nature and purpose of the safety case

Safety assessments are carried out periodically throughout repository planning, construction, operation, and prior to closure, and are used to develop and progressively update the safety case. A safety case is the synthesis of evidence, analyses and arguments that quantify and substantiate a claim that the repository will be safe after closure and beyond the time when active control of the facility can be relied on. The safety case becomes more comprehensive and rigorous as a programme progresses, and is a key input to decision making at several steps in the repository planning and implementation process. A key function of the safety case is to provide a platform for informed discussion whereby interested parties can assess their own levels of confidence in a project, determine any reservations they may have about the project at a given planning and development stage, and identify the issues that may be a cause for concern or on which further work may be required.

A detailed safety case, presented in the form of a structured set of documents, is typically required at major decision points in repository planning and implementation, including decisions that require the granting of licenses. A license to operate, close, and in most cases even to begin construction of a facility, will be granted only if the developer has produced a safety case that is accepted by the regulator as demonstrating compliance with applicable standards and requirements. Less detailed technical evaluations and safety assessments may be adequate to support some levels of internal planning and decision making by the developer. 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 and visibly considered at each project stage.

Developing a safety case for the post-closure period is a challenging task that differs in some key respects from the demonstrating pre-closure safety, as well as the safety of other types of nuclear facilities. These differences relate in particular to the limited possibilities for monitoring and corrective actions after closure, and to the uncertainties, arising from the long time over which post-closure safety is assessed.

Elements for documenting the safety case

A clear statement of purpose and context is an intrinsic part of the safety case. In addition, recognising that format and content should be adapted to the decision context of each safety case, elements that contribute to the safety case may include the following:

(i) 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. All national programmes aim at management strategies that accord with good management and engineering principles and practice. This includes maintaining sufficient flexibility within a step-wise 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.

(ii) 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 depends 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.

(iii) Evidence, analyses and arguments

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

(iv) Synthesis

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

General considerations when presenting the safety case

General considerations when presenting the safety case should include:

(i) Purpose and context statement

An outline of the programme and the current step or decision point within the programme against which the safety case is presented should be given. This will set the context in which the current strength of the safety case and the importance of remaining uncertainties can be judged.

(ii) Concerns and requirements of the intended audience

The emphasis placed on particular lines of argument and analyses and other aspects of the style of presentation must take account of the interests, concerns and level of technical knowledge of the intended audience. This may include the regulator, political decision makers or the public, as well as technical specialists within the implementing organisation itself. Multiple levels of documentation may thus be required, but these products must remain consistent amongst one another. There is only one safety case, but it may be cast in different "language" at different levels of detail for various audiences. At all technical levels, the presentation must be based on a sound scientific and engineering foundation and the research and development (R&D) work that has actually been done. Flexibility needs to be maintained to respond to the requests of the intended audience. Over-simplifications could lead to unsupported or overly optimistic declarations of safety, and this should be avoided.

(iii) Other considerations

A number of other considerations must be taken into account in preparing the safety case and to establish its credibility. These include:

- Transparency – a safety case should be presented in ways that are both clear and understandable to the intended audience; the objective is to inform the audience's organisational or personal decisions regarding safety;

- Traceability – with respect to the step by step decision making process and for more technical audiences, it must be possible to trace all key assumptions, data and their basis, either through the main documents or supporting records;

- Openness – with respect to current uncertainties, open questions and other factors that may affect the confidence that may reasonably be achieved in the potential safety of the disposal system should be discussed;

- 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 waste from fuel reprocessing, must be contained and isolated from humans and the environment for many thousands of years. Engineered 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 [1]. Engineered geological disposal has been judged to be technically feasible in principle [2]; it has also been judged to be acceptable from an ethical and environmental viewpoint [3]; and it is also accepted from an international legal perspective [4]. 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 world wide in order to protect humans and the environment both now and in the future.

A repository will only be licensed for construction, operation and closure if it can be shown to be safe. A repository is said to be safe, from a technical point of view, if it meets the relevant safety standards, such as are internationally recommended or specified by the responsible national regulator. The present report 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:

- the security of the waste against unauthorised interference or recovery;

- the 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; and

- 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 as a necessary step to gaining planning approval.

The process of analysing the 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, and under what circumstances, radionuclides might be released from the repository, how likely such releases are, and what the radiological 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 in concert to prevent, lower the likelihood of, or attenuate such releases. This in turn involves collating data, developing models and performing analyses related to safety. In addition, in recent years, 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 [5].

Safety assessments are performed periodically throughout repository planning, construction, operation, and prior to closure. They are used to develop and progressively update a safety case, which is a formal compilation of evidence, analyses and arguments that quantify and substantiate a claim that the repository is safe. The safety case may be seen as analogous, in some respects, to a legal case, in which multiple lines of evidence are produced, and for which the quality of each line of evidence must be evaluated to allow a judgement to be reached on the adequacy of the case to support a decision. An initial safety case can be established early in the course of a repository project. The safety case becomes, however, more comprehensive and rigorous as a result of work carried out, experience gained and information obtained throughout the project, including any pre-closure monitoring phase.

Box 1: Definitions of safety assessment and the safety case

From: IAEA/NEA draft Safety Requirements for Geological Disposal, DS154, 2004[6].

Safety assessment is the process of systematically analysing the hazards associated with the facility and the ability of the site and designs to provide the safety functions and meet technical requirements.

The safety case is an integration of arguments and evidence that describe, quantify and substantiate the safety, and the level of confidence in the safety, of the geological disposal facility.

The aim of this report is to define and to discuss the purpose of safety cases for geological repositories for long-lived radioactive waste, although aspects of the discussion are also applicable to repositories for other types of radioactive and non-radioactive waste. It is intended to provide both a point of reference for those involved in the development of safety cases, and an explanation of the particular nature of such cases for safety experts in other fields, and for those with responsibility for, or interest in, decision making in radioactive waste management.

The report 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.

Chapter 2 describes the elements of the safety case and discusses a number of general considerations for its presentation.

Chapter 3 deals with the high-level approach adopted for achieving safe disposal – the safety strategy – and its elements, namely the management strategy, the siting and design strategy and the assessment strategy.

Chapter 4 deals with the information and analysis tools for safety assessment – the assessment basis.

Chapter 5 describes the types of evidence, analyses and arguments that can contribute to a safety case, and how these are synthesised for the purposes of making a safety case, as well as the issue of confidence.

Finally, Chapter 6 presents concluding remarks.

It is noted that several documents are being produced by the IAEA that include discussion of the safety case. The key document concerning safety requirements for the geological disposal of radioactive wastes is being developed collaboratively with the NEA [6].

2. THE SAFETY CASE AND CONSIDERATIONS FOR ITS PRESENTATION

2.1 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, as well as a substantial amount of skilled human, economical and technical resources. Planning and implementation typically proceed in a stepwise manner, punctuated by decision points. Stepwise planning and implementation are aspects of management strategy, as discussed in Chapter 3. 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 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 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 be focused on obtaining any necessary legal or regulatory approvals for construction, operation and eventually, closure.

A detailed safety assessment and the presentation of a safety case in the form of a structured set of documents are typically required at major decision points in repository planning, implementation and operation, including decisions that require the granting of licenses. A license 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. 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.[2] Less detailed technical evaluations and

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[2] Here, a stakeholder is any actor, institution, group or individual with a role to play in the decision-making process [7].

safety assessments may be adequate to support internal planning and decision making by the developer. 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 and visibly considered at each project stage.

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 (subject to social, political and other legal constraints) to proceed. Otherwise, a review may be needed to establish what modifications are required or where improvement in confidence can be found. Options include waiting pending further studies to clarify uncertainties; taking actions to gain social, legal or political approval; or, if necessary, stepping back, e.g. looking again at alternatives, such as new design concepts, or even retrieving emplaced waste.

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, determine any reservations they may have about the project at a given planning and development stage, and identify the issues that may be a cause for concern or on which further work may be required. This may reduce the likelihood of the project failing due to discrepancies between the understanding and expectations of the different stakeholders.

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. The foundation, however, should always be consistently based on sound scientific evidence and arguments utilising established technical experience and competent analyses.

2.2 Safety objectives of a repository

Repositories are designed with the primary aim of containing and isolating the waste. Isolation means keeping the major part of the waste and its associated hazard away from the biosphere,[3] making deliberate human intrusion to the waste difficult without special technical capabilities. The avoidance of locations that may attract inadvertent human intrusion is typically a factor in repository siting. Since complete containment and isolation cannot, in practice, be guaranteed for the whole of the period that the waste presents a potential hazard, a second aim is to ensure that any eventual releases do not present an unacceptable risk. Safety after closure of the repository is provided by the passive protective functions of the geological environment and the engineered barriers placed around the waste, as well as the stability of the waste form itself.

Although some monitoring and controls may be implemented to assure societal comfort and acceptance, such actions should not be relied upon 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.

Thus, post-closure safety and security must rest on the main protective functions of waste isolation, and of 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.

2.3 Elements for documenting the safety case

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 1.

The *purpose and context of the safety case* should be made clear. This includes 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.

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[3] In this report, biosphere means 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.

The *safety strategy*, which is the high-level approach adopted for achieving safe disposal, should also be described. This includes the strategies for the overall management of the various activities required for repository planning and implementation, for siting and design, and for performing safety assessments, see Section 3.1. 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 – that is a description of the repository design including the engineered barriers,[4] the geologic setting and its stability, how both engineered and natural barriers are expected to evolve over time, and how they are expected to provide safety;

- the scientific and technical information and understanding, including the detailed support for the expected evolution of the disposal system and assessments of the uncertainties in scientific understanding;

- the methods of analysis, computer codes 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 also be addressed as part of the safety case.

Finally, a *synthesis* must be made that draws together key findings from the safety assessment, namely the principal *evidence, analyses and arguments* that quantify and substantiate a claim that the repository is safe, including an evaluation of uncertainty. It also presents the additional evidence and arguments on which the author of the safety case – typically the developer – has come to a judgement that the decisions at hand can be safely taken (e.g. planning and development of the disposal system should continue). This judgement is 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.

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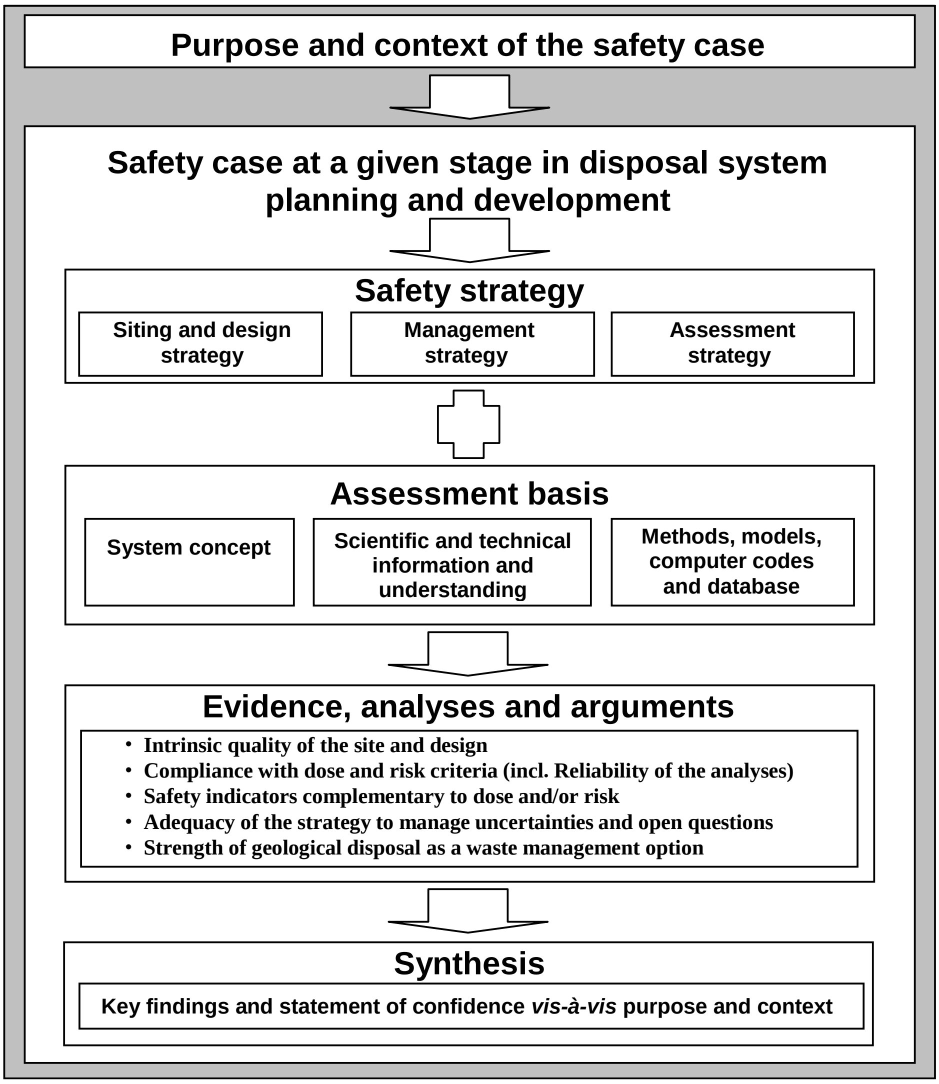
4. The Engineered Barrier Systems (EBS) consist of the materials placed within a repository, including the waste form itself, waste canisters, buffer materials, backfill, seals, and plugs [8].

The safety strategy, the assessment basis, the types of evidence, the analyses and arguments that are available and their synthesis within a safety case are described in subsequent chapters. The remaining sections of this chapter address some general considerations when presenting the safety case.

Figure 1. **An overview of the relationship between the different elements of a safety case**



2.4 General considerations in the presentation of a safety case

Purpose and context of a safety case

The adequacy of the safety case has to be judged in the context of the stage reached in the process of planning and implementing a repository, and any forthcoming decisions that must be taken. The description of the purpose and context of the safety case should include:

- the stage in the process currently reached;
- how the required attributes of the geological setting of the repository will be tested or confirmed;
- how the feasibility of the manufacture or construction of the engineered barrier system will be achieved;
- how the repository will be constructed, operated and closed; and
- how these procedures will be controlled, as well as programmatic and practical factors that constrain the way this process proceeds.

It also may be advisable to describe the key decisions that have already been taken or must be taken in future, and actions that will follow from positive decisions, and the responsibilities of different organisations within the decision-making process.

Governments must provide an appropriate legal and organisational framework within which geological disposal facilities can be sited, designed, constructed, operated and closed. The national regulator(s) will define the radiological safety standards, including dose and/or risk constraints, that define the levels of physical harm and probability of harm (risk) that are acceptable for given circumstances, and given types of facilities (the interpretation of evaluated doses and risks is discussed in Section 3.4). These will be set within the framework of international treaties, advisory regulations and guidance for activities relating to radioactive waste management to assure control of the associated radiological hazards [9, 10, 11, 12]. The developer will plan and construct the facility with these requirements as goals. The regulator will review the work of the developer as it proceeds (including the safety case), and may develop or refine requirements and guidance to arrive at an appropriate set of standards, requirements and control procedures for the facility during its construction, operation and closure. The safety case should meet, and show compliance with, the requirements established in the regulatory documents, consistent with the maturity of the programme and decision step that has been reached.

Concerns and requirements of the intended audience

Depending on its purpose, the primary intended audience for the safety case could be the regulator, political decision makers, the wider scientific community or the public, as well as technical specialists within the implementing organisation itself. The emphasis placed on the different lines of argument and analyses and other aspects of the style of presentation must take account of the interests, concerns and level of technical knowledge of the intended audience. 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. Flexibility and traceability needs to be maintained to deal with possible requests for clarification from the audience.

Technical specialists, including regulators and also the wider scientific community, will typically expect a detailed presentation and rigorous analyses and arguments related to safety. A safety case submitted to the regulator will need to show compliance with applicable standards and requirements, but should also provide a description of the whole scientific and engineering enterprise to date; including the record of work done that provides the basis for statements made in the safety case.

Specialists are often engaged to assist political decision makers (and regulators), and may carry out independent technical reviews of a safety case. These specialists are typically experts in some field of science or engineering but not necessarily specialists in the application of these branches of science or engineering in a safety case for geological disposal. The safety case must assist this audience by making clear the implications of scientific and technical knowledge and uncertainties for safety in the context of the decision in hand.

Political decision makers are accountable to the public, and decisions regarding whether, when and how to implement geological disposal are likely to require thorough public examination and the involvement of all relevant stakeholders. Indeed, in the case of a social action like a referendum, the public is the decision maker.

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

A safety case intended as a platform for discussion with a broadly based audience, including the general public, may place emphasis on different lines of evidence, arguments and analyses compared to a safety case aimed at regulators and other technical specialists. As described in [2, 13, 14], the first few hundred years following emplacement of the waste is probably the period of highest concern to many members of the public and could possibly be emphasised to a greater degree when safety cases are presented to the public. Highlighting less quantitative evidence for safety, including evidence from natural analogues, may be more accessible, more convincing and of more interest to the public than, say, the results of complex mathematical models. The monitoring that may be carried out in the operational and immediate post-closure period may also potentially contribute to public confidence. Arguments relevant to very long timescales may be of less interest to some of the public. The public is, however, heterogeneous and, if possible, steps should be taken to ascertain where public concerns lie and address these issues specifically.

For all audiences, it will be necessary to engage in a dialogue to ensure that the messages of the safety case are clear, to understand the possibly diverse concerns and interests of each audience, and to respond to concerns by giving supplementary information or providing alternative presentations. All versions of the safety case must be consistent with each other and based on a sound scientific and engineering foundation that includes the R&D work that has actually been done. Flexibility needs to be maintained to respond to the requests of the intended audience. Over-simplifications leading to false representations of the disposal system and its evolution and unsupported or overly optimistic statements of safety must be avoided.

General considerations

When presenting a safety case, a number of considerations must be taken into account in order to establish or demonstrate its credibility and thus promote the confidence of the intended audience in its findings. These include:

Transparency

A safety case should be presented in a way that is both clear and understandable, and meets the needs and expectations of the intended audience. More technical audiences may, for example, wish to examine the justification behind key assumptions, and will expect this information to be readily available to them. The goal is to support the organisational or personal decision making of the audiences regarding potential system safety.

Traceability and historical perspective

Technical audiences (such as the regulator and technical reviewers) are likely to require traceability of all key assumptions within a safety assessment to an extent that would allow them, if they so desire, to reproduce important results. Furthermore, the confidence of the audience is likely to be enhanced if it is shown that the strategy put forward at earlier stages of a project to manage, for example, safety-relevant uncertainties, has indeed been followed and been successful. This requires that accessible records are kept of each important decision and its basis or rationale, including decisions on the siting and design of the repository, the planning and implementation of the research programme, interpretation of observed data, the derivation of scenarios for further assessment, and the development of conceptual models and the representation of those conceptual models in computer codes. Given the variability of information, evidence and arguments that usually form the safety case, a hierarchical documentation structure with the level of detail increasing with depth might be appropriate. If such a structure is used, it is necessary to make information flow visible by means of accurate referencing, and possibly by using information flow charts.

Openness with respect to current uncertainties, open questions and other factors that may affect the confidence that may reasonably be had in the potential safety of the system as it evolves

Some uncertainties and open questions are inevitable, particularly at early stages of a project. There may, for example, be inconsistencies in site-specific data or disagreement amongst technical experts regarding some of the evidence, analyses and arguments related to safety. A safety case should acknowledge uncertainties, show how they have been identified and taken into account, discuss their implications and explain how any that are critical to safety are to be further addressed or otherwise managed in future project stages. This may include keeping open several alternative design options or variants to cope with as yet unresolved uncertainties.

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 stakeholders. In addition to waste management specialists, the wider scientific and technical community may also be part of an external review, in support of its own or another organization’s stakeholder interests. The key questions to be asked by reviewers seeking a basis for judging system safety should involve the underlying science, and not only, say specific models, codes or databases. What is the basis for the selection of processes and the modelling of interactions between processes that are difficult to observe over the times and spaces being modelled? What is the basis for the scientific content, the parameter ranges and their distributions and uncertainties? It is especially these types of scientific enquiries that the safety case must anticipate and address.

3. THE SAFETY STRATEGY

3.1 Definition and components

The safety strategy is the high-level integrated approach adopted for achieving safe disposal. It includes strategies to select a site, to design and implement a repository, and to develop a safety case that is adequate to satisfy the needs and expectations of decision makers at any project stage. The adequacy of the safety strategy for achieving project goals is itself a part of the safety case and must thus be considered when the safety case is documented. 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. Three components of a safety strategy (see Figure 1) can be differentiated:

- the overall management strategy of the various activities required for repository planning, implementation and closure, including siting and design, safety assessment, site and waste form characterisation and through siting and design, and construction investment. As more information becomes available, the strategy for uncertainty management may change. It is important, for the sake of openness, to acknowledge when uncertainties increase or design changes have to be made because of the results of more testing and evaluation. To selectively advertise only scientific work that lends support to existing concepts or to the current strategy for managing uncertainty is likely to negatively affect stakeholder confidence in the long run.

3.2 Informing principles

The precautionary principle

The safety strategy may differ between national programmes, according, for example, to the types and amounts of waste to be disposed and the potential host rocks and geological environments that are available, as well as various national preferences and choices. All national programmes, however, aim at strategies that accord with good management, siting, and engineering principles and practices, including the principle of "precaution", which is understood to mean "erring on the side of caution". In accordance with the precautionary principle:

- a siting and design strategy are 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, ease of quality control and an absence of, or relative insensitivity to, detrimental phenomena arising either internally within the repository and host rock, or externally in the form of geological and climatic phenomena, and uncertainties with the potential to compromise safety; and

- an assessment strategy is adopted that provides a range of arguments and analyses for the safety case that are well-founded, supported, where possible, by multiple lines of evidence, and adequate in their treatment of uncertainty – the 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 that are well-understood and reliable, such as long-lived corrosion resistant canisters and stable properties of the host rock. On the other hand, potentially detrimental processes or features should be disclosed and taken into account in the assessment.

The need for flexibility

There should be a degree of flexibility 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 [15].

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 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 are carried out concurrently in an iterative, step-wise manner, providing a framework for:

- comprehensive 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; and

- opportunities for political and social consultation and other involvement.

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 keeps realism in the decision process.

3.3 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 and favourable geochemical conditions, should be unlikely to change significantly over relevant timescales. 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, and

- lacking in natural resources that might attract exploratory drilling, 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 the beneficial characteristics of the selected site and 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. In this respect there are advantages in using engineered materials that have already been used in comparable applications. Waste forms are the subject of specifications that the producers of the waste have to meet in order to be accepted for disposal in a geological repository. More generally, there are quality assurance (QA) procedures 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 such that remaining uncertainties have limited consequences in terms of safety so that the required performance is comfortably achieved (see Box 3 in Section 4.2). For example, the performance of long-lived canisters, which are envisaged for most high-level waste repositories, mitigates 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, these processes 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 at least to estimate 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 barriers that operate in concert to isolate the waste, and prevent, delay and attenuate the potential radionuclide release to the biosphere. The barriers should be complementary, with diverse physical and chemical components and processes contributing to safety, 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. Initially, a number of 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. Complete containment in canisters, geochemical immobilisation and retardation, and the reduction of the rate of groundwater movement by a backfill are examples of complementary safety functions.

3.4 Characterising and managing uncertainties

A key output from safety assessment is the identification of uncertainties that have the potential to undermine safety. Thus, safety assessment needs to be integrated within the management strategy. In the safety case, the connection needs to be made between key uncertainties that have been identified and the specific measures or actions that will be taken to address them, especially with regard to the R&D programme, in order eventually to arrive at a safety case that is adequate for licensing.

Some uncertainties can be reduced by methods including site characterisation, design studies, fabrication and other demonstration tests, experiments both in the laboratory and in underground test facilities. As a programme matures, studies will increasingly focus on key safety-relevant uncertainties and the specific data and measurements needed to resolve these. 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. For instance, if there are important uncertainties over the corrosion processes affecting a waste container, then the material or thickness specification might be changed; if there are uncertainties over the performance of a buffer material at high temperatures, then a greater volume of material may be introduced or the thermal design of the system modified. If there are uncertainties over processes occurring near to rock fracture and fault zones, then the layout might be adjusted to avoid such zones. Initially, a number of potential sites may be selected and a number of design options kept open. Indeed, repository design may not be finalised until late in the development process. The process of choosing between alternatives and optimising the dimensions of engineered components can be aided by analyses of system performance. However, the inherent uncertainties in estimating the long-term performance of such systems make comparisons between alternatives of uncertain value. Furthermore, different stakeholders may wish to attach different weights to impacts that may occur with different probabilities and over different temporal and spatial scales and demographic distributions. Thus, the aim of a flexible siting and design strategy is to identify a system that is capable of providing adequate safety, and not to identify the “best possible” system.

Robust and reliable systems are amenable to a well-founded and convincing analysis of safety. Safety assessments must nevertheless capture, describe and analyse residual uncertainties that are relevant to safety, and investigate their effects. These include uncertainty about whether all the relevant features, events and processes have been considered, uncertainty in their description and how they should be modelled, and uncertainty in the data that is needed in an analysis.

Many uncertainties can be bounded, or even quantified, and methods exist to take these uncertainties into account in evaluating compliance with regulatory safety criteria. These include:

- the use of probabilistic techniques, or a set of individually performed deterministic calculations, in order to address data or model uncertainties or to explore a wide range of scenarios, or possibilities for system evolution, and

- the use of parameter values and conservative assumptions that ensure that models used to assess the radiological consequences of a repository err on the side of pessimism – for example, poorly understood features, events and processes that are favourable to safety are often excluded from quantitative analyses of system performance (see Box 2).

Some safety assessments also examine “what if?” cases that, while not necessarily physically impossible, lie outside the range of possibilities supported by scientific evidence. The analysis of such cases is intended to test the robustness of the system with respect to hypothetical perturbations, and in some cases may be viewed as an example of the precautionary principle.

Some uncertainties that can have a significant effect on evaluated levels of safety are difficult to quantify or bound, and are less amenable to the above-mentioned methods, particularly in cases where the range of possibilities is very wide or uncertain. The evolution of the biosphere and the nature and timing of future human actions, for example, become highly speculative even over relatively short times into the future. Methods to at least partly address, or in some cases avoid, uncertainties that are difficult to quantify or bound include the use of safety and performance indicators complementary to dose and risk, as discussed, for example, in [16], and the use of stylised approaches. Doses and risks calculated on the basis of stylised approaches should be interpreted as illustrations based on agreed sets of assumptions for particular scenarios and not as actual measures of future health detriments and risks.

Box 2: Features, Events and Processes (FEPs) that are conservatively omitted from quantitative analyses of system performance in a recent Swiss safety assessment [13]

NOTE: **These are examples from a specific safety assessment and may not be applicable to other systems, or even to similar systems in other settings.**

Reserve FEPs

Note: *Reserve FEPs are those that are currently omitted on the grounds of conservatism, but good prospects for improved scientific understanding, models and data means that they may be included at a later stage of the repository programme.*

- The co-precipitation of radionuclides with secondary minerals derived from SF, glass and canister corrosion.
- Sorption of radionuclides on canister corrosion products.
- Natural concentrations of isotopes in solution in bentonite porewater, which could reduce the effective solubilities of some radionuclides.
- Long-term immobilisation processes (precipitation/co-precipitation) in the geosphere.
- The long resaturation time of the repository and its surroundings, which delays the commencement of corrosion and dissolution processes (likely to be of negligible importance for SF/HLW except in the case of earlier than expected canister breaching).
- The delayed release of radionuclides, due to the slow corrosion rate of ILW metallic materials (e.g. hulls and ends), as well as a period of complete containment by ILW steel drums and emplacement containers.
- Irreversible sorption of radionuclides in the near field or in the geosphere (e.g. surface mineralisation).
- Degassing of volatile $^{14}CH_4$ in the biosphere.

Other FEPs that are treated conservatively

- A period of complete containment provided by the SF Zircaloy cladding following canister breaching (conservatively omitted in all cases).

- The conditions under which mechanical failure of the corroded canisters will occur (the Reference Case breaching time of 10^4 years errs on the side of pessimism).
- The spreading of radionuclide releases in time due to the fact that SF/HLW canisters would not be breached simultaneously (conservatively assumed that all canisters are breached simultaneously, except in cases addressing initial defects in the copper/steel canister design option).
- The transport resistance provided by internal spaces (fractures) within the waste forms, by the breached SF/HLW canisters and by corrosion products (conservatively omitted in all cases).
- The spreading of radionuclide releases in space and time due to the lateral extent of the repository and the three-dimensional nature of diffusive transport (transport paths from the repository to the biosphere are assumed to be 1-D and identical in length in all cases).
- The barrier efficiency of regional aquifers (conservatively omitted in all cases).

4. THE ASSESSMENT BASIS

4.1 Components of the assessment basis

The assessment basis is the collection of information and analysis tools for safety assessment and includes:

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

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

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

The system components

The system components that are described include the host rock and surrounding geological environment, the surface site, 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 description of each should include:

- its geometry and constituents;

- 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; and

- a general description of its expected evolution and performance, that is, for example, the period over which it is expected to fulfil the function.

Any design constraints or criteria should also be included, such as the maximum temperature that should not be exceeded within the buffer.

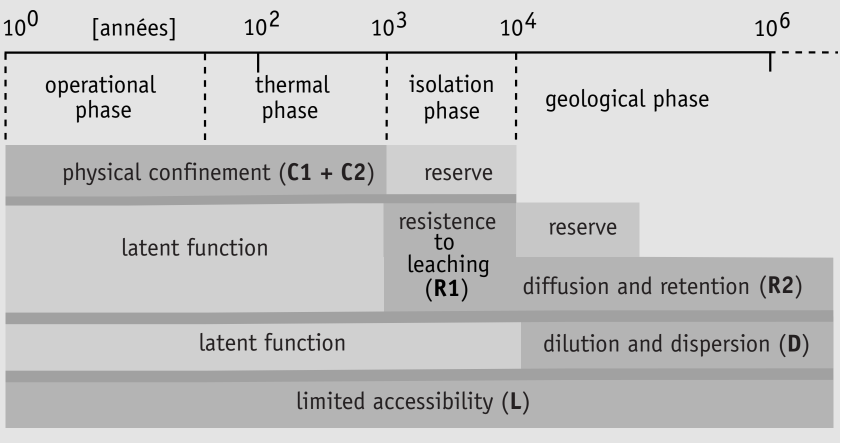
When describing the safety functions, their changing role or reliability in different periods or time frames should be considered. Box 3 *s*hows an example of this from the ONDRAF/NIRAS SAFIR 2 study [17].

It must be shown that the system considered in the safety assessment is one that can be realised in practice. The description should thus also include:

- site characterisation procedures that have or will be carried out to support the properties of the geological environment assumed in the safety assessment;
- any quality management procedures and waste acceptance criteria to ensure that the specifications of the engineered features, including the waste form itself are met; and
- an evaluation of feasibility of actually implementing (constructing, operating and closing) the facility at the selected site.

Box 3: The safety functions identified in the SAFIR 2 study and the time frames or phases over which they are expected to operate [17]

NOTE: These are examples from a specific safety assessment and may not be applicable to other systems, or even to similar systems in other settings



A **latent function** operates if other safety functions fail to operate. A **reserve** function is one that may enhance safety, but, due to uncertainty, is not relied on during the indicated time frame.

Physical containment (C): isolation of the radionuclides from their immediate environment, especially from water, achieved by:

- water tightness (C1): primarily associated with the engineered barriers; and
- limitation of water influx (C2): mainly associated with the natural barrier but also the capacity for certain engineered barriers to delay the ingress of water.

Delay and spread the release (R): after, or in the event of, breaching the physical containment, this second function delays and spreads the migration of the radionuclides towards the biosphere for, and over, as long a time as possible, achieved by:

- resistance to leaching (R1): the system inhibits the release of the radionuclides from the matrix in which they are contained (spreading the release over time); and
- diffusion and retention (R2): the system retains the radionuclides once released from their matrices (locally in the EBS and also in the near geosphere).

Dilution and dispersion (D): in the long term, these processes (associated with the further geosphere and biosphere interface) ensure that the radionuclides will be diluted and dispersed by flows of groundwater in the geosphere and surface water in the biosphere.

Limitation of access (L): the aim of this function is to prevent or limit the probability and consequences of deliberate or inadvertent human intrusion into the repository (and also long-term natural processes, such as erosion).

The first three safety functions occur successively (with overlaps) during the evolution of the disposal system, while the fourth is required to fulfil its role independently over all time frames. In addition, **radioactive decay** contributes positively to safety as it leads to a reduction in radiotoxicity, and hence in the risk, over time.

Many waste management organisations have programmes involving both surface laboratories and underground research laboratories (URLs) aimed at actively demonstrating the feasibility of implementing a given disposal system using currently available or readily achievable technology.

At least two broad categories of URLs can be distinguished [15]:

- facilities that are developed for research and testing purposes at a site that will not be used for waste disposal, but provide information that may support disposal elsewhere, …termed “generic URLs”; and

- facilities that are developed at a site that is considered as a potential site for waste disposal and may, indeed, be a precursor to the development of a repository at the site… termed “site-specific URLs”.

The majority of NEA member countries also consider that the development of URLs has benefits beyond those connected with research, development and the demonstration of technology. In particular, making URLs available for stakeholder visits can promote greater confidence in the disposal project by giving physical evidence of there being a basis for the scientific statements and explanations in the safety case.

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 safety assessment. Any relevant uncertainties should, where possible, be quantified or bounded, including how uncertainties vary over time. Expected features, events and processes (FEPs) that are potentially important for the safety of a system, as well as those that are unexpected but still plausible should be considered.

With respect to the quality and reliability of the scientific and technical understanding and data, the presentation should show that:

- comprehensive research and site investigation programmes have been implemented;
- diverse sources of information (and methods of acquisition) have been brought together to form a consistent picture of the characteristics and history of a site, from which a reliable prognosis of future evolution can be made – this can include the formulation of feasible alternative futures and models, and may make use of appropriate natural analogue and palaeohydrogeological information; and
- both the research and other information must be described in traceable documentation that presents all data and provides clear records of their use, as part of a quality system to ensure the reliability of data and their application.

A data quality control system is useful for auditability and ensuring that changes in the data used in a safety analysis are justified, for example when new, improved data become available. It also demonstrates how any potentially conflicting data are reconciled or handled.

Assessment methods, models, computer codes and databases

The assessment methods, models, computer codes and databases must also be clearly and logically presented. Arguments for their reliability include that:

- the approach is logical, clear and systematic;
- the assessment is conducted within an auditable framework;
- the approach has been continually improved through an iterative process;
- the approach has been subject to peer review;
- effective communication has taken place between those engaged in research and site investigation programmes and safety assessors to

ensure that safety assessors are informed of all relevant information as it is acquired;

- sensitivity analyses have been carried out to ensure that scenarios and calculational cases address key uncertainties affecting the performance of the disposal system;
- suitable criteria have been developed for the exclusion or inclusion of features, events and processes (FEPs) from scenarios for evaluation;
- features, events and processes (FEPs) to be included in the assessment are audited against international FEP lists [18];
- 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, made 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;
- computer codes are developed in the framework of a QA procedure, and verified, for example by comparison with analytical solutions and alternative codes and confidence is increased by means of the simulation of experiments and of natural settings; and
- a clear strategy and methods exist for the handling of uncertainties (see Chapter 3).

5. EVIDENCE, ANALYSES AND ARGUMENTS AND THEIR SYNTHESIS IN A SAFETY CASE

5.1 Types of evidence, arguments and analyses

Most national regulations give safety criteria in terms of dose and/or risk, and the evaluation of these indicators, using either mathematical analyses or more qualitative arguments, for a range of 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:

General evidence for the strength of geological disposal as a waste management option

A safety case will generally focus on evidence, analyses and arguments that pertain to a particular site and design. A safety case may, however, also contain more general evidence for the strength of geological disposal as a waste management option and may argue that it is prudent to pursue that option on an appropriate time schedule. Examples of such evidence and arguments are given in Box 4. The purpose of citing such evidence and arguments is not to explore alternatives to geological disposal, as part of the safety case, but rather to show that geological disposal in a suitably sited and designed repository is a well-chosen strategy.

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. Further examples of evidence for key characteristics that provide safety are given in Box 5.

Safety indicators complementary to dose and risk

Complementary safety indicators can be used to provide supporting arguments for the low consequences of any radionuclide releases to the surface environment. For example, the release rate of radioactivity to the surface environment provides a safety indicator that can be compared with naturally occurring radioactivity fluxes [19]. The radiological toxicity of the waste provides a safety indicator that can be used to compare the hazard of the waste to that of a naturally occurring uranium ore body, and tracking of the location of radionuclides over time can show that these are predominantly contained or decay within the repository and its surroundings. The choice of indicators is highly dependent on the context of each national programme.

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. There are also some uncertainties over 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 account of the uncertainty in the dose-risk relationship [11]. Other uncertainties can be shown by safety assessment not to have the potential to compromise safety. A safety case should, however, show that any uncertainties that do have potential to compromise safety, as well as open questions regarding, for example, design options, can be adequately dealt with in future project stages via an appropriate research programme and management strategy (Chapter 4).

Box 4: Examples of general evidence for the strength of geological disposal as a waste management option (adapted from [13])

- **The existence of suitable rock formations** – Deep rock formations exist in many locations worldwide in which events and processes that might convey radionuclides to the surface environment are either absent, or extremely rare or slow.

- **Observations of natural systems –** Indirect support for the possibility of safe geological disposal also comes from observations of natural systems, including the longevity of uranium ore deposits in many different geological environments around the world. Furthermore, there is ample evidence of the importance of the natural processes of solubility control, sorption and diffusion in attenuating concentrations of species dissolved in porewater. Archaeological analogues may also be used to evaluate specific interactions between relevant materials and natural processes.
- **Characteristics of surface facilities versus geological disposal** – Radioactive waste can be stored for a time in surface facilities. The safety of these facilities is, however, dependent on continued societal stability, which is subject to uncertainties that are far greater than those associated with the evolution of conditions deep underground in geological formations that would be suitable to host a repository. As a long-term waste management option, deep geological disposal has the positive attribute that, if the site and design are chosen appropriately, societal stability allowing for government and regulatory control is not a pre-requisite for long-term safety. No burden is placed on future generations to maintain and control a disposal site once the facility has been closed. Although such control is certainly possible and is not being discouraged, it should not be necessary to an assurance of safety.

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 management of uncertainty in the safety assessment (Chapter 3);
- 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 (Chapter 4); and
- quality management requirements for performing safety assessment calculations.

Due to the use of pessimistic parameter values and conservative assumptions, the performance of the repository is likely to be more favourable than that indicated by the analyses. 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, and greatly to be preferred to optimism, but should be used and managed judiciously.

Box 5: 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 [16]

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

5.2 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, as discussed in Chapter 2;
- 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; and
- 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 and as each project develops.

In presenting a safety case, emphasis is placed on those safety functions that are expected to be most effective, 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 containment 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 containment function. At later times, complete containment cannot be relied upon, and arguments based, for example, 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 both data and models. At still later times, when even the stability of the geological environment cannot be relied upon with confidence, arguments based on radioactive decay and the resulting decreased hazard potential of the waste are likely to receive more prominence. Although an evaluation of dose or risk may still be required by regulations, a less rigorous assessment of these indicators may well be acceptable on account of this decreased hazard potential at extremely long time.

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 and between implementers, regulators and the public, as discussed in [14, 16].

5.3 Synthesis of evidence, analyses, arguments and a statement of confidence

In general, a safety case will conclude that there is adequate confidence in the possibility of achieving a safe repository to justify a positive decision to proceed to the next stage of planning or implementation. This is a *statement of confidence* on the part of the author of the safety case 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. mobilising more of the information available in the assessment basis), the assessment basis modified, the design revised, or even the site itself reconsidered, before presenting a safety case for the decision at hand.

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 will decide for itself whether it believes the reasoning that is presented is adequate and comprehensive, and whether it 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 (see Chapter 2).

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 currently available 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 (see Chapter 3). At the earliest 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.

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.

6. CONCLUDING REMARKS

Disposal and its long-term safety

Disposal of long-lived radioactive waste in engineered facilities, or repositories, located deep underground in suitable geological formations, is being investigated world wide in order to protect humans and the environment both now and in the future. A repository is said to be safe, from a technical point of view, if it is assessed to meet the relevant safety standards, such as are internationally recommended or specified by the responsible national regulator. The NEA has been involved in studies of repository safety for over two decades [20].

The process of analysing the performance of a repository and showing, with an appropriate degree of confidence, that it will remain safe over a prolonged period, beyond the stage when active control of the facility can be relied upon, is termed post-closure safety assessment. In recent years, it has been recognised that the results of such quantitative analyses need to be supplemented with a collation of the broader range of evidence that supports and gives a context to the safety argument. The broader term “post-closure safety case”, or simply “safety case”, is used to refer to these studies.

The necessity of developing a long-term safety case for geological disposal of high-level, long-lived radioactive waste has been addressed in the “Safety Requirements for Geological Disposal” document by the IAEA and the NEA [6]. This brochure complements the definition and requirements statements in that international advisory standard.

Key role(s) of a safety case

Repository development will involve 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 that will help in giving confidence in the feasibility and safety of a proposed concept. The depth of scientific understanding and technical information available to support decisions will increase from step to step. The safety case that is stepwise developed to increase its confidence by integration of the state of knowledge is thus a key input to support the decision to move to the next stage in repository development. In the context of the decision making at each stage, the safety case can serve as a platform for dialogue amongst the involved stakeholders.

The management of uncertainties within the process of safety assessment, as well as the analyses of system and subsystem performance, provide the implementer with input to internal decisions, such as design optimisation and allocation of resources to site characterisation or other aspects of repository development. The safety case reflects the status and results of repository development undertaken at a certain stage, and informs decisions concerning future repository development efforts. Its preparation – as well as its subsequent review – serves to focus activities and project goals within implementing and regulatory organisations. The need for integration of diverse repository development results promotes dialogue between project staff involved in different activities, such as modelling and site characterisation.

The specificity of a post-closure safety case

Making a post-closure safety case is a challenging task that differs in some key respects from the task of demonstrating pre-closure safety, as well as the operational safety of other kinds of nuclear facilities. These differences relate in particular to the limited possibilities for active monitoring and corrective actions after closure, and to the uncertainties arising from the long timescales over which post-closure safety is assessed.

During their operating period, repositories typically will be regulated in accordance with the safety standards and criteria to ensure the safety of workers and members of the public and the security of the waste. There are precedents for most of the operations and processes that are necessary to ensure that these standards and criteria are met. Furthermore, there is substantial experience in the development and demonstration of safety for operating nuclear facilities of various types. As with other types of nuclear installations, repositories can be monitored during the construction and operating periods and any perturbations from expected behaviour can be evaluated to understand their significance regarding post-closure safety. They may also be subject to monitoring and controls after their final closure, but the long-term continuity of such active measures should not be required, consistent with the aim of passive safety.

The scales of space and time to be addressed in a safety assessment mean that uncertainty in the characteristics and evolution of the repository and its surroundings is inevitable. Uncertainty exists in any human endeavour, however, and decision making always has to take uncertainty into account.

Some uncertainties can be avoided or their effects mitigated by, for example, the choice of a suitable geological environment. Others are addressed in the course of repository planning by site characterisation, design optimisation and confirmatory testing and monitoring. Those uncertainties that remain must be shown not to compromise safety. The management of uncertainties in the course of a project, and the making of a safety case that is adequate for decision making in the presence of uncertainty are key issues discussed in this report.

An important management challenge in developing a post-closure safety case

Making a safety case successfully, whether for the operating life of a facility or for the long-term, is first of all a management matter. The need is to have the right expertise and talent available so that the integration and documentation of the work will have the necessary strength, clarity and traceability in making the case for there being sufficient confidence in safety to allow moving to the next step in the decision-making process.

Feedback from safety assessment to the repository planning and development process, such as design and site characterisation, is vital to the quality and efficiency of repository planning and development. Thus safety assessment and the development of the safety case is a process that must be defined, financed and scheduled as an integral part of the overall repository management programme.

Documenting a safety case

There is no universal format or plan for the documentation of safety case, except that is widely agreed that the documentation should include a clear presentation of the safety concept. In addition, to a complete technical documentation, a short, higher-level document with only a minimum of technical details would be desirable for the less technically-oriented stakeholders.

A key issue concerns how to deal with information that becomes available after development of a specific safety case. To this effect, a safety case should point forward to the nature, type and general schedule for continuing work, and should describe how the new work will be evaluated in terms of confirming or challenging the current safety estimates.

Confidence building through peer review

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 on repository developments. There is clear evidence, in the resulting responses by organisations undergoing such reviews, that peer reviews of all types such as national regulatory reviews are helpful. In some countries, there are appointed advisory committees that conduct continuing, long-term reviews.

Societal considerations in decision making

Although the safety of any proposed disposal system is paramount, decisions on the management of radioactive waste and development of geological disposal facilities will be made taking additional account of economic, social and political perspectives not related to safety. The acceptability of geological disposal and the socio-political decision-making process is not discussed in this report, although the impact on the presentation of the safety case of the need to gain understanding and to communicate more widely has been considered. Indeed, it may well be that a clear and easily understood as well as technically correct account of the safety case will have a positive impact on the public and political acceptability of a repository project. Learning and adapting to societal requirements are important challenges to all long-term radioactive waste management programmes [21].

Continued commitment by the technical community

The safety case is about managing and integrating technical information. Although there is confidence that information needs can be identified and that methods have been developed to address and manage the various types of uncertainty, implementing and regulatory organisations continue to be involved in the investigation and resolution of issues associated with evaluating and documenting repository safety. International *fora*, such as those provided by the NEA, will continue to play an important role in exchange of information on the development and regulatory scrutiny of safety cases, leading to a convergence of views on best practice in methods and processes to be applied under the different situations of national programmes.

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