Radioactive Waste Management

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Confidence in the Long-term Safety of Deep Geological Repositories

Its Development and Communication

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ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT

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The OECD Nuclear Energy Agency (NEA) was established on 1st February 1958 under the name of OEEC European Nuclear Energy Agency. It received its present designation on 20th April 1972, when Japan became its first non-European full Member. NEA membership today consists of all OECD Member countries, except New Zealand and Poland. The Commission of the European Communities takes part in the work of the Agency.

The primary objective of the NEA is to promote co-operation among the governments of its participating countries in furthering the development of nuclear power as a safe, environmentally acceptable and economic energy source.

This is achieved by:

– *encouraging harmonization of national regulatory policies and practices, with particular reference to the safety of nuclear installations, protection of man against ionising radiation and preservation of the environment, radioactive waste management, and nuclear third party liability and insurance;*
– *assessing the contribution of nuclear power to the overall energy supply by keeping under review the technical and economic aspects of nuclear power growth and forecasting demand and supply for the different phases of the nuclear fuel cycle;*
– *developing exchanges of scientific and technical information particularly through participation in common services;*
– *setting up international research and development programmes and joint undertakings.*

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

FOREWORD

Confidence in the long-term safety of deep geological disposal, and the ways in which this confidence can be obtained and communicated, are topics of great importance to the radioactive waste management community.[1]

The technical aspects of confidence have been the subject of considerable debate, especially the concept of model *validation*. It has, for example, been pointed out that it is impossible to describe fully the evolution of an open system, such as a repository and its environment, that cannot be completely characterised and may be influenced by natural and human-induced factors outside the system boundaries.[2] A complete description is not, however, a requirement of decision making in repository development. Repository development proceeds in stages, and the depth of understanding and technical information available to support decisions will vary from stage to stage. Decision making requires only that a description of the possible evolutions of the system has been compiled that gives adequate confidence in safety to support the decision at hand, and that an efficient strategy exists to deal at future stages with any uncertainties in the description which have the potential to compromise safety. Furthermore, flexibility should be built into the process of repository development, allowing account to be taken of new understanding and technical information, as well as the demands of societal review.

This report is aimed at practitioners of safety assessment and at technical specialists wishing to become versed in the subject. In its current form, it is intended to improve communication among these specialists by clarifying the concepts related to the development of confidence, and by placing the various measures that are employed to evaluate, enhance and communicate confidence in the technical aspects of safety in a clear, logical framework. These measures are increasingly embodied in actual procedures applied in today's safety assessments, and can be incorporated in a common framework, despite differences in approaches, practices and constraints both within and between repository projects.

When communicating confidence in the findings of a safety assessment, clarity in the communication of concepts is always required. Consistent with this requirement, key concepts are specifically defined in the main text of the report.

Finally, it is noted that a viable repository project depends on confidence in long-term safety on the part not only of technical specialists in implementing and regulatory organisations and in the wider scientific community, but also of political decision makers and the general public. This wider audience is also concerned with non-technical issues affecting the decisions related to repository development. Interaction with a wider audience on issues relevant to long-term safety are addressed in the present report. Non-technical issues are identified, but not elaborated on in detail.

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1. Although the discussion in this document focuses primarily on deep geological disposal, many of the general principles presented could also be applied to shallow land burial of radioactive waste.
2. See, for example [ORESKES 1994].

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

EXECUTIVE SUMMARY

The technical aspects of confidence have been the subject of considerable debate, especially the concept of model validation. It is impossible to describe completely the evolution of an open system, such as a repository and its environment, that cannot be completely characterised and may be influenced by natural and human-induced factors outside the system boundaries. A complete description is not, however, a requirement of decision making in repository development. Repository development proceeds in stages, and the depth of understanding and technical information available to support decisions will vary from stage to stage. Decision making requires only that a safety case has been compiled that gives adequate confidence to support the decision at hand, and that an efficient strategy exists to deal at future stages with any uncertainties in the description which have the potential to compromise safety.

The safety case involves descriptions of the possible evolutions of the system. Although not capable of proof in a rigorous sense, these descriptions can be supported by relevant observations of the behaviour of the various components of the system, while relying on an understanding of its geological history. Furthermore, flexibility should be built into the process of repository development, allowing account to be taken of new understanding and technical information, as well as the demands of societal review.

The safety case that is provided at a particular stage in the planning, construction, operation or closure of a deep geological repository is a part of a broader decision basis that guides the repository-development process. The basic steps for deriving the safety case at various stages of repository development involve:

- A safety assessment, which includes:
  - the establishment of an assessment basis in which there is confidence, i.e. the strategy for the building of a safety case, the selection of a site and design, and the assembly of all relevant information, models and methods;
  - the application of the assessment basis in a performance assessment, that explores the range of possible evolutions of the repository system and tests compliance of performance with acceptance guidelines;
  - the evaluation of confidence in the safety indicated by the assessment and modification, if necessary, of the assessment basis.
- The documentation of the safety assessment, a statement of confidence in the safety indicated by the assessment, and the confirmation of the appropriateness of the safety strategy, either in anticipation of the next stages of repository development or in response to interaction with decision makers.

The safety case should make explicit the principles adopted, and methods followed, in order to establish confidence. The approaches to establish confidence in the evaluation of safety should aim to ensure that the decisions taken within the incremental process of repository development are well-founded. Various aspects of confidence in the evaluation of safety, and their integration within a safety case, are presented in detail in the present report. The key messages arising from their analysis are highlighted below.

- A safety case should make explicit the approaches that are implemented in order to establish confidence in the safety indicated by an assessment.

- The assessment basis, as defined in this report, is a key element of any safety case. In order to establish confidence in the safety indicated by an assessment, confidence in the elements of the assessment basis must be evaluated. If necessary, the elements must be modified with a view to achieving confidence enhancement.

- Confidence evaluation and enhancement are performed iteratively in the preparation of a safety case.

- Methods exist to evaluate confidence in the safety indicated by an assessment in the inevitable presence of uncertainty. In many cases, it can be determined whether safety is compromised by specific uncertainties through a sensitivity analysis, in which the consequences of such uncertainties are evaluated.

- Means exist whereby confidence in the safety indicated by an assessment can be enhanced, by ensuring the robustness of the system concept, the quality of the assessment capability, the reliability of its application in performance assessment and the adequacy of the safety strategy to deal with unresolved, safety-relevant issues.

- Observations of natural systems play an important role in the qualitative evaluation and enhancement of confidence, since such systems have evolved over extremely long time-scales.

- A statement of confidence in the overall safety indicated by the performance-assessment results is part of the safety case and should include an evaluation of the arguments that were developed, in relation to the decision to be taken.

When communicating confidence in the findings of a safety assessment, clarity in the communication of concepts is always required. Consistent with this requirement, key concepts are specifically defined in the main text of the report. An index of definitions is provided in Appendix 4. Figures and tables are listed in the table of contents.

1. INTRODUCTION

1.1 Background

Disposal represents the end point in the process of radioactive waste management. A disposal concept should provide long-term protection from the hazards of radioactive waste in a manner that does not place undue burdens on future generations. For long-lived waste, the waste management community has developed the concept of deep geological disposal in repositories that should be sited and designed in such a way that they are both safe and resistant to malicious or accidental disturbance. Long-term safety is based on a passive system of multiple barriers with a range of safety functions. Deep geological disposal does not preclude monitoring and maintenance, but these should not be required to ensure safety. Similarly, society may choose to use long-term institutional controls as a management tool, but, even if such tools were to fail, human health and the natural environment should still be protected.

Relevant organisations in many of the OECD Member countries are involved in the investigation and resolution of safety issues associated with repository development. Safety must be demonstrated[3] to the satisfaction of the implementing organisations, of the regulatory bodies, of the wider technical community (peer review), of political decision makers and of the general public. In particular, convincing arguments are required that instil in these groups confidence in the safety of a particular concept for the siting and design of a repository (the system concept), given the uncertainties that inevitably exist in its *a priori* description and in its evolution.

> *Confidence*
>
> To have confidence is to have reached a positive judgement that a given set of conclusions are well-supported.

In the field of radioactive waste disposal, particular difficulties are faced by those seeking to assess safety, and to achieve confidence in the findings of safety assessments, due to the uncertainties associated with the long time-scales over which safety must be evaluated and the limited possibilities for monitoring and intervention. Thus, even more than in other fields of engineering (e.g. reactor safety), confidence in safety rests on the quality of the chosen site and system design, and on the reliability with which the system can be assessed (at least such that radiological consequences are not underestimated). Furthermore, due for example to the different types and amounts of waste to be disposed of and the different host geological environments that are available, there is no possibility to

3. The term "demonstration of safety", as used in the present report, is not intended to imply a rigorous proof of safety, in a mathematical sense, but rather a convincing set of arguments that support a case for safety. A "convincing and indirect demonstration" of a sufficient level of safety is called for in the NEA/IAEA/EC international collective opinion of 1991 [NEA 1991].

standardise repository designs internationally, which increases the challenges facing those seeking to demonstrate quality and reliability.

Several national programmes are now progressing from an R&D phase towards a more focused, siting and development-and-demonstration phase, with its associated licensing processes. Consequently, regulatory organisations are approaching a period in which they may be called on to make, and explain licensing decisions. The actions of both implementing and regulatory organisations are increasingly subject to detailed public and political scrutiny. The subject of this report is the development of confidence in the evaluation of safety of deep geological repositories, which must be regarded as a topic of wide concern.

1.2 Aims

This report is written primarily for specialists involved in safety-assessment and site-characterisation programmes and in system design for deep geological repositories, although many of the considerations presented herein would also apply to near-surface disposal. It aims:

- to improve communication among these specialists by clarifying the concepts related to the development of confidence in the post-closure safety of a repository;

- to place, within a logical framework, the various measures that are employed to evaluate, enhance and communicate confidence.

The report thus focuses on technical measures that are employed to achieve confidence and, in particular, on the concepts and methods used to evaluate and communicate the confidence in the findings of safety assessments, and to enhance confidence where necessary. A viable repository project also requires confidence – on the part of the wider technical community, political decision makers and the general public – in broad, non-technical aspects of repository development. Detailed discussions of these aspects are considered to be beyond the scope of the report. They are, however, incorporated in the framework developed in this report (Chapter 2) and a few examples are given of measures to develop confidence in these non-technical aspects.

When communicating confidence in the findings of a safety assessment, clarity in the communication of the concepts involved is always required. There already exists a degree of "common understanding" of the meaning of many of the key concepts discussed in this report. *For the purposes of this report, however, precise and consistent definitions are considered to be essential*. Consistent with the aim of achieving clarity, selected key concepts are defined in boxes and in the body of the report. An index of definitions is provided in Appendix 4. It is acknowledged that some of these definitions represent a departure from usage in earlier NEA reports. For example, the definition of *performance assessment* is restricted to the application of methods, models and data that are contained within the *assessment basis*. This definition is far narrower than that of *safety assessment*, which includes the assessment basis, performance assessment and the evaluation of confidence in the safety indicated by the assessment (Figure 3).

The need for clarity in the technical aspects of confidence is demonstrated by the controversy that has surrounded the concept of the "validation", as discussed in the following box.

Validation

In recent assessment literature, much attention has been given to the "validation" of assessment models and databases [NEA 1994a, PESCATORE 1995, NEA 1996]. Validation has been identified as a process necessary to develop confidence in models and data, and hence is essential to confidence in overall assessment results.

Some repository programmes have used the term "validation" to mean suitability for the intended purpose within the staged process of decision making related to the licensing of a deep geological repository. These programmes take the view that many years will pass before a final case is made to support a decision to close the repository and that, at stages preceding closure, not everything needs to be, nor can be, known at the same level of detail. Rather, confidence must be built incrementally during the process of repository development and licensing.

The Oxford Dictionary of Computing [ODC 1986] offers the following definition of "validation" in its "verification and validation" entry:

> *Although a precise distinction is not always drawn, the verification aspect refers to the completely objective checking of conformity to some well-defined specification, while the validation aspect refers to a somewhat subjective assessment of likely suitability in the intended environment.*

This definition of validation is in line with the aim of safety assessment, which is to give broad support to a conclusion that possible impacts will not exceed certain acceptable limits, rather than to provide a precise description of system evolution. The definition is also consistent with the qualitative nature of the concepts of "confidence evaluation" and "confidence enhancement" used in this report and with the concept of "reasonable assurance". Rigorous criteria and procedures can be sought that provide "validation", in that they support and enhance confidence in likely suitability of a model or database in the intended environment through, for example, model testing and the demonstration of a scientific foundation for the knowledge base that underlies the analyses. Counter-indications to validity can also be sought. Lack of consistency and internal contradictions are clear signs of error. Lack of clarity is detrimental to confidence. There remains, however, a subjective, qualitative aspect of validation – in particular, the decision as to what and when is enough.

The subjective, qualitative aspect of validation has often been lost in definitions of the term that suggest that validation implies a rigorous proof of the correctness of model predictions. This view, expressed by some scientists working in areas where precise, quantitative prediction and accuracy in the supporting evidence are critical for the decisions being made, is often not appropriate for the safety analyst working in radioactive waste disposal who needs to draw on a broader tool kit of methods. Thus, the concept of incremental validation by the safety analyst is linked to decision making and is complementary to the concept used in other areas of applied science.

Given the lack of a single accepted definition of validation and the confusion that the use of this term can generate, and given the practical convergence, for safety-assessment purposes, of the concepts of validation, "confidence evaluation" and "confidence enhancement", the two latter terms are the preferred ones for use in this report.

In adopting a tutorial style, it is intended that the report should promote clear communications, which will, for example, favour constructive dialogue between implementers, regulators and other stakeholders. Such dialogue should, in turn, favour wider confidence in the licensing process.

Other waste management options, such as long-term surface storage, have been discussed in public and technical fora. Although the framework for confidence enhancement, evaluation and communication presented in the present report is tailored to the option of deep geological disposal, a similarly systematic approach to confidence in long-term safety should be imposed, irrespective of the waste management option that a national programme adopts.

1.3 Organisation of the report

This document links safety assessments to decision making in repository development; rationalises how a safety case is built; identifies and describes the role of confidence evaluation, enhancement and communication; and gives some examples of confidence-building procedures.

The discussion of the technical aspects of confidence evaluation, enhancement and communication is organised as follows:

- Chapter 2 outlines the stages of repository development, the associated decision-making process and the incremental development of a case for long-term safety.

- Chapter 3 gives a detailed description of the making of a safety case within a development stage, including the elements of a safety case and their iterative refinement. The role of the assessment basis, which provides the foundation for the safety case, is emphasised.

- Chapter 4 presents the methods by which the assessment basis can be modified with a view to achieving confidence enhancement.

- A summary and conclusions of the report are provided in Chapter 5.

Appendix 1 describes the various factors that constrain the way in which repository development proceeds. Appendix 2 outlines the steps that typically characterise the process of performance assessment. Appendix 3 gives examples of safety indicators that have been used in Germany. Appendix 4 is the index of definitions of terms as used in the present document.

2. THE INCREMENTAL DEVELOPMENT OF A REPOSITORY AND ITS SAFETY CASE

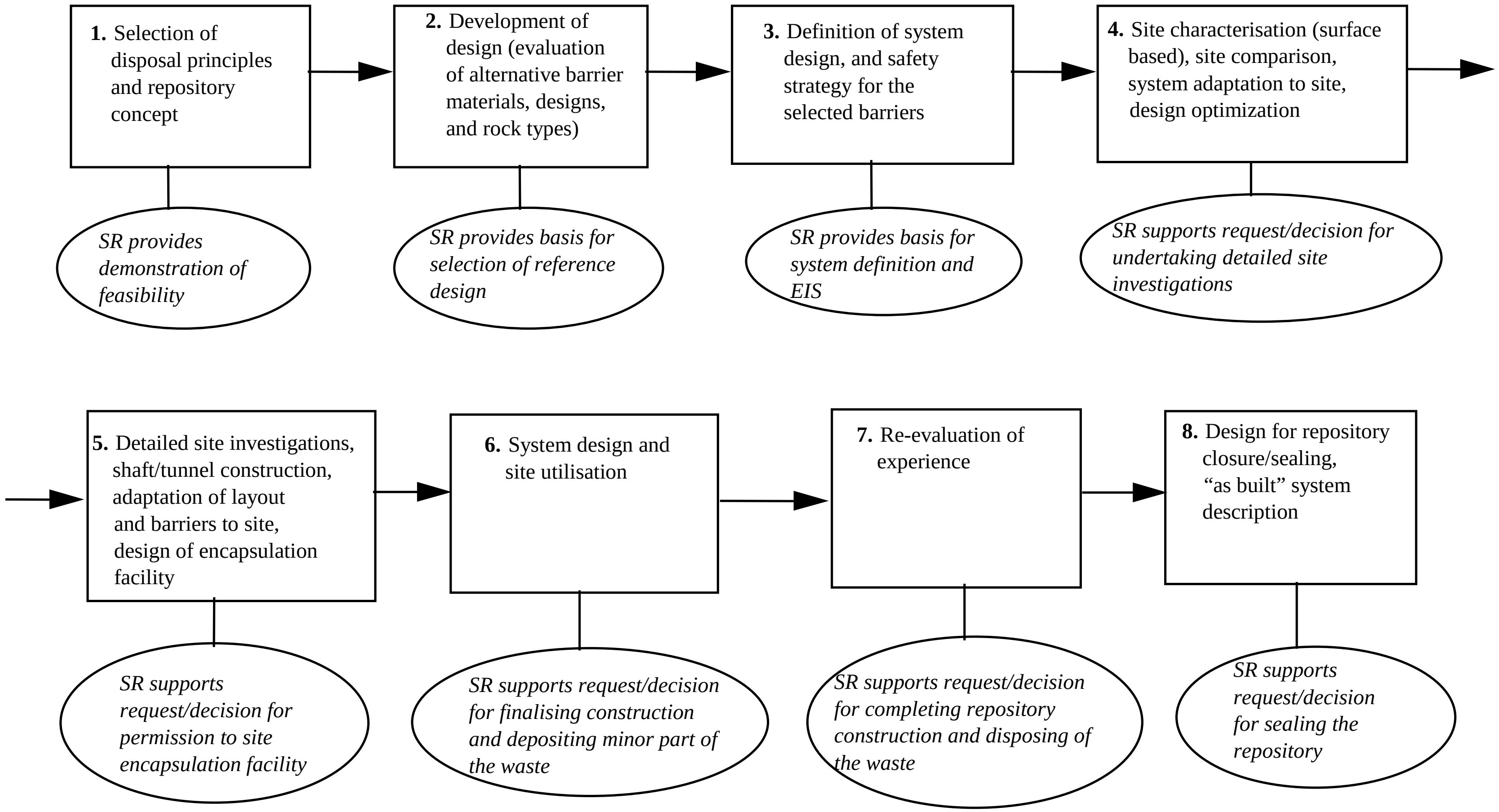
Development and licensing of a repository takes place in a number of iterative stages. In addition, a number of different organisations and groups participate in decision making. Chapter 2 outlines the stages of repository development and the associated decision-making process. The need for a flexible approach is discussed in Section 2.1. Technical and non-technical aspects of decision making in repository development are described in Section 2.2. The need for confidence on the part of decision makers is discussed in Section 2.3. Section 2.4 discusses the incremental development of a safety case through the course of a repository programme and Section 2.5 focuses specifically on the need for confidence in long-term safety. This sets the scene for a discussion of the making of a safety case and the evaluation of confidence in long-term safety in Chapter 3.

2.1 The need for a flexible approach in repository development

As illustrated in Figure 1 (an example from the Swedish programme), the development of a deep geological repository is characterised by several stages and, overall, requires several decades for completion. The long duration of the development process reflects, in part, the novelty and complexity of the tasks of developing a repository concept, evaluating its technological feasibility and long-term safety, developing the technology for implementation and finally constructing, operating and closing the repository.

It is accepted that the novelty and complexity of these tasks mean that detailed planning of the entire repository-development process at the outset of a project is not possible. Although discrete stages can be defined at the outset, detailed planning must proceed iteratively, as information and experience are acquired. In particular, information and experience acquired during the course of one stage can provide a basis for the decision whether to proceed with the next stage, to modify the development programme (perhaps returning to an earlier stage), or, in an extreme case, to re-assess the programme as a whole. Thus, a number of interdependent decisions regarding siting and design, safety assessment, site characterisation and research and development activities, are taken throughout the planning, construction, operation and, finally, closure of the facility. This *flexible approach* allows planning to be responsive to the accumulation of increasing data in site characterisation, to the findings of safety assessment, and to the possibility of changes in the constraints within which a programme must operate, such as the legal and regulatory framework that a country imposes (Appendix 1). A flexible approach means that alternative options are, where possible, kept open. It may, for example, involve designing a repository in such a way that future attempts to change the repository or to retrieve the waste are not impaired. Complete flexibility cannot, of course, be retained undiminished throughout the development process, since progressively firmer decisions must be taken in proceeding from one development stage to the next. Also, in order to preserve credibility, and confidence in the stage-wise approach itself, there must be an understanding, by all stakeholders, of what is to be broadly achieved at each step and what would be required, in terms of information and confidence, to make the step (see also Section 2.2).

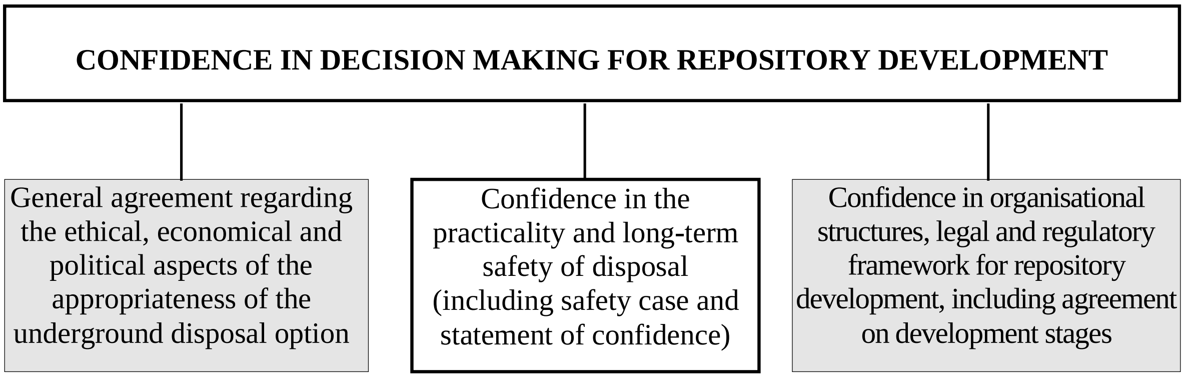
Figure 1. **The incremental process of developing a deep repository system (an example from Sweden) [SR = Safety report; EIS = Environmental Impact Statement]**



2.2 Technical and non-technical aspects of decision making in repository development

The decisions made in the course of a repository programme vary in that they are the responsibility of different organisations or groups. The decisions that are the responsibility of technical specialists and managers within an implementing organisation, and the regulatory bodies that oversee their activities, are likely to require technical arguments that give *confidence in the feasibility and long-term safety of the proposed concepts*. Other decisions may be the responsibility of political decision makers and the general public (e.g. in local referendums). These non-technical stakeholders also require confidence in the *technical aspects* of repository development, but this confidence may be based on less technical, more qualitative arguments.[4]

Figure 2: **Confidence in decision making for repository development rests on these basic elements**



In addition, the wider audience of scientists, politicians and the general public require confidence in *non-technical aspects* of repository development in order for implementation to be acceptable. Thus, with reference to Figure 2, additional elements contributing to confidence in decision making are:[5]

- **Confidence, on the part of the wider technical community, in the ethical, economical and political aspects of the appropriateness of the underground disposal option for radioactive waste.**

  A wide consensus within this community should be constantly maintained concerning the acceptability of deep geological disposal and, in particular, that it represents an ethical path (imposing a minimal burden on future generations) and an appropriate management of resources (the principle of "sustainable development"). These issues have already been

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4. Confidence of these groups in the technical aspects of repository development is likely, for example, to be closely related to the credibility of the implementing and regulatory organisations. This, in turn, is more likely to be achieved if support for the technical arguments of these organisations can be gained in the wider scientific community.
5. It is noted that obligations regarding these aspects are defined in the recently signed Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management [IAEA 1997b].

discussed [NEA 1994b, NEA 1995a], and are being discussed, among, for example, the decision-makers involved in repository development.

- **Widely held confidence (including public confidence) that the organisational structures, legal framework and regulatory review process provide a well-defined, logical and "credible" decision-making path.**

  A wide consensus should be developed that appropriate organisational structures have been implemented, with clearly defined roles for the implementer and regulator,[6] as well as appropriate interactions between the organisations and competent decision-makers within the organisations. Specific aspects are:

  (i) The basic principles of radiological protection (e.g. protection against potential exposure).

  (ii) The adequacy of the legal framework and regulatory procedures and criteria by which a repository would be either licensed or rejected, i.e., an incremental, stage-wise approach to repository development in which there is wide confidence.

  (iii) The value of "reasonable assurance" as a basis for decision making at all stages of repository development.[7]

  Some of these issues are being addressed, for example, by the IAEA within its RADWASS programme.

A few examples of confidence-enhancing measures regarding non-technical aspects are given in Table 1, but further consideration is taken to be beyond the scope of the present report. Confidence in the *feasibility* of a proposed concept is also important, and largely fits into the framework presented in the report, although it too is not discussed further. Rather, the report focuses on *confidence in the long-term safety of disposal* (Figure 2), on the part of decision makers within the relevant implementing and regulatory organisations.

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6. The respectives roles of the implementer and regulator vary from country to country. A role of the regulator is to define criteria, for use as a "measuring stick", against which to judge the safety case presented by the implementer. Another role of the regulator is to form a judgement as to whether sufficient confidence has been achieved that the criteria have been met. The role of the implementer is to provide good solutions to the problems of waste disposal. It is not generally the case that the implementer is required to demonstrate that a particular solution is the optimum that can be achieved, given that there will be competition for available resources from other areas that may be at least equally important.
7. "*... assessments with different levels of sophistication will be required at each decision point and this fact should influence how reasonable assurance of safety is to be understood at each decision point.*" [IAEA 1997a].

Table 1: **Some examples of measures to enhance confidence in broad, non-technical areas**

The ethical, economical and political aspects of the appropriateness of the underground disposal option for radioactive waste
Measures to enhance confidence
• Careful, incremental approach to decision making, with the possibility of reversing decisions (including, for example, design that facilitates retrievability).
• Wide debate on basic principles (public involvement, collective opinions of the NEA for waste management, IAEA safety fundamentals, etc.).
• Study of the existence and feasibility of alternatives to deep geological disposal.
Organisational structures in the legal and regulatory framework for repository development
Measures to enhance confidence
• Involvement of the scientific community via, for example, peer review and international collaboration, to ensure the technical competence of both the implementer and the regulator.
• Internal and external audits to ensure the adequacy of the management and structure of the implementer and the regulator, and their independence.
• Openness regarding the reasons for specific decisions, including the criteria by which license applications are judged.
• Accessible information – for example, publication in the open literature.
• The establishment of a well-defined licensing process, generally characterised by a series of decision points.
• Public involvement in the licensing process.
• International harmonisation in regulations, safety objectives, safety-assessment methodologies, time-frames, retrievability.
• Obligation of the implementer to prepare safety reports with a view to demonstrating safety, as well as compliance with regulations.

2.3 Confidence in decision making in repository development

Table 2 presents examples of project decisions within the organisation charged with the implementation of a repository, and decisions that are the responsibility of the regulator *and* the legislative bodies responsible for authorising progression from one development stage to the next.

Table 2: **Examples of decisions in the incremental development of a deep geological repository**

Examples of "project decisions"
• The adoption of a particular system concept (e.g. choice of host rock, choice of backfill or buffer material, choice of canister material) – e.g. Stages 1-3 in Figure 1. • The adoption of a particular safety strategy, e.g.: the focusing of resources to achieve realism in the representation of some phenomena while using conservative estimates for others – Stage 3 in Figure 1. • The submission of a license application to the regulator – e.g. Stages 4-8 in Figure 1. • Design refinements for the purpose of incorporating new knowledge, new safety functions, or general optimisation.
Examples of decisions that are the responsibility of regulators and legislators
• The acceptance, rejection or requirement for modification of an application for detailed investigations at a particular site – e.g. Stage 4 in Figure 1. • The acceptance, rejection or requirement for modification of applications to either construct or operate a repository – e.g. Stages 5-7 in Figure 1. • The decision to request more information from the implementer in advance of a regulatory decision.

Decisions are based on different types of supporting information or arguments, according to the nature of the decision to be made and the responsible organisation or group. In general, however, a positive decision requires *confidence* on the part of the decision maker, i.e. the decision-maker needs to have reached the judgement that a positive decision is well supported by relevant arguments. In particular, *the arguments must give sufficient confidence, or reasonable assurance,*[8] *to the decision makers within the relevant organisations that the decision is an appropriate course of action and consistent with applicable requirements and objectives, e.g., operational safety, flexibility of the disposal concept, post-closure safety, benefit to society, etc. In arriving at the decision, and in determining the level of confidence needed, the decision makers need to evaluate the risk and consequences of the decision proving to be incorrect.*

8. The meaning of the term "sufficient confidence", as used here, is similar to that of "reasonable assurance", as described and defined by the US Nuclear Regulatory Commission in [NRC 1983] and employed by the IAEA in [IAEA 1997a]. This concept is similar to that of "reasonable expectation", as used by the US Environmental Protection Agency in [EPA 1985].

The level of confidence required in the arguments that support a decision (and the risk and consequences of an incorrect decision) are dependent on:

- **The commitment of resources on the part of the implementing organisation that is required to proceed with the next stage of repository development.**

  Decisions with far-reaching implications, involving a large commitment of resources,[9] should be supported by a similarly high degree of confidence. For other decisions, such as minor modifications to optimise a design, confidence in the supporting arguments is less critical, since the commitment involved is relatively low.

- **The uncertainties that will inevitably exist at that stage.**

  A decision may prove incorrect if, for example, later analyses of a proposed repository indicate that the required level of long-term safety will not be achieved. The elements that contribute to confidence in safety, and the procedures followed establish these elements (including the treatment of uncertainty), must therefore be evaluated by the decision makers, in order to assess the prospects of achieving a facility with acceptable long-term safety.

- **The prospects for reversing a decision, should it prove incorrect (reversal would itself be a decision, requiring its own level of confidence).**

  In order to preserve credibility in the eyes of the regulator and of the public, the implementer must make clear that the commitment of resources involved at any stage is not so large that the decision to proceed could not be reversed should the level of confidence fall, due, for example, to the discovery of unexpected and negative features at a site.

If the level of confidence is judged to be sufficient, then the decision is likely to be positive. If the evaluated confidence is judged to be insufficient, then the arguments supporting the decision, and possibly the development strategy itself, must be re-assessed, in order that:

- **The commitment involved in progressing to the next stage is reduced.**

  The implementer may choose, for example, to introduce additional "project decisions", and thus increase the number of stages, so that the commitment required for any particular stage reflects the level of confidence that is judged to be attainable. This general approach is adopted, for example, in Sweden [PAPP 1998]. Specific examples are:

  – An investigation stage in an underground, in-situ laboratory, before the decision is taken whether or not to proceed with repository construction.

  – A phase of monitoring, between the end of the waste-emplacement stage and the decision to close a repository.

9. Such decisions generally represent discrete choices, such as the "project decision" to select a particular host rock and the decision to either accept or reject a license application.

- **Arguments can be formulated in which greater confidence can be placed.**

  This may involve, on the part of the regulator, a request for more information from the implementer and/or, on the part of the implementer, additional site characterisation and R&D to increase the level of understanding of phenomena relevant to a particular concept. It may also involve changes to the design and, in extreme cases, the abandonment of one site in favour of another.

The outcome of such re-assessments is itself a part of the decision-making process.

It is emphasised that, at a particular stage, having sufficient confidence does not imply that all the issues that affect repository planning and development have been resolved, but rather that these issues are not judged as critical in the decision to progress to the next stage and there are good prospects to resolve them in future stages. Thus, for example, in authorising progression to the next stage, a regulator or licensing organisation may still need to be convinced about the final acceptability of the project, and will, in subsequent stages, require more information from an implementer. *The perception that this is the case is important in maintaining public confidence in the independence of regulator or licensing organisation in their role as a "judge" of the acceptability of the project and supervisor of the licensing process.*

2.4 The incremental development of the safety case

Due to the prolonged period over which a deep geological repository should provide safety, the evaluation of long-term safety is a demanding task. At any stage in repository development, the case for long-term safety is based on the findings of a *safety assessment* and on information that supports confidence in those findings.

Safety assessment

Safety assessment is the evaluation of long-term performance, of compliance with acceptance guidelines and of confidence in the safety indicated by the assessment results.

Safety case

A safety case is a collection of arguments, at a given stage of repository development, in support of the long-term safety of the repository. A safety case comprises the findings of a safety assessment and a statement of confidence in these findings. It should acknowledge the existence of any unresolved issues and provide guidance for work to resolve these issues in future development stages.

Generic understanding of the factors relevant to long-term repository safety, as well as site- and concept-specific models and data, are initially limited and there will be many unresolved issues. Existing experience and understanding (from other repository programmes and from other fields of science and engineering) can only partially be drawn upon in order to develop the necessary understanding and analysis of relevant phenomena. Site characterisation and safety assessment activities therefore run in parallel to, and interact with, the step-wise planning and implementation processes (the flexible approach to planning and implementation, discussed above), with the *safety case* developed incrementally.

The process of incremental development should lead ultimately to a safety case that is adequate for licensing decisions; i.e. one that represents:

- A sufficient understanding of the phenomena that are critical to the safety of a repository (which may vary with time);
- A choice of site and design for which compliance with acceptance guidelines is relatively insensitive to the presence of remaining unresolved issues; and
- The capability to judge the level of safety provided by the proposed repository in a manner that does not underestimate consequences.

2.5 The need for confidence in the technical evaluation of long-term safety

The importance of the *safety case* in supporting decisions will vary from one decision to the next. For many (but not necessarily all) decisions, a safety case is one of several sources of information on which the decision is based.[10] *For a decision that relies heavily on confidence in long-term safety, the confidence in long-term safety must correspond to the confidence needed for the decision*. If other factors are also influential in making the decision (e.g. timing, public acceptance, budget constraints), then the confidence in the decision will be a weighted combination of confidence in the contributing factors.

As repository development progresses through successive stages, the task of achieving sufficient confidence in long-term safety does not necessarily become simpler, since, on the one hand, the implementer will strive to reduce unnecessary conservatism and, on the other, the decisions that are supported will tend to demand a higher commitment and therefore a higher level of confidence (e.g. the decision to accept or reject applications to construct, operate or close a repository). Thus, efforts may need to be made continuously to ensure that confidence in the evaluated safety (i.e. the safety indicated by the assessment and communicated in the safety case) remains sufficient to support the decision-making process.

The making of a safety case at a given development stage, which is itself an incremental process, forms the subject of Chapter 3. Confidence enhancement, both within and between development stages, is discussed in Chapter 4.

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10. For example, a decision by a hydrogeologist on the design of a site-characterisation programme to improve confidence in the understanding of the groundwater-flow regime will require different information regarding long-term safety and its evaluation than a decision by a programme manager on how to partition funds between site characterisation and safety assessment. This will again differ from the information needed for a decision by a programme director to seek approval to begin exploratory excavation.

3. THE DEVELOPMENT OF A SAFETY CASE

As discussed in Chapter 2, the safety case for a repository, at a given development stage, provides one set of arguments to support the decision to progress from one development stage to the next. In this Chapter, generic, broad steps of a typical, structured procedure to prepare a safety case are identified and described. Important decision points in the successful development of the safety case, are 1. following an assessment of safety, the decision by the implementer to compile and present a safety case; 2. the decision by the regulator and other stakeholders regarding the acceptability of the proposed safety case. The first decision is based on an evaluation of confidence, which is carried out as part of the safety assessment. A positive outcome for the second decision is facilitated by the provision, within the safety case, of a statement of confidence. Criteria and practical measures for evaluating confidence in the various elements that lead to, and constitute, a safety assessment are described, as well as the typical contents of a statement of confidence. It is remarked that a safety case must make explicit the steps that were taken to reach sufficient confidence in safety, and should indicate the residual uncertainties that need to be resolved at a later development stage.

3.1 Confidence cycles in the development of a safety case

The safety case for a repository is developed in a framework set by a number of practical and programme specific constraints, which may vary with time (Appendix 1). Specific aspects of the procedure for the making of a safety case may thus vary, both between repository programmes, and within a programme. The broad steps of a typical, structured procedure can, however, be identified (Figure 3).

Firstly, a safety assessment is carried out by the implementer. The safety assessment comprises:

- The establishment of an assessment basis, i.e. the strategy for the building of a safety case, the selection of a site and design, and the assembly of relevant information, models and methods to evaluate performance.

- The application of the assessment basis in a performance assessment, which explores the range of possible evolutions of the repository system and tests compliance of performance with acceptance guidelines.

- The evaluation of confidence in the safety indicated by the assessment.

The implementer must decide whether or not the assessment has been sufficiently successful, in terms of the confidence that it provides in long-term safety, to justify the compilation of a safety case. If the decision is negative, then the assessment basis must be modified with a view to confidence enhancement and a new assessment carried out. A positive decision is followed by:

- The compilation of the safety case, which involves the documentation of the safety assessment and a statement of confidence in the safety indicated by the assessment, including an indication of the strategy needed to deal with remaining issues in future development stages.

Following the compilation of the safety case, its contents are assessed by decision makers (the implementer, the regulator and/or others). The decisions makers may conclude either that there is sufficient confidence in safety, as presented in the safety case, to justify proceeding to the next repository development stage, or that the assessment basis should be modified and a new safety case compiled. An alternative strategy to modifying the assessment basis is to reduce the commitment involved in progressing to the next stage of repository development, as discussed in Chapter 2.

Figure 3**: A typical structured procedure for the development and compilation of a safety case, at any particular stage of repository development**

(i) ***Establish an*** **ASSESSMENT BASIS**

– define a safety strategy that describes a suitable approach to the building of a safety case,
– define the repository site and design (system concept),
– assemble the available understanding of the repository system, together with methods, models and data to evaluate its performance (assessment capability)

(ii) ***Carry out a*** **PERFORMANCE ASSESSMENT**

– evaluate repository performance for the assessment cases,
– assess compliance with acceptance guidelines
– carry out sensitivity analyses

(iii) **EVALUATE CONFIDENCE *in the calculated safety and modify, if necessary, the assessment basis***

Steps (i), (ii) and (iii) define the *SAFETY ASSESSMENT*

(iv) ***Compile a*** **SAFETY CASE**

– document the safety assessment
– state confidence in the safety indicated by the assessment
– provide guidance for further work in future development stages

Interact with decision makers and modify, if necessary, the assessment basis

This discussion indicates that decisions must be taken both during and following the development of the safety case, based on an evaluation of confidence. Also indicated is the key role of the assessment basis, which must be modified if the evaluated confidence is insufficient for the decision at hand. The development of the assessment basis also benefits from the experience gained in previous development stages.

The decisions, and the feedback to the assessment basis, are illustrated in Figure 4. As discussed in the following sections of this Chapter, the feedback loops, or confidence cycles, guide the development of the assessment basis, indicating those components of the assessment basis where refinements should be made in order to achieve a higher level confidence in the evaluated safety. The concept of confidence cycles reflects the current dynamic approach to achieving confidence, especially during the early stages of repository development, when information increases rapidly in quantity and quality. The iterative process of confidence evaluation and enhancement aims to achieve an assessment basis that provides sufficient confidence in long-term safety to support a positive decision.

3.2 Confidence to compile and present a safety case

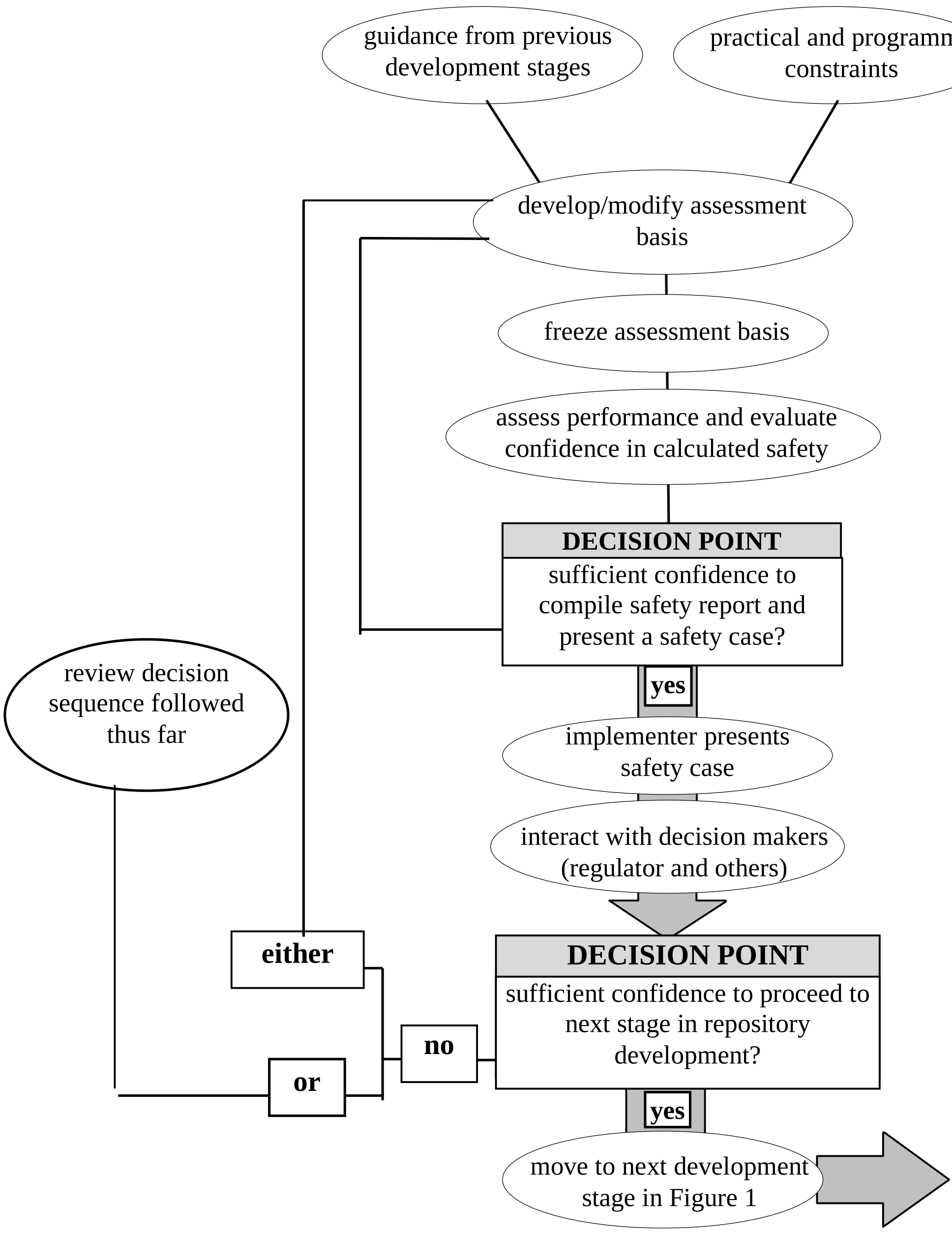
The innermost confidence cycle in Figure 4 leads to a decision to compile and present a safety case, and represents the process of safety assessment.[11] This cycle includes:

- The development and modification of the assessment basis (Section 3.2.1), followed by a temporary freeze of the assessment basis elements, which is necessary in order to carry out a traceable[12] performance assessment of the repository and its component parts.
- A performance assessment, including an assessment of compliance with acceptance guidelines and the evaluation of safety margins (Section 3.2.2).
- The evaluation of confidence in the safety indicated by the results of the performance assessment (Section 3.2.3).
- Decision making based on the evaluated confidence (Section 3.2.4).

The purpose is to show that there is sufficient confidence in the safety indicated by the assessment findings to justify the compilation and presentation of a safety case.

11. It should be recognised that Figure 4 gives a simplified representation of the process of repository development and of the role of performance assessment within that process. For example, performance assessments may be carried out as learning exercises that build competence, and not only to provide support for a specific decision within the repository-development process.
12. Traceability of the elements of the assessment basis is a pre-requisite for the decision making that follows the carrying out of the assessment.

Figure 4: **The iterative steps in the development of a safety case within a repository development stage. Proceeding beyond each decision point may imply an increasing commitment of resources.**



3.2.1 The assessment basis

The *assessment basis* is the combination of three elements which are developed in concurrence with one another. Namely:

- The safety strategy.
- The system concept.
- The assessment capability.

The present section is limited to a description of the three components of the assessment basis. A whole chapter, Chapter 4, is devoted to the development and modification of the assessment basis, with a view to *confidence enhancement*.

> *The safety strategy* defines the chosen approach to the building of a safety case, i.e. for achieving safety and for arguing the case for safety convincingly (demonstrating safety).
>
> *The system concept* comprises a description of:
>
> - the features of the disposal system (the site, the waste, the waste matrix, the engineered barriers, etc.);
> - the expected influences of these features with respect to safety and the performance objectives assigned to these features in selected situations (the "design basis");
> - the construction, operational and control procedures (as far as they impact on the feasibility of repository implementation and on long-term safety);
> - quality management to assure that the specifications of the disposal–system features (e.g. manufacturing specifications) are fulfilled.
>
> *The assessment capability* represents the means available to assess safety and comprises:
>
> - the identification and conceptualisation of safety-relevant features, events and processes (FEPs), through, for example, site characterisation;
> - the identification and development of appropriate assessment models, and coupling amongst models, and the compilation of the required data;
> - the implementation of the models, normally in the form of computer codes;
> - quality management to assure a proper application of the methodology, models, databases and codes in a performance assessment.

The development of the assessment basis is guided by the *safety strategy*. The latter may be considered to have two parts:

(a) The strategy for *achieving* safety (i.e. achieving a *robust system concept*).

(b) The strategy for *demonstrating* or "*proving*" safety, i.e. for achieving an *assessment capability* that can generate a performance assessment of adequate quality and reliability.

The first part, the achievement of a *robust system concept*, involves avoiding, or forcing to very low probability or consequences, most phenomena and uncertainties that could be detrimental to safety and its evaluation through the choice of repository site and design. Two categories of robustness can be distinguished, as described in the following box. Examples of both categories of robustness are given in Table 3.

Engineered robustness: Intentional design provisions that improve performance with respect to safety, in order either to compensate for known phenomena and uncertainties or to guard against the possible consequences of undetermined phenomena, are said to provide "engineered robustness" (e.g. – conditioning the waste with more durable matrices, over-dimensioning of certain barriers, changing the lay-out of the facility, etc.).

Intrinsic robustness: Intentional siting and design provisions that avoid detrimental phenomena and the sources of uncertainty through the incorporation of features that are simple, for which there is practical experience, and which are acted upon by processes that are well understood, are said to provide "intrinsic robustness" (e.g., the selection of a site and design that has the potential to provide long-term isolation, with features that are amenable to a credible performance assessment).

The second part, the achievement of an *assessment capability* that can generate a performance assessment of adequate quality and reliability, involves:

- The acquisition of adequate information relevant to the system concept.
- The development and application of adequate methods and models to assess this information.

Having developed an assessment basis, its components can then be temporarily frozen and a performance assessment initiated.

3.2.2 The performance assessment

In discussing performance assessment, it is useful to distinguish between:

- The actual performance of the repository, which can never exactly be known, due to uncertainties in its description and in the processes by which it evolves.
- The range of possible performance, due to the presence of uncertainty, that might be explored through the use of a performance-assessment method.
- Bounding performance estimates, that employ reasonably conservative arguments and assumptions where there is uncertainty.
- The required performance of the repository system or its components, as specified, for example, by acceptance guidelines.

Performance assessment: the analysis of the performance of the system concept, with the aim of developing confidence that the system will (or can be designed to) perform within acceptable bounds. *Acceptance guidelines:* Guidelines, that are usually programme-specific, as to the safety to be provided by a repository and how the safety should be judged. The guidelines may provide quantitative (e.g. performance indicators) or qualitative criteria (e.g. the types of scenarios, or families of scenarios, to be considered) against which to judge performance-assessment results. They may also provide indications as to the principles, features and procedures, or safety requirements, the adherence to which gives confidence in the assessment basis. *Performance indicators*: Quantitative measures of performance, that may include, for example, risk, dose, environmental concentration and radionuclide flux through the different barriers and to the biosphere, or a combination of these, with risk and dose regarded as the most fundamental to safety [ICRP, 1997].

Performance assessment is used to explore possible evolutions of the system concept (scenarios) in terms of their likelihood and/or consequences. Consequences are expressed as ranges of possible performance and/or bounding performance estimates, measured in terms of performance indicators. Bounding estimates are relevant where demonstration of compliance with acceptance guidelines is sought. Realistic estimates may, however, also be made, where, for example, a repository concept is being either developed or optimised and where technical principles for siting and design are being devised.

Table 3: **Examples of the use of engineered and intrinsic robustness to enhance safety margins and to reduce uncertainty and sensitivity to uncertainty**

Examples of engineered robustness
The use of several long-lasting barriers makes it possible to limit the consequences of one of the barriers performing significantly worse than expected, particularly if the barriers are designed to minimise the likelihood of common-mode failure.
The conditioning of waste in a homogeneous and stable matrix, manufactured in accordance with strict quality criteria, considerably reduces the risk of rapid release of radionuclides in the case of a disruptive event. This procedure also enhances the robustness with respect to the possibility of hydrogeological short-circuits and human intrusion. A cost (detriment)/benefit analysis may be required to show that the disadvantage of extra processing and handling is outweighed by the benefits of the improved waste-form characteristics.
The backfilling of access routes and the use of markers as a measure to guard against future inadvertent human intrusion.
The physical separation of waste into sets of packages of limited size to limit the effects of a single package performing poorly.
The use of institutional surveillance (for a limited time).[13]

13. Institutional surveillance (even for a limited time) only provides a line of defence if accompanied by plans for action or remediation if problems are identified.

Table 3 (continued): **Examples of the use of engineered and intrinsic robustness to enhance safety margins and to reduce uncertainty and sensitivity to uncertainty**

Examples of intrinsic robustness
The use of materials for which possible alterations are determined by well understood mechanisms.
The use of deep sedimentary layers with self-healing properties that ensure the closure of any natural or repository-induced fractures that may occur. Such environments could, therefore, be regarded as robust with respect to the possibility of long-term hydrogeological short-circuiting.
The positioning of the repository deep down gives robustness with respect to uncertainty related to future underground workings.
The siting away from resources of exceptional interest.
The use of a geological formation for which the past history is uneventful and can be explained over a much longer period than that considered for the safety assessment of a disposal facility. Such an environment could be regarded as robust with respect to uncertainty in the evolution of the system (possibility of significant instability of a natural origin).
The choice of sites with a suitable geochemical environment (reducing Eh conditions) at the repository level, with the aim of achieving low solubility of most radionuclides, can enhance the robustness of the system with respect to uncertainty in the evolution of the local chemistry and with respect to possible hydrogeological short-circuits.
The choice of sites that display long-term geological stability and are "simple", meaning that they are comparatively easy to characterise.
The choice of sites located in regional recharge areas, in order to provide long radionuclide transport paths, favouring the attenuation by decay of the release of safety-relevant radionuclides.
The selection of a host rock that creeps (salt).
The use of a host formation (geological structure) that allows flexibility in the final positioning of the repository and which can be judged to be robust with respect to the possibility of subsequent detection of significant localised geological shortcomings (e.g. major faults).

The performance assessment, by evaluating the likelihood or consequences of relevant phenomena, and taking account of the ranges of uncertainty in models and data, provides a test of the robustness of the system concept. In particular, the performance assessment enables an evaluation to be made of:

- The safety margins that are available with the current assessment basis.

- The phenomena, model assumptions and data to which the performance evaluated in the assessment is most sensitive, within the identified ranges of uncertainty.

Typical steps in the carrying out of a performance assessment are described in Appendix 2. Briefly:

- A set of individual performance-assessment cases ("envelope scenarios") is established, and qualitative arguments or quantitative methods are developed to analyse those cases in terms of their consequences, their likelihood of occurrence, or both.

- The analysis is carried out and the results evaluated in terms of their implications for safety. Such an evaluation may be seen as an assessment of the adequacy of, and confidence in, the factors underlying the performance-assessment calculations, i.e. a part of the evaluation of the confidence in the assessment basis.

The characteristics of system concept will change over time, and the extent to which such changes can be predicted varies between the different elements of the system, according to the uncertainties that affect those elements.

Some uncertainties are amenable to quantification and reduction, whereas others may not be. Examples of the latter are uncertainties regarding:

- Inadvertent human intrusion (although the likelihood of this event can be reduced by appropriate site selection).

- The evolution of the surface environment and the relationship between dose and effect for (diverse) individual human beings.

Rather than attempting to model in detail, or assess the likelihood of, these aspects of the system, a performance assessor may choose to acknowledge that uncertainties make this impractical and to treat the corresponding part of the repository system in a stylised or simplified manner. The performance assessor makes a set of assumptions regarding these aspects, based on, for example, expert elicitation and, where this is available, international consensus. These assumptions may be regarded as a part of the assessment capability. Examples are:

- The definition of a set of stylised human-intrusion scenarios.

- Stylised biospheres and the "standard-man" assumption for the dose-effect relationship.

Such stylised treatments should be traceable, transparent and invoke as few arbitrary assumptions as possible.[14] The acceptability of stylised treatments cannot be decided by the performance assessor alone, although the performance assessor may contribute with suggestions on how to treat such situations. If results for comparison with regulatory criteria are being calculated, then the regulator will judge whether a stylisation is acceptable or not [NEA 1997]. Confidence in the safety indicated by the assessment need not be compromised provided that the documentation clearly acknowledges that these assumptions have been made and that, due to the presence of irreducible uncertainties, the results of the assessments are to be viewed as indicators of system behaviour based

14. The consequences of alternative assumptions regarding the biosphere can be explored using stand-alone biosphere models, and can be used to assess whether the benchmark models are sufficiently conservative with respect to the distribution of potential doses.

on these assumptions, rather than as predictions of consequences that will actually occur in the future (ICRP 1997).

3.2.3 Evaluation of confidence in the safety indicated by an assessment

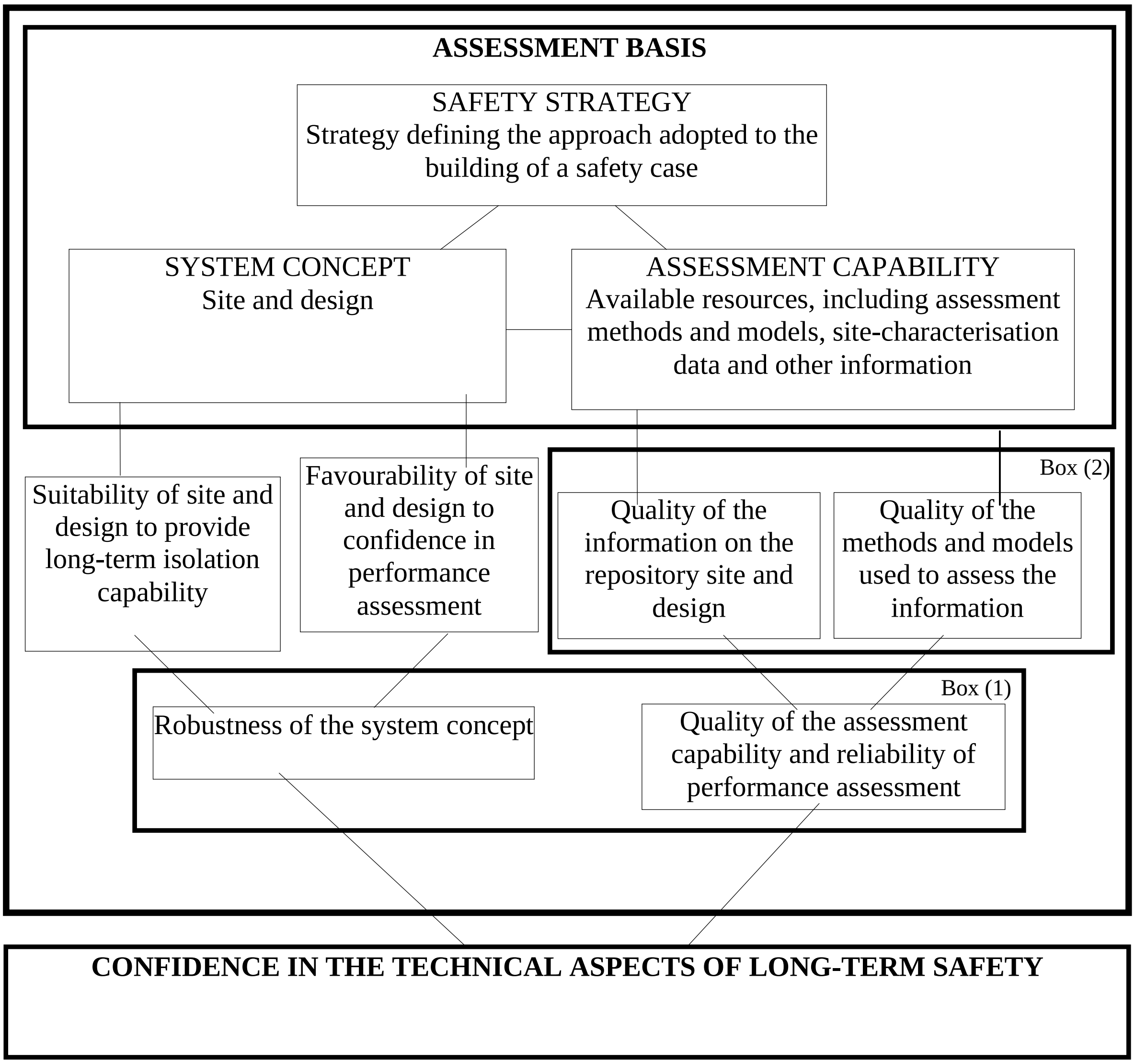
3.2.3.1 General aspects of confidence evaluation

An evaluation of confidence in the repository safety, as indicated by the findings of a performance assessment, is a necessary component of a safety assessment and provides essential input to a safety case. Confidence in long-term safety rests principally (see Figure 5) on an evaluation of:

- The robustness of the system concept (Section 3.2.3.2).
- The quality of the assessment capability and the reliability of its application in performance assessment (Section 3.2.3.3).

It has already been noted that the development of the assessment basis is subject to various programme constraints, some of which are intended to increase confidence in the final choice of a site and design for the repository (Appendix 1). *Consideration of the constraints that have led to the adoption a particular system concept and assessment capability (the "historical perspective") is thus also a part of the evaluation of confidence.*

Figure 5: **The elements to be considered in the evaluation of confidence in long-term safety**



3.2.3.2 Testing the robustness of the system concept

Testing the robustness of the system concept includes:

- The confirmation that appropriate criteria and procedures are observed.

The system concepts (sites and designs) considered by different national programmes vary according, for example, to the potential host rocks that are available and the characteristics of the wastes. Many common considerations, however, underlie the various principles, guidelines and procedures that aim to ensure robustness, by favouring safety and minimising uncertainties and/or the effects of uncertainty on safety.

Evaluation of confidence in the robustness of a system concept involves the confirmation that appropriate principles, guidelines and procedures are observed. Examples are presented in Table 4, along with their rationale.

Table 4: **Examples of principles, guidelines and procedures to be considered for confidence evaluation in the *robustness of the system concept* [quotes are taken from ICRP-64 (ICRP 1993)].**

Principles	***Rationale***
The adoption of multiple safety provisions, giving rise to a robust disposal concept, in which either uncertainties are avoided or safety can be demonstrated in the presence of remaining uncertainties. This includes the multi-barrier concept, in which over-dependence on any single safety provision is avoided.	*"low overall probabilities of failure are most easily achieved by a combination of independent protective layers such that the probabilities of failure are multiplicative"*
The adoption of a flexible strategy to design development and improvement in order to ensure efficient use of the safety potential of the host rock (e.g. "design-as-you-go").	This strategy acknowledges that some uncertainties in the characteristics of geological and hydrogeological structures can be most efficiently resolved by reliable investigation methods, applied during the construction of the repository.
"design, construction and operation of the repository should be based on sound engineering principles and practice"	*This principle aims to make full use of scientific knowledge and engineering experience.*
Guidelines	***Rationale***
Guidelines related to the characteristics of a site, e.g. a site that is structurally simple and/or simple with respect to processes and events – including geological events and possible inadvertent human intrusion.	Select a site that is easy to characterise, with characteristics that are favourable to safety[1] and amenable to performance-assessment modelling, with little uncertainty and little susceptibility to perturbing events and processes – the aim, however, is to select a suitable site, rather than "the best" site.

Table 4 (continued): **Examples of principles, guidelines and procedures to be considered for confidence evaluation in the robustness of the system concept**

Exclusion guidelines/criteria for a site and for zones within a site, e.g. recent volcanism, exclusion zones around geological features with unfavourable properties, regional zones of weakness.	Avoid constructing the repository at a site, or in a zone within a site, that is prone to events and features that could compromise safety – geological stability is an indicator of safety.
Guidelines/criteria related to waste conditioning, e.g. prohibition of liquid waste forms, use of a stable waste matrix, use of a long-lived container.	Ensure prolonged containment in, and slow release from, the engineered barriers. This reduces the effects of uncertainties in the modelling of radionuclide transport in the geological barrier, especially in the initial time period of high activity.
Guidelines related to tunnel excavation, e.g. adopt drilling methods to minimise damage.	Avoid hydrogeological "short circuits" related to excavation damage.
Guidelines related to the design basis, e.g. a minimum depth for the repository may be specified; a site may be sought that is larger than the minimum necessary; the possibility for retrievability and monitoring may be incorporated in the design.	Use the host rock effectively to provide safety, flexibility in case of unexpected features and public reassurance (likely to be country-specific).
Procedures	***Rationale***
Peer-review procedures for decisions regarding siting and design.	Use fully the current state of knowledge in relevant fields and minimisation of the possibility of errors.
Quality-assurance procedures for site-characterisation, waste and container fabrication, repository construction and operation.	Minimise the likelihood of defects and errors.

Note (1): A source of confidence in safety could, for example, be the non-potability (salinity) of the groundwater to which any radionuclides released from the repository would be transferred, as is the case at the Waste Isolation Pilot Plant (WIPP).

- The use of performance assessment as a test of robustness across a range of "envelope scenarios"

A performance assessment considers the evolution of the system concept for a range of cases or scenarios (Appendix 2). The likelihood of occurrence of particular scenarios may be evaluated, either quantitatively or qualitatively. If scientific understanding is adequate, the consequences of the scenarios are evaluated in terms of performance indicators and compared to acceptance guidelines. The sensitivity to various sources of uncertainty is also considered. In this way, performance assessment tests whether, for a given system concept, phenomena (and uncertainties) that could be detrimental to safety are avoided, or forced to very low probability or consequences, i.e. whether the system concept is robust. This is one element contributing to confidence in long-term safety.

For a particular scenario, a conclusion that is favourable in terms of confidence in long-term safety would be, for example, that:

(a) Consequences are not expected to occur before a given time.

There is confidence that the consequences of a scenario will not be encountered within a certain time interval (e.g. those associated with glaciation within 10^4 years and those associated with severe geological disruption within 10^6 years).

(b) There is confidence that the consequences and likelihood remain below (or within) acceptance guidelines across the ranges of model and parameter uncertainty.

Understanding of the scenario is judged to be adequate to bound the consequences. The calculated consequences comply with acceptance guidelines.

(c) Consequences at or above acceptance limits have been identified, but there is confidence that the likelihood of such a scenario is very low.

Understanding of the scenario is judged to be adequate to bound the consequences and to assess likelihood. In some cases, the consequences are above certain acceptance limits, but, due to the low likelihood of these cases, the corresponding risk is acceptably low (e.g. the instantaneous release of 129I – for most system concepts, this would require the unlikely failure of several safety functions; furthermore, in this particular case, the consequences would constitute only a limited hazard to human health).

(d) Consequences at or above acceptance limits have been identified, but consequences unrelated to the presence of the repository are deemed to be the more important.

Understanding of the scenario is judged to be adequate and high potential consequences may occur, but the presence of the repository does not dominate the overall consequences to human health (e.g. meteorite impact, nuclear war).

Less favourable possible conclusions would be that:

(e) Consequences at, or above, acceptance limits have been identified; the likelihood of such a scenario is not known at present.

Either understanding of the scenario is judged to be inadequate or models and data are known to be unreliable in some circumstances. Such “open issues” may, in some cases, be addressed by changes to the assessment basis (e.g. further R&D work). In other cases, the uncertainties in completeness, models or data may be concluded to be irreducible and are treated, for example, by simplified, stylised representations that are agreed upon by implementers, regulators and other stakeholders (e.g. human intrusion, future lifestyles, and other “what-if” events and the discovery, at later times, of new laws of science that would falsify current models).

(f) Consequences at, or above, acceptance limits have been identified and the likelihood of such consequences is judged to be significant.

Understanding of the scenario is judged to be adequate and there is, therefore, confidence that the problem can be bounded. Performance calculations based on this understanding give results that do not comply with acceptance guidelines. Changes to the assessment basis are required to improve the performance of the system concept.

There may exist cases where the assessment is more qualitative (though perhaps involving scoping calculations to bound possible consequences). For all cases, the use of independent evidence, such as observations of natural systems and analogues, may play a role in supporting the findings of the assessment (i.e. other lines of quantitative, semi-quantitative or qualitative reasoning that support the performance and robustness of the system concept). Examples of supporting observations of natural systems in German studies are given in Appendix 3.

The existence of cases for which high potential consequences have been identified, and for which the likelihood of occurrence cannot be shown to be low, does not necessarily preclude the compilation of a safety case at a particular development stage. The safety case must, however, give confidence that the safety strategy will deal adequately with such cases at a later stage; i.e. that confidence in long-term safety can ultimately be achieved.

3.2.3.3 Evaluation of confidence in the quality of the assessment capability and the reliability of its application in performance assessment

The evaluation of confidence in the quality of the assessment capability involves an assessment of:

- **The quality of performance assessment methods and models**

The performance-assessment methods and models adopted may also differ among national programmes, since they are developed to suit site- and design-specific needs. Many common considerations, however, underlie the features of the methods and models that should be sought in order to ensure confidence in their quality. Evaluation of confidence in involves the confirmation that appropriate features are implemented that ensure the quality of:

(a) the approach adopted to performance assessment;

(b) the level of understanding of the safety-relevant features, events and processes;

(c) the conceptual and mathematical models and computational tools that are available.

Examples of these features are presented in Table 5.

- **The quality of information on the repository site and design**

  Confidence in the quality of information on a repository site and design is achieved if the data are, where possible, supported by a wide range of evidence from experiment and site investigation[15] and quality assured to minimise the possibilities of errors.

Table 5: **Examples of features that are to be considered in the evaluation of confidence in the *quality of performance assessment* methods and models**

Features of the assessment capability that ensure adequacy of:	***Rationale***
(a) the approach adopted to performance assessment	
The placing of emphasis on components of the disposal concept that can confidently be expected to contribute to safety, at a particular development stage.	At any stage of development, uncertainties are likely to be more significant is some aspects of the system concept than others. For example, the robustness of the copper canisters is emphasised in the SKB concept, and the robustness of the salt-dome host rock is emphasised in the BfS concept. In many cases, the retention function of the geological barrier is considered only within a relatively well-characterised, “respect distance” of the repository.
Use of a small number of stylised treatments (e.g. of human intrusion and the biosphere) where there are uncertainties that are, in practice, impossible to quantify and to reduce, thus decoupling this part of the analysis from the rest of the performance assessment.	This approach (in the case of biosphere): – allows performance assessors to concentrate on the analysis of aspects of the disposal system responsible for ensuring isolation and containment of waste; – allows biosphere assessors to examine biosphere uncertainties, less constrained by the idea that the models they develop will be used directly in compliance calculations. More generally, the approach facilitates exchange between the implementer, regulator and the public, by isolating and allowing separate illustration and discussion of non-quantifiable and irreducible uncertainties.

15. Where uncertainty remains, parameter values for models are typically chosen such that performance assessment calculations either bound the possible outcomes of a scenario, or do not underestimate the consequences.

Table 5 (continued): **Examples of features that are to be considered in the evaluation of confidence in the *quality of performance assessment* methods and models**

Consideration of an appropriate range of envelope scenarios (each envelope representing a family of scenarios) for the evolution of the system.	No safety-relevant scenarios should be overlooked; i.e. an adequate coverage of the range of uncertainty in possible evolutions of the repository system should be ensured with due account taken of the description of the system concept at the stage of development under consideration and the corresponding uncertainties.
Consideration of alternative conceptual models.	The importance, in terms of safety, of uncertainties in the representation of an envelope scenario should be evaluated.
Consideration of parameter uncertainty.	The importance, in terms of safety, of uncertainties in the parameterisation of assessment models should be evaluated (e.g. through sensitivity and uncertainty analysis, carried out either deterministically or through stochastic sampling).
(b) the level of understanding of the safety-relevant features, events and processes (FEPs)	
Understanding and completeness of FEPs that describe the system concept.	All safety-relevant FEPs should be discussed with regard to their conceptualisation; all FEP-relevant data should be considered.
(c) the conceptual and mathematical models and computational tools that are available	
Formulation, where possible, of conceptual models of relevant processes, the applicability of which is supported by a wide range of independent evidence.	The quality of the modelling of each envelope scenario should be ensured, in terms of the completeness of features, events and processes included within that envelope scenario and the reliability of the conceptual model by which they are represented in its application to a specific disposal concept (for instance, through comprehensive testing, consistency with analogues or through its foundation on fundamental laws or scientifically-accepted principles).
The use of "reasonably" conservative assumptions in performance assessment, where there is uncertainty (and where it is possible to show that the assumptions are, indeed, conservative).	A well-defined and rational assessment procedure should be followed, such that the effects of uncertainties on the conclusions of the assessment, in terms of safety, are minimised (for instance, one may choose not to take credit for FEPs that are favourable but uncertain – e.g. neglecting the favourable processes of dispersion, decay, and retention during transport through poorly characterised parts of a repository host rock).

Table 5 (continued): **Examples of features that are to be considered in the evaluation of confidence in the quality of performance assessment methods and models**

Development of appropriate assessment models and parameterisation.	The conceptual models and datasets may need to be simplified in order to perform assessment calculations; the consequences of such simplification should be shown to be insignificant or to give rise to conservative results.
Use of codes, that solve the equations for the mathematical representation of the conceptual models, that are verified (e.g. through comparison with analytical solutions and independent codes).	Mathematical models and computing codes must be shown to be numerically accurate and without error, within the bounds that they will be required to operate (benchmarking provides a means of verification).

Furthermore, an evaluation of confidence is required in:

- **The reliability of the application of methods, models and data in performance assessment**

Confidence in the reliability of the application of methods, models and data in performance assessment can be achieved through procedures, examples of which are given in Table 6.

Table 6: **Examples of the procedures that are available to evaluate confidence in the reliability of the application of methods, models and data in performance assessment**

Procedures	**Rationale**
Quality assurance procedures for the analyses that have been performed, including peer-review procedures.	Full use of current state of knowledge in relevant fields; minimisation of the possibility of errors and omissions in the scenarios, models, data and calculations.
Use of independent evidence (e.g. natural analogues).	Provides overall confidence in the "reasonableness" of assumptions underlying the calculations (see Table 8 for examples).
Demonstrate a broad understanding of the results (e.g. through the use of simplified models of key processes).	Provides overall confidence in the "reasonableness" of calculational results.

3.2.4 Decision making based on the evaluated confidence

Having evaluated confidence on long-term safety through the process of safety assessment, i.e. having assessed:

- the robustness of the system concept; and
- the quality of the assessment capability and the reliability of its application in performance assessment;

and having considered the constraints that have led to the adoption of a particular system concept and assessment capability (the "historical perspective"), the decision maker (the implementer in this case) must judge whether confidence is sufficient to proceed with the compilation and presentation of a safety case. Broadly, this will be the case if either the range of possible performance (if this is known), or conservative performance estimates, indicate a higher degree of safety than that required for the decision. If the range of possible performance, or conservative performance estimates, are judged to be insufficient, the elements of the assessment basis must be modified,[16] as discussed in Chapter 4, and the confidence cycle repeated, in order to achieve enhanced confidence.

3.3 Confidence to proceed to the next development stage

Should the safety assessment prove to be satisfactory, the implementer may then:

- compile a safety case, which may include documentation in the form of a safety report (Section 3.3.1);
- interact with external reviewers and decision makers responsible for authorising progression to the next development stage, including, regulatory bodies and other decision makers (Section 3.3.2);

in order to allow

- decision making based on the confidence in long-term safety communicated in the safety case (Section 3.3.3).

These steps are part of the outermost confidence cycle in Figure 4, the purpose of which is *to establish sufficient confidence to support progression to the next development stage*. It is understood that progression to the next stage may not necessarily be judged to be advisable, and that an alternative strategy is to review and revise the decision sequence followed thus far in repository development. This possible outcome of the confidence cycle is also represented in Figure 4.

16. The assessment basis must also be modified if the system concept proves not to be amenable to performance assessment. That is, the site and design must be chosen such that it is possible to acquire the necessary data and to model their performance. If this possibility is compromised, then the site and/or design must be modified.

3.3.1 The compilation of the safety case

3.3.1.1 Elements of the safety case

The decision to progress from one repository-development stage to the next is normally supported by a documented safety case and, when required, the approval of this case by the regulator or other decision makers. For such key decisions, a successful safety case should, in general, include:

- a description of the status of development of the assessment basis and the performance-assessment findings and an evaluation of confidence in the safety margins indicated by the findings;
- a description of the approaches adopted to achieve confidence and a formal statement of that confidence;
- feedback to the assessment basis for future development stages and a confirmation of the safety strategy;

within a system of documentation that is adequate in terms of:

- completeness;
- transparency; and
- traceability of the results, via a chain of decisions and calculations, to their sources.

Such a system of documentation facilitates the evaluation of confidence (e.g. by peer review and review by regulators) and thus promotes acceptance by the scientific community and by stakeholders, including the politicians and the public.[17]

3.3.1.2 Description of the safety assessment and evaluation of confidence

The description of the status of development of the assessment basis and of the performance-assessment findings (that together constitute the safety assessment) should provide a "trail of evidence" on which findings are based. Concerted and documented efforts should be made to identify all sources of uncertainty, thus providing insights into the features that provide safety and, ultimately, enhancing confidence in the quality of the safety case.

Included should be:

- a discussion of the components of the repository system (the functions of which are often coupled) in terms of their contribution to safety;

17. Interaction with reviewers can be assisted by adopting a system of documentation, the structure of which remains constant with time. The aim is to give reviewers a "historical perspective", enabling them to understand the reasons for the changes that occurred during successive development stages. SKB has recently proposed a reference structure to their safety reports [SKB 1995].

- a full description of the practical methods that have been implemented to avoid, characterise and, if necessary, reduce uncertainties or their impact on the safety assessment;

- the calculational results themselves, which should be fully disclosed and subjected to quality-assurance and review procedures;

- an identification of the assumptions and uncertainties that contribute most to the residual lack of confidence regarding safety;

- an indication of the possibilities, if any, to further reduce them (an evaluation of confidence in the achievability of the required safety);

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

In the case of the components of the repository system, highlighting, within the documentation, the connections between safety and the role of the various barriers within the multi-barrier concept is a practical and useful approach for improving these aspects and demonstrating that safety can be achieved. It also heightens the role of safety assessment as a support to decision making, rather than an academic exercise in analysis, or an analysis only to show compliance with regulatory targets.

It can also be useful to place the findings of a performance assessment in a wider context, and express them in a form that is tailored to the intended audience, that may include laymen and technical audiences outside the waste-disposal field. For example, in the Kristallin-I safety assessment of a high-level waste repository in Switzerland, a "Results in Perspective" report was prepared, in which the doses and associated risks arising from the repository were compared with doses and other forms of radiation (e.g. terrestrial, cosmic, man-made), and with risks associated with toxic materials (e.g. from smoking), ordinary illness and disease, and everyday behaviour that has associated hazards (e.g. flying or driving) [NAGRA 1994].

3.3.1.3 Description of the approaches adopted to achieve confidence and formal statement of confidence

The approaches used to achieve confidence should be presented within the framework of the logical structure of repository development. This is necessary in order to ensure transparency, both in the choice of methods and in the balance between them. The discipline that this involves itself enhances confidence in the quality of the safety case.

> *Statement of confidence*
>
> A statement of why the intended audience, and, in particular, decision makers, should have confidence in the prospect of achieving a facility with acceptable long-term safety.

The notion of a formal statement of confidence, at specific important points in the repository development process, is introduced specifically to indicate the types of argument that should be included in a safety case to explain how confidence has been evaluated and enhanced to a degree that justifies proceeding to the next development stage. The confidence statement should thus evaluate the strength of arguments on which the findings of the safety assessment are based.[18] It should, for example, convey confidence that:

- all relevant data and information, together with their associated uncertainties, have been given consideration;
- the models used have been adequately tested;
- a well-defined and rational assessment procedure has been followed;
- results have been fully disclosed and subjected to quality-assurance and review procedures.

Furthermore, the statement of confidence should be formulated in a manner that is helpful to decision makers. In particular, the decision maker needs to know that:

- all identified[19] safety-related issues that are important for the decision under consideration at the current development stage have been addressed,
- the safety strategy is appropriate to handle remaining, not-fully resolved safety-related issues, during future stages.

Thus, the statement of confidence should provide assurance that the decision to be made is not unduly affected by uncertainty.

3.3.2 Interaction with decision makers

In general, the safety case compiled by an implementer will be presented periodically to the regulator for review and, ultimately, to support license applications. In addition, however, the regulator, and stakeholders, should have a broader role in the iterative development of the safety case. Stakeholders can, for example, provide input regarding the range of scenarios to be considered and the definition of reference biospheres. There is, furthermore, a continual need, throughout the iterative refinement of the assessment basis and during the process of performance assessment, for the implementer and regulator to inform each other concerning their views and activities. For this reason, a transparent system of internal record-keeping for decisions made by the implementer can be invaluable. The regulator may, for example, wish to be informed by the implementer about the reasoning behind the implementer's decisions. In addition, through the formulation of criteria, principles, features and technical and managerial principles, the regulator may provide guidance as to what will be considered an acceptable safety strategy, system concept and assessment capability. The degree of formality of this interaction is, however, likely to be country-specific.

Although regulatory decisions, and other decisions that are made externally to a repository project, e.g. by funding agencies or legislative bodies, are supported by the safety case made by the implementer, other considerations are also relevant. For example, the decision maker may have to

18. The "trail of evidence" that supports the safety-assessment findings should therefore appear in the documentation of the assessment.
19. The method used to identify safety-related issues will be specific to the assessment methodology adopted.

judge the competence of the implementer to carry out the proposed safety strategy and thus resolve any remaining safety-related issues. Thus, although the effective presentation of the safety case is an essential part of the decision-making process, some decisions are not solely based on the technical information developed included in the safety case. Measures to enhance confidence in broad, non-technical areas are discussed in Chapter 2.

3.3.3 Decision making based on the safety case

If the outcome of the interaction with decision makers does not lead to a consensus on acceptability, then it may be necessary to make further iterative changes to the assessment basis, or even to review the decision sequence followed thus far. Conversely, following a favourable review, the experience from this confidence cycle provides guidance for the next stage of repository development (Fig.4). In any event, in arriving at the decision, and in determining the level of confidence needed, the decision makers should evaluate the risks and consequences of the decision proving to be incorrect (see Sect. 2.3).

4. CONFIDENCE ENHANCEMENT THROUGH THE MODIFICATION OF THE ASSESSMENT BASIS

Chapter 3 indicated that, when a need for confidence enhancement in the evaluated long-term safety is identified, this requires a re-evaluation and modification of the assessment basis. This Chapter describes measures that aim to enhance confidence in long-term safety by increasing the intrinsic safety offered by the system concept and by increasing the quality of the assessment capability, and the balance between these measures that must be provided by the safety strategy.

4.1 Considerations to guide confidence enhancement

Modification of the assessment basis, with a view to confidence enhancement, is limited by the practical and programme constraints[20] listed in Appendix 1 and is guided mainly by specific factors (Figure 6). The constraints on modification are of a practical or programmatic nature, while guidance for modifications to the elements of the assessment basis is given through the following factors:

i) *Experience from previous development stages.*

ii) *The evaluated confidence in the safety indicated by an assessment (the inner confidence cycle in Figure 4).*

The evaluated confidence gives an indication of the need for enhanced robustness of the system concept, for enhanced quality of the assessment capability and for enhanced reliability of its application in performance assessment. In particular, it provides the basis for a judgement as to the adherence of the system concept to various internally or externally imposed principles, guidelines and procedures, that aim to provide robustness, and indicates the potential impact of phenomena and uncertainties that could be detrimental to safety.

iii) *Interaction with decision makers and stakeholders on the adequacy of the safety case (the outer confidence cycle in Figure 4).*

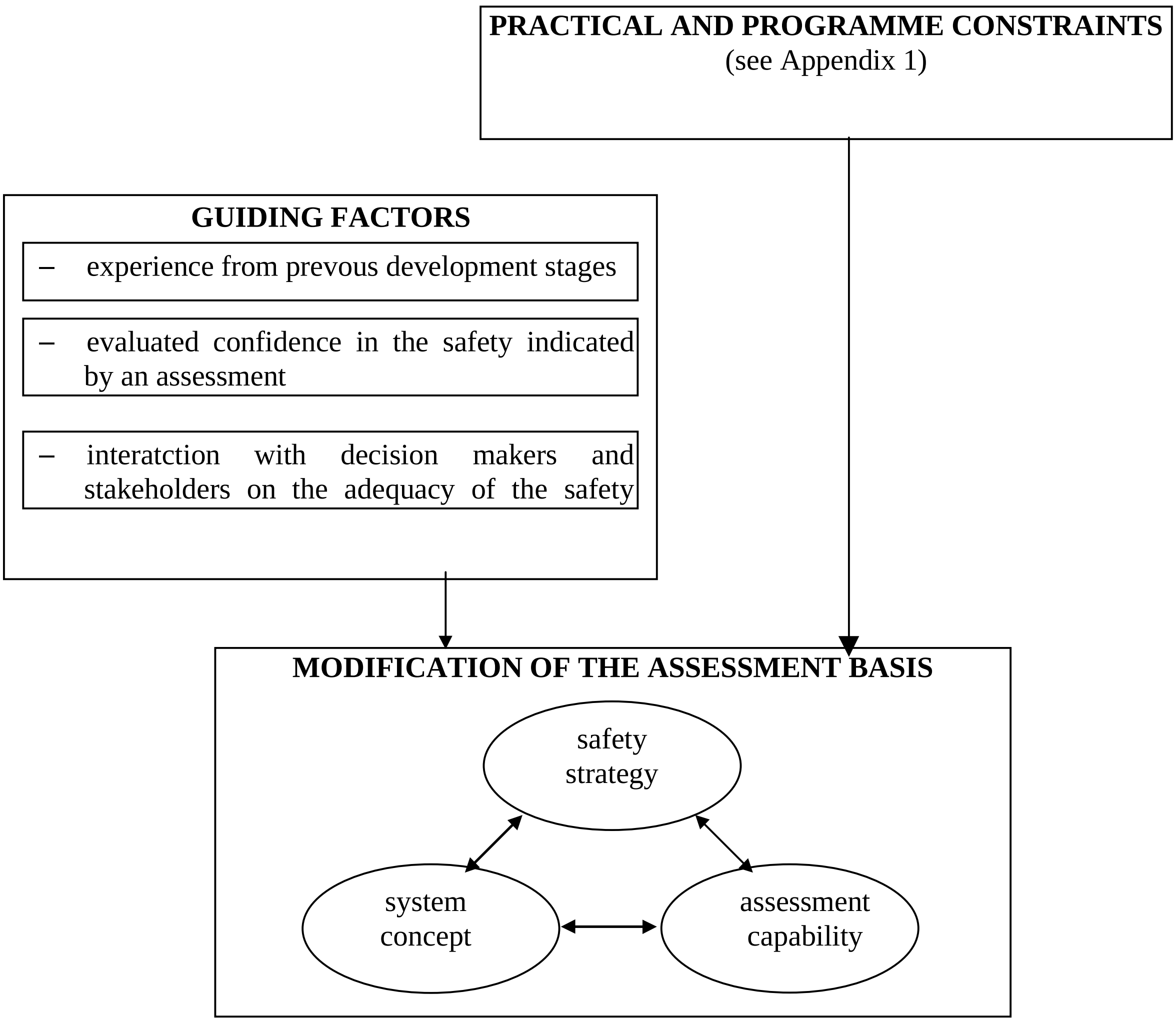
Interaction with decision makers and stakeholders indicates whether the safety case is adequate for the decision at hand and, in particular, whether the strategy for dealing with safety-relevant issues has proved (and will continue to prove) to be efficient.

20. Some of which may be designed to favour enhanced confidence in the final choice of a site and design for the repository, e.g., the strategy to examine more than one design option.

Modifications to the three elements of the assessment basis proceed concurrently, because of the strong coupling between the elements. For example, the two-way arrows in Figure 6 illustrate that:

- The safety strategy guides the progressive development of the system concept and the capability basis – in doing so, it must take into account how the changes in the system concept might affect the requirements for the assessment capability, and vice versa.
- The system concept may need to be adapted, for example if the performance indicated by the assessment proves to be inadequate;
- The assessment capability may be modified to suit both the chosen system concept and the safety strategy.

Figure 6: **Factors guiding, and constraints limiting, the iterative development and modification of the assessment basis**



4.2 Re-evaluation of the safety strategy

The safety strategy must ensure that, in the assessment basis, an appropriate balance is achieved between those measures that enhance the robustness of the system concept and those that enhance the quality of the assessment capability (and the reliability of its application in performance assessment). In particular, improvements in the quality of the assessment capability cannot fully compensate for lack robustness in the system concept. Similarly, the selection of a more favourable site and improved design cannot fully compensate for uncertainties in the models and data that are available to demonstrate their safety [Figure 5, box (1)].[21]

The safety strategy will vary during the course of repository planning and implementation, in response to the available level of scientific understanding and technological development. For example, where the scientific understanding is limited, and the system concept is not fixed in detail, as in the early stages of repository development, the assessment capability is likely to comprise a methodology, models and data that are highly simplified.[22] The safety strategy is then likely to emphasise the robustness of the system concept. In such circumstances, confidence in evaluated safety can be achieved by:

- adopting a system concept with ample reserves of safety;
- ensuring, through the demonstration of conservatism (where this is possible), that the simplified methodology, models and data do not underestimate the radiological consequences.

At later stages of development, increased understanding may lead to an assessment capability of higher quality. This allows (and efficient use of resources favours) an optimised design that has smaller reserves of built-in safety, together with more realistic modelling of safety-relevant processes. The safety strategy must therefore be periodically re-evaluated in order to ensure that it:

- continues to reflect the available level of scientific understanding and technological development, emphasising, for example, those parts of the system where characterisation is most reliable and where the safety function is least affected by uncertainty, at a particular development stage;[23]
- takes account of feedback from ongoing and previous stages of repository development and safety assessment and, in particular, the current level of confidence (on the part of the implementer, the regulator and stakeholders) in the ability of the implementer to analyse each safety feature, focusing, for example, future research and development on enhancing understanding of phenomena that are important to confidence in long-term safety;

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21. The limitations of models and data for performance assessment may, however, be compensated for, to some extent, by other lines of quantitative, semi-quantitative or qualitative reasoning that support the performance and robustness of the system concept (Chapter 3).

22. Indeed, performance assessments may be carried out for a generic host-rock type, rather than for a specific site or siting region.

23. Even if the safety strategy is changed, it must be recognised that all uncertainties with the potential to undermine the safety case will need to be addressed at later stages of the development programme.

- accounts for how changes in the system concept affect requirements for the assessment capability, and vice versa;
- achieves an efficient use of available resources (financial resources and availability of project staff; see practical constraints in Appendix 1);
- takes into account certain general technical and managerial principles, examples of which are given in Table 7.

Table 7: **Examples of technical and managerial principles relevant to the safety strategy [quotations are taken from ICRP-64 (ICRP 1993)]**

Examples	***Rationale***
The adoption of a step-wise approach to repository development.	An appropriate system concept and assessment capability cannot be achieved in a single development stage; a step-wise approach can take into account the increasing availability of information as development proceeds and allows feedback from experience acquired during the previous step.
The establishment of a "safety culture", i.e. "a consistent and pervading approach to safety" governing actions associated with repository development.	This principle aims at the "achievement of personal dedication and accountability of all individuals engaged in any activity" that has a bearing on safety. Examples of safety culture practices are given in IAEA 1997c.

The safety strategy selected will be partly subjective, and weighted according to cost/benefit judgements and other programme-specific constraints. *Irrespective of the strategy that is decided upon, however, the development of a carefully laid out strategy to refine the elements of the assessment basis iteratively through the stages of repository development, and the discipline built through the traceable and transparent documentation of the evolution of the assessment basis, within a logical structure, contribute to confidence in the quality of the safety case. In particular, the view is fostered that the detrimental effects of uncertainties have been reduced to the maximum possible extent.*

4.3 Re-evaluation and modification of the system concept and assessment capability

4.3.1 General considerations

Uncertainty is the result of limited knowledge. In evaluating the evolution of the disposal system in performance assessment, uncertainties in the available scientific understanding, models and data are inevitable, due to system complexity and the long time-scales involved. The result of these uncertainties is a corresponding uncertainty in the evaluated performance of the system. If the degree of uncertainty in the evaluated performance is such that the confidence in the safety that it indicates is judged to be unacceptable, then a number of measures can be employed to enhance confidence.

The aim of these measures is to generate an assessment in which, while acknowledging the presence of uncertainty, there is sufficient confidence, or reasonable assurance, in the safety that it indicates to support a positive decision (by the implementer) to compile and present a safety case, and subsequently, a positive decision (by the regulator) to proceed to the next stage of repository development.

Two groups of measures can be distinguished:

- those that aim to increase the robustness of the system concept; and

- those that aim to increase the quality of the assessment capability and the reliability of its application in performance assessment.

Although discussed individually in the following sections, the two groups of measures are interrelated. In particular, an increase in robustness may be achieved by adopting a system concept that is simpler, and characterised by fewer uncertainties. This should give rise to increased quality in the corresponding assessment capability, since confidence in models and datasets can be achieved more easily.

In either case, sensitivity analysis, carried out as part of a performance assessment, provides a powerful tool for evaluating the consequences of specific measures. It can, for example, indicate the consequences for the performance that will follow from adopting specific siting or design changes. It can also indicate the changes in siting and design, and refinements in the assessment capability (through research to develop basic understanding, through model development and through data acquisition, including future phases of site characterisation), that are likely to result in the greatest reduction in uncertainty in the evaluated performance.

4.3.2 Enhancing robustness in the system concept

Robustness facilitates both the perception of intrinsic safety and the evaluation and communication of safety, and thus the incorporation of robustness in the system concept is a confidence-enhancement measure. Measures that aim to increase the robustness of the system concept may involve:

- modifying the system concept with a view to increasing safety margins, so that compliance with acceptance guidelines is relatively insensitive to the presence of any unresolved issues and uncertainties;

- selecting a site and design with a view to simplicity, so that uncertainties that could be detrimental to the evaluation and communication of safety are avoided, or forced to very low probability.

These measures may involve relatively minor changes, such as increasing the thickness of a particular engineered structure or modifying the repository layout. They may, however, in extreme cases, also involve a radical change in design, or the abandonment of one site in favour of another.

Examples of principles, guidelines and procedures that aim to ensure the robustness of the system concept are given in Table 4. *The existence of principles, guidelines and procedures, as well as the recording of adherence, implementation and observation, are in themselves a source of confidence in the quality of the resulting safety case.*

Principles, guidelines and procedures related to the robustness of the system concept may be devised either by implementers or by regulatory organisations. In the early stages of the development of the system concept, they are mainly generic in nature. *One may, however, expect that these aspects will converge towards a set of safety requirements specific to the repository under consideration, as has happened in other fields of nuclear safety. Some of these requirements may form the basis for progressively refined regulatory guidance.* The identification and observation of such requirements will contribute increasingly to confidence in long-term safety. Furthermore, as the requirements are refined, the number of iterations (confidence cycles) needed to ensure the desired degree of confidence in the evaluated safety may be reduced.

4.3.3 Enhancing the quality of the assessment capability and the reliability of its application in performance assessment

General features that aim to ensure quality of the assessment capability, and the reliability of its application in performance assessment, are presented in Chapter 3 (e.g. Table 5). Incorporation of these features should:

- ensure that assessments take full account of current understanding of phenomena that are relevant to long-term safety, including uncertainty in these phenomena, so that performance is evaluated in a manner that does not underestimate consequences, while avoiding excessive simplification;

- ensure that the computational tools for quantitative assessments are verified;

Current understanding of safety-relevant phenomena can also by enhanced, and uncertainty better characterised or reduced, by:

- improving the quality of the available information regarding the site and design (e.g. through the acquisition of information from site characterisation and R&D),

- improving the quality of, and support for, the methods and models used to assess the information (e.g. through seeking support for model assumptions from observations of natural geological systems).

Both the quality of methods and models and the completeness of data for a site and design contribute to the quality of a performance assessment and the improvement of either one of these aspects cannot fully compensate for deficiencies in the other [Figure 5, box (2)].

Examples of practical methods to identify and reduce uncertainty are given in Table 8, where distinction is made between the three classes of uncertainties that are commonly identified in performance assessments:

- Completeness uncertainty (also termed scenario uncertainty) related to the ability of the analyst to identify and evaluate all potential evolutions of the disposal system that are relevant to overall long-term safety of the system. It can also be considered as the problem of correctly identifying what features, events and processes (FEPs), and combination of FEPs, should be included in assessment models and calculational cases. It may be regarded as a type of modelling uncertainty, although a special one.

- Model uncertainty refers to uncertainty about the model used to represent a given set of FEPs and interactions. This may arise because several alternative conceptual models are consistent with the data and scientific understanding, although only one or none of the models may be representative over the full range of conditions of interest in safety assessment. It can also arise from simplification of models and the choice of temporal and spatial scales in a model.

- Parameter uncertainty refers to uncertainty in the parameter values used in a model. It may arise from the need to estimate parameter values from data that are incomplete, and also from the need to represent temporal and spatial variability where the statistical distribution of parameter values may be estimated, but exact values in space and time are not known. It should be remarked that the classical theories of data analysis and statistics deal only with parameter uncertainty.

There is overlap between these three classes, and allocation to a particular class may be arbitrary, and depend on the manner in which an analyst chooses to formulate the problem.

Some uncertainties may be identified that are, in practice, impossible to quantify and to reduce, e.g. those associated with human intrusion[24] *and the treatment of the biosphere (Section 3.2.2). The decoupling of these from other aspects of performance assessment may be viewed as a method to achieve quality and reliability in the assessment.*

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24. A system concept comprising multiple lines of defence, incorporating both engineered and intrinsic robustness, is a useful strategy to guard against human intrusion, and may either prevent such events occurring, or mitigate their consequences.

Table 8: **Methods to identify and reduce uncertainties in the three classes of uncertainty within the assessment capability**

All classes of uncertainty	
Method	**Example**
Focus of R&D efforts to better characterise or reduce uncertainty in phenomena that are important to safety.	Confidence can be enhanced through acquisition of more comprehensive data and, provided the data exist to support them, by the development and testing of either more realistic models or models with well-proven conservatism. In the case of geological and hydrogeological characterisation, the data-acquisition strategy must take into account the complexity of geological features, the limitations of available characterisation techniques and the need to avoid perturbations to the favourable properties of a host rock.
Completeness/scenario uncertainty	
Method	**Example**
Expert elicitation and peer review.	Such methods can, for example, independently provide confidence that there are no undetected geological features or that the intrusion of oxidising water as a result of climatic events will not occur.
Draw on general scientific and technical experience and literature (theoretical and experimental experience from inside and outside the radioactive waste field).	General scientific and technical experience can be used, for example, to identify uncertainties regarding secondary processes affecting radionuclide migration.
Adoption of a structured approach to system description.	By using, for example, "Interaction Matrices", processes and interactions between different elements of the system can be systematically sought in striving for completeness [SKAGIUS et al. 1995].

Table 8 (continued): **Methods to identify, quantify and reduce uncertainties in the three classes of uncertainty within the assessment capability**

Model uncertainty	
Method	**Example**
Identification of the range of conceptual models that is consistent with available information, and comparison of results of different conceptual models to evaluate the consequences of uncertainty.	This has been applied, for example, in Sweden to models of groundwater flow and fuel dissolution. Such methods can be use to focus site characterisation and experimental studies on reducing key uncertainties.
Natural analogues.	Natural analogues can be used to quantify uncertainties related, for example, to the effects of high temperature on host rock (intrusion of basaltic melts into evaporite formation). They can also be used to enhance confidence in, and support assumptions regarding, the operation of key processes that lead to long-term safety. Examples are given in NAGRA 1994 of analogues that support: – the long-term retention, under repository conditions, of the swelling capacity, permeability and cation-exchange capacity of bentonite; – the minimum lifetime of the waste containers; – the stability and resistance to corrosion of the waste matrix; – the low solubility/immobility of key radionuclides under repository conditions. Other examples are: – evidence for the stability of cement gels, for the absence of colloids and organic complexants and for very low levels of microbial activity at the Maqarin site in Jordan, and in Oman; – evidence for rock matrix diffusion of uranium in granite at El Berrocal, Spain, in crystalline rocks in Northern Switzerland and at the Grimsel Test Site;

Table 8 (continued): **Methods to identify, quantify and reduce uncertainties in the three classes of uncertainty within the assessment capability**

	– support for the USDOE of thermochemical data used with the EQ3/6 code to model rock-water interactions, through studies of geochemical data from wells at the Wairakei geothermal field in New Zealand; – insights into the oxidation of uranium and the migration of uranium dioxide through NRC studies of analogue sites in Mexico and Greece; – development of understanding of the processes controlling the performance of spent fuel in a repository in plutonic rock, in a reducing environment and protected by clays from work in the Cigar Lake uranium deposit natural analogue in Canada.
Expert elicitation.	Expert elicitation can be used to identify uncertainties related, for example, to physico-chemical processes in the corrosion of the waste matrix and the canister and the evolution of buffer materials.
Draw on general scientific and technical experience and literature (theoretical and experimental experience from inside and outside the radioactive waste field).	The concept of channelling and, in particular "fast pathways" for fluid flow through the geosphere could be supported by experience from, e.g., the oil and gas industry.
Examination of past behaviour of similar rock formations.	Such geological studies can quantify uncertainties and support assumptions regarding, for example, the evolution of the host rock, esp. long-term processes (e.g. age of groundwater, effects of earthquakes, effects of heat) and the long term degradation of engineered materials.
Large-scale field and rock-laboratory studies.	Such studies can identify and reduce uncertainties regarding, for example, processes relevant to radionuclide transport through the geosphere over relevant spatial scales.
International co-operation.	International co-operation plays a part in the identification and reduction of uncertainties regarding, for example, sorption mechanisms and modelling.

Table 8 (continued): **Methods to identify, quantify and reduce uncertainties in the three classes of uncertainty within the assessment capability**

Parameter uncertainty	
Method	**Example**
Identification of critical, safety-relevant parameters (through sensitivity and uncertainty analysis) and reduction of uncertainties in these parameters through site-characterisation and experimental programmes.	The degree of sorption on, for example, backfill materials and rock matrix is critical in many safety assessments; isotherms and Kd values can be evaluated experimentally.
Development of mechanistic models for extrapolation of laboratory measurements to *in situ* conditions.	Mechanistic sorption models, though still under development, have the potential to support the allocation of sorption parameters values in performance assessment models.
Expert elicitation.	Expert elicitation can be used, for example, to estimate the likelihood of failure of canister, shaft seals, etc. within a given period.
Draw on general scientific and technical experience and literature (theoretical and experimental experience from inside and outside the radioactive waste field).	General scientific experience and literature can, for example, be used to reduce uncertainties in nuclear data (e.g. half lives).
International evaluation.	Evaluation of experiments conducted throughout the world can be used, for example, to reduce uncertainties in thermodynamic databases [WANNER 1988, NEA 1995b] and in the radiotoxicities of elements.

5. SUMMARY AND CONCLUSIONS

The role of confidence in the decision-making process

The novelty and complexity of the task of repository development mean that detailed planning of the entire development process at the outset of a project is not possible. Rather, detailed planning proceeds iteratively, as information and experience are acquired. This flexible, step-wise approach involves a number of development stages, punctuated by interdependent decisions regarding siting and design, safety assessment, site characterisation and research and development activities, that are taken throughout the planning, construction, operation and, finally, closure of the facility (Figure 1 and Table 1).

All positive decisions must be well-supported by relevant arguments. In particular, the arguments must give *sufficient confidence*, or reasonable assurance, that the benefits following from a correct decision outweigh the risk and consequences of the decision proving to be incorrect. If confidence is judged to be insufficient, then either the commitment involved in progressing to the next stage must be reduced, or arguments must be formulated in which enhanced confidence can be placed. Some decisions are the responsibility of technical specialists and managers within an implementing organisation, and the regulatory bodies that oversee their activities (Table 2). For these decisions, a positive outcome is likely to require technical arguments that give confidence in the feasibility and long-term safety of the proposed concepts. Other decisions may be the responsibility of political decision makers and the general public (e.g. in local referendums). These non-technical stakeholders also require confidence in the technical aspects of repository development, but confidence may be based on less technical, more qualitative arguments. In addition, the wider audience of scientists, politicians and the general public require confidence in non-technical aspects of repository development in order for implementation to be acceptable (Figure 2).

Sufficient confidence for a positive decision does not imply that all relevant issues have been resolved, but rather that these issues are not judged as critical for the decision at hand and that there are good prospects to resolve them in future repository-development stages. Thus, for example, in authorising progression to the next stage, a regulator or licensing organisation may still need to be convinced about the final acceptability of the project, and will, in subsequent stages, require more information from an implementer. *The perception that this is the case is important in maintaining public confidence in the independence of the regulator or licensing organisations in their role as a "judge" of the acceptability of the project and supervisor of the licensing process.*

The role, development and presentation of the safety case

The importance to decision making of convincing arguments for long-term safety will vary from one decision to the next. For many (but not necessarily all) decisions, a safety case is one of several sources of information on which the decision is based. Generic understanding of relevant phenomena, as well as site- and concept-specific models and data, are initially limited, with many unresolved issues. Site-characterisation and safety-assessment activities therefore run in parallel to, and interact with, the step-wise repository-development processes, with the safety case developed incrementally. As repository development progresses through successive stages, the task of achieving sufficient confidence in long-term safety does not necessarily become simpler. On the one hand, the implementer will strive to reduce unnecessary conservatism and, on the other, the decisions that are supported will tend to demand a higher commitment and therefore a higher level of confidence. Thus, efforts may need to be made continuously to ensure that confidence remains sufficient to support the decision-making process.

The safety case, at a given stage of repository development, is based on the findings of a safety assessment carried out by the implementer (Figure 3). Safety assessment involves:

- the establishment of an assessment basis, i.e. the safety strategy (the strategy for the building of a safety case), the system concept (the selection of a site and design), and the assessment capability (the assembly of relevant information, models and methods to evaluate performance);

- the application of the assessment basis in a performance assessment, which explores the range of possible evolutions of the repository system and tests compliance of performance with acceptance guidelines;

- the evaluation of confidence in the safety indicated by the assessment.

The implementer must decide, on the basis of the evaluation of confidence, whether the safety assessment has been sufficiently successful, in terms of the demonstration of safety, to justify the *compilation and presentation of the safety case*. The safety case then serves as a basis for a further decision, by the implementer, the regulator and/or others, as to whether there is sufficient confidence in safety to justify proceeding to the next repository development stage. A successful safety case should, in general, include:

- a description of the status of development of the assessment basis and the performance-assessment findings, and an evaluation of confidence in the safety margins indicated by the findings;

- a description of the approaches adopted to achieve confidence and a formal statement of that confidence;

- feedback to future development stages and, in particular, reasonable assurance that the safety strategy is appropriate to handle remaining, not fully resolved, safety-related issues during future stages.

The safety case must be presented within a system of documentation that is adequate in terms of completeness, transparency and traceability of the results, via a chain of decisions and calculations, to their sources. Highlighting, within the documentation, the connections between safety and the role of the various barriers within the multi-barrier concept is a practical and useful approach for improving these aspects and demonstrating that safety can be achieved. It also heightens the role of safety assessment as a support to decision making, rather than an academic exercise in analysis, or an analysis only to show compliance with regulatory targets. Such a system of documentation facilitates the evaluation of confidence (e.g. by peer review and review by regulators) and thus promotes acceptance by the scientific community and by stakeholders, including politicians and the public.

In general, the safety case compiled by an implementer will be presented periodically to the regulator for review and, ultimately, to support license applications. In addition, however, the regulator, and stakeholders, should have a broader role in the iterative development of the safety case. Stakeholders can, for example, provide input regarding the range of scenarios to be considered in performance assessment and the definition of reference biospheres. There is, furthermore, a continual need for the implementer and regulator to inform each other concerning their views and activities. For this reason, a transparent system of internal record-keeping for decisions made by the implementer can be invaluable.

The evaluation of confidence

An evaluation of confidence in long-term safety principally entails the evaluation of *the robustness of the system concept*, i.e. the extent to which the system concept favours safety and minimises uncertainties and/or the effects of uncertainty on safety (Table 3), *the quality of the assessment capability* and *the reliability of its application in performance assessment* (Figure 5). Furthermore, consideration of the constraints that have led to the adoption of a particular system concept and assessment capability (the "historical perspective") is a part of the evaluation of confidence.

An evaluation of robustness of a system concept involves the confirmation that appropriate principles, criteria and procedures are observed (Table 4). Such principles, guidelines and procedures may be devised either by implementers or by regulatory organisations. In the early stages of the development of the system concept, they are mainly generic in nature. One may, however, expect that these aspects will converge towards a set of safety requirements specific to the repository under consideration, as has happened in other fields of nuclear safety. Some of these requirements may form the basis for progressively refined regulatory guidance. The identification and observation of such requirements will contribute increasingly to confidence in long-term safety. Furthermore, as the requirements are refined, the number of iterations (confidence cycles) needed to ensure the desired degree of confidence in the evaluated safety may be reduced.

Performance assessment also provides a test for the robustness of the system concept. A performance assessment considers the evolution of the system concept for a range of cases or scenarios. The likelihood of occurrence of particular scenarios may be evaluated, either quantitatively or qualitatively. If scientific understanding is adequate, the consequences of the scenarios are evaluated in terms of performance indicators and compared to acceptance guidelines. The sensitivity to various sources of uncertainty is also considered. In this way, performance assessment tests whether, for a given system concept, phenomena (and uncertainties) that could be detrimental to safety are avoided, or forced to very low probability or consequences, i.e. whether the system concept is robust. Cases may also exist where the assessment is more qualitative. For all cases, the use of independent evidence, such as observations of natural systems and analogues, may play a role in supporting the findings of the assessment (multiple lines of reasoning).

The existence of cases for which high potential consequences have been identified, and for which the likelihood of occurrence cannot be shown to be low, does not necessarily preclude the compilation of a safety case at a particular development stage. The safety case must, however, give confidence that the safety strategy will deal adequately with such cases at a later stage, i.e. that confidence in long-term safety can ultimately be achieved.

The evaluation of the quality of the assessment capability involves the confirmation that appropriate features are implemented that relate to the approach adopted to performance assessment, the level of understanding of the safety-relevant features, events and processes and the conceptual and mathematical models and computational tools that are available (Table 5). Furthermore, confidence in the quality of information on a repository site and design is achieved if the data are, where possible, supported by a wide range of evidence from experiments and site investigation, and quality-assured in order to minimise the possibilities of errors. Reliability of the application of methods, models and data in performance assessment can be achieved through the adoption of relevant procedures, examples of which are given in Table 6.

Confidence cycles and the enhancement of confidence

If, either following the safety assessment itself or following the compilation and presentation of a safety case, the evaluated confidence is found to be insufficient, then the assessment basis must be re-evaluated and modified with a view to confidence enhancement and a new assessment carried out. If, following the (repeated) compilation of a safety case, convergence to sufficient confidence is not achieved, then the decision sequence that drives repository development may need to be revised. The iterative process of confidence evaluation and enhancement may be viewed in terms of “confidence cycles” (Figure 4). The concept of confidence cycles reflects the current dynamic approach to achieving confidence, especially during the early stages of repository development, when information increases rapidly in quantity and quality.

Modifications to the three elements of the assessment basis proceed concurrently because of their strong interaction (Figure 6), and are guided by the evaluated confidence in the safety indicated by an assessment and by interaction with decision makers and stakeholders on the adequacy of the safety case. The safety strategy has a key role in that it must provide an appropriate balance between those measures that enhance the robustness of the system concept and those that enhance the quality of the assessment capability, and the reliability of its application in performance assessment. Measures that enhance the robustness of the system concept can proceed by:

- modifying the system concept with a view to increasing safety margins, so that compliance with acceptance guidelines is relatively insensitive to the presence of any unresolved issues and uncertainties;

- selecting a site and design with a view to simplicity, so that uncertainties that could be detrimental to the evaluation and communication of safety are avoided, or forced to very low probability.

Measures that enhance the quality of the assessment capability, and the reliability of its application in performance assessment, proceed by enhancing current understanding of safety-relevant phenomena, by better characterising or reducing uncertainty (Table 8) and by incorporating features to:

- ensure that assessments take full account of current understanding of phenomena that are relevant to long-term safety, including uncertainty in these phenomena, so that performance is evaluated in a manner that aims at not underestimating consequences, while avoiding excessive simplification;

- ensure that the computational tools for quantitative assessments are verified.

The safety strategy must be continually re-evaluated during the course of repository planning and implementation, in response to the changing level of scientific understanding and technological development. The re-evaluation can draw on the results of sensitivity analysis, carried out as part of a performance assessment, which provides a powerful tool for evaluating the consequences of specific confidence-enhancement measures. It is, however, partly subjective and must take into account certain general technical and managerial principles (Table 7), as well as the need for an efficient use of resources. A carefully laid-out strategy for the refinement of the assessment basis through successive development stages, and the traceable and transparent documentation of the process of refinement, should foster the view that the detrimental effects of uncertainties have been reduced to the maximum reasonable extent. This should promote confidence in the quality of the safety case.

Conclusions

The achievement of the impossible, viz: to describe completely the evolution of an open system, such as a repository and its environment, that cannot be completely characterised and may be influenced by natural and human-induced factors outside the system boundaries, is not a requirement of decision making in repository development. Decision making requires only that a safety case has been compiled that gives adequate confidence to support the decision at hand, and that an efficient strategy exists to deal at future stages with any uncertainties in the description which have the potential to compromise safety.

The key messages related to the safety case and the confidence that it should convey are highlighted below.

- A safety case should make explicit the approaches that are implemented in order to establish confidence in the safety indicated by an assessment.

- The assessment basis, as defined in this report, is a key element of any safety case. In order to establish confidence in the safety indicated by an assessment, confidence in the elements of the assessment basis must be evaluated. If necessary, the elements must be modified with a view to achieving confidence enhancement.

- Confidence evaluation and enhancement are performed iteratively in the preparation of a safety case.

- Methods exist to evaluate confidence in the safety indicated by an assessment in the inevitable presence of uncertainty. In many cases, it can be determined whether safety is compromised by specific uncertainties through a sensitivity analysis, in which the consequences of such uncertainties are evaluated.

- Means exist whereby confidence in the safety indicated by an assessment can be enhanced, by ensuring the robustness of the system concept, the quality of the assessment capability, the reliability of its application in performance assessment, and the adequacy of the safety strategy to deal with unresolved, safety-relevant issues.

- Observations of natural systems play an important role in the qualitative evaluation and enhancement of confidence, since such systems have evolved over extremely long time-scales.

- A statement of confidence in the overall safety indicated by the performance-assessment results is part of the safety case and should include an evaluation of the arguments that were developed, in relation to the decision to be taken.

Appendix 1

PROGRAMME AND PRACTICAL CONSTRAINTS IN REPOSITORY DEVELOPMENT

A number of factors constrain the way in which development proceeds. As discussed in [NEA 1997], these may be divided broadly into:

(i) programme constraints, that apply to a waste-management programme as a whole;

(ii) practical constraints, that apply at a particular stage in repository development.

Some examples of these two classes of constraints are presented in Table A1.1.

During the prolonged period of repository development, such constraints may vary: overall strategies may change, regulations may be refined (or even change) and technical progress in relevant areas may be achieved. The uncertainty surrounding these factors make it desirable that:

- clear and effective lines of communication are maintained between the implementing and the regulatory organisations;
- the reasoning behind decisions (by both implementers and regulators) are easily traceable and documentation is presented in a transparent manner;
- an effective system of long-term record-keeping is in place so that decisions can be placed in a broad, historical context;
- ample reserves of safety are included in the repository concept, particularly during the early planning stages of development;[25]
- the implementer adopts – and the regulator allows – a flexible approach to repository development, in which alternative options are, where possible, kept open and where it is understood that safety allowances may shift in time from one part of the disposal system to another.

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25. Optimisation needs to be considered throughout the repository-development process, although it will generally take place during later stages, when most data have been acquired, models have been refined and the various constraints have become clearly defined.

Table A1.1**: Examples of programme and practical constraints affecting the development of the safety case for a deep geological repository**

Programme constraints
• the legal requirement that any repository for domestically produced radioactive waste should be located in that country; • the licensing framework requiring a safety case to be made at defined points within a repository-development programme; • the strategy to pursue, in addition to the domestic option, the possibility of international disposal options; • the strategy either to reprocess spent nuclear fuel or to pursue direct disposal; • the strategy to investigate one or more host-rock options; • the strategy to examine more than one design option (e.g. alternative canister materials); • the time constraints on repository implementation, which may be affected, for example, by the capacity available for interim storage; • the strategy to implement a repository in stages, beginning with an initial “demonstration repository” for a portion of the waste to be disposed; • the legal requirement to provide for some degree of retrievability in the repository design.
Practical constraints
• the development status of waste-management technology (e.g. canister-fabrication technology); • the means for acquisition of both general understanding and specific data, including laboratory facilities (e.g. underground laboratories in generic and site-specific geological settings), experimental methods and research models for the interpretation of data; • the availability of data (e.g. from site characterisation) and performance-assessment tools at each particular development stage; • the externally controlled programme funding; • the manpower available to the organisation, including the availability of experienced project staff; • schedule issues, including externally-set deadlines; • the manner in which acceptance requirements are formulated.

Appendix 2

TYPICAL STEPS IN PERFORMANCE ASSESSMENT

In spite of the differences in the details of performance-assessment methodology between national programmes, certain steps can be identified as common to most performance assessments. These steps are illustrated in Figure A2.1 and consist of:

(a) Scenario development:

The definition of envelope scenarios, each representing (in a simplified manner) a family of scenarios that include particular features, events or processes (FEPs). The nature and impact of such FEPs determine the measures taken to ensure the quality and robustness of the disposal-system components; the envelope scenarios provide the basis for specific cases to be considered, either quantitatively or qualitatively, in the assessment.

(b) Consequence analysis:

The application of methodologies, models, databases and codes from the assessment basis in the quantitative evaluation of repository performance (in terms of dose, radionuclide fluxes, etc.) for specific cases, including:

- the assignment to the models or codes in the assessment basis of parameter values that define the source of radionuclides, as well as their containment, isolation, and possible transport in the man-made barriers, in the geological barrier, and in the biosphere;
- the execution of model or code calculations;
- the evaluation of sensitivity to uncertainty with the purpose to investigate whether or not safety is compromised by any specific uncertainty.

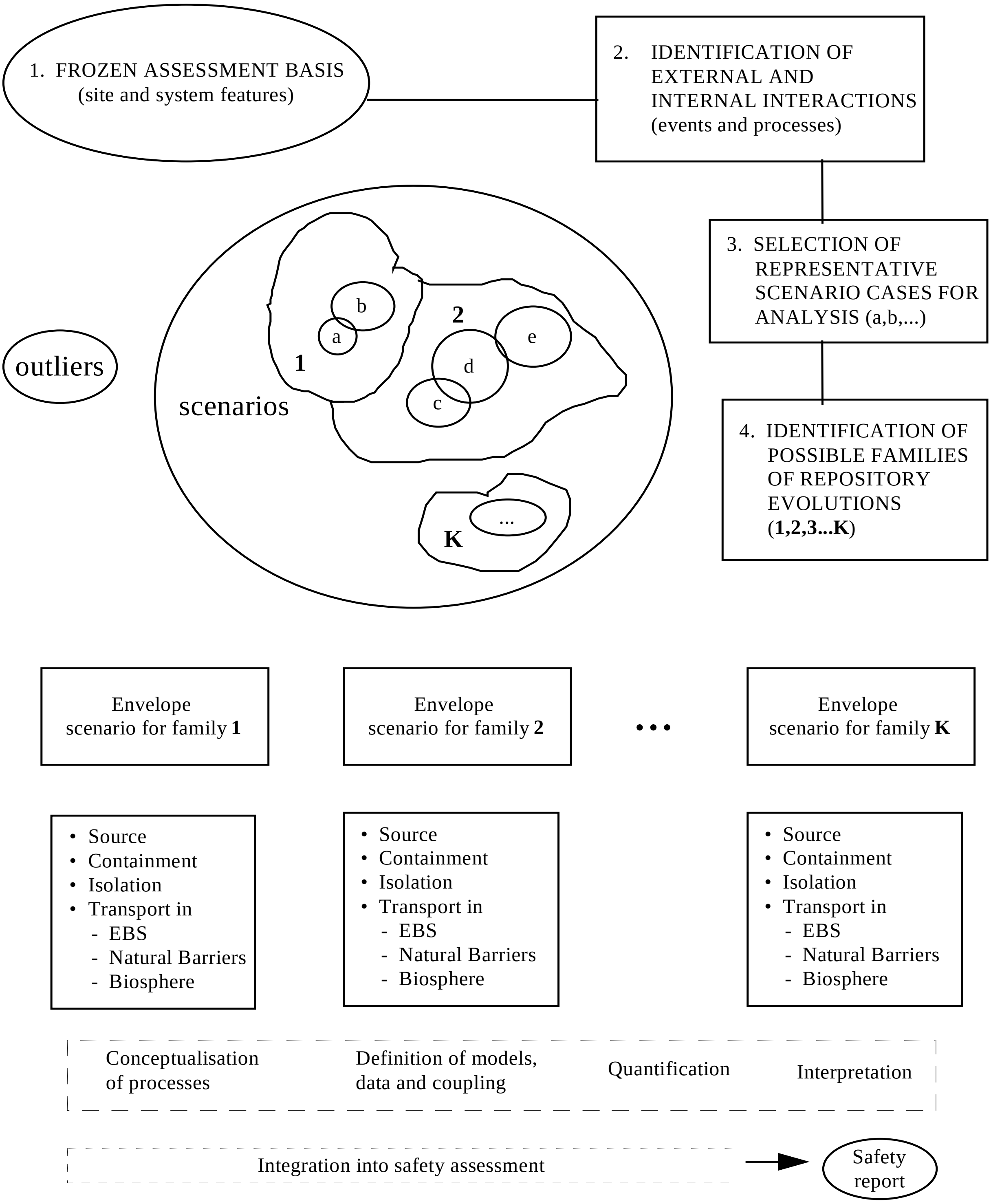
(c) Comparison of the repository performance indicated by the consequence analysis with pre-established acceptance guidelines and an assessment of the available safety margins.

The long-term consequences of the evolution of the repository system, evaluated in performance assessment, are regarded as indicators of safety that characterise the performance of the repository in time [IAEA 1994]. The indicators evaluated for a range of envelope scenarios describing possible evolution paths, and their likelihood of occurrence,[26] form a basis for the compilation of a safety case. A safety case can be made

26. The evaluation of likelihood of occurrence need not be a quantitative estimate of probability, but can also take the form of a qualitative assessment of whether a scenario is expected to occur within a given period (Section 3.2.3.2).

most effectively by the combined use of several lines of reasoning, including the use of various safety indicators, such as risk, dose, environmental concentration and radionuclide flux through the different barriers and to the biosphere. Appendix 3 gives examples of safety indicators, complemented by observations of natural systems, that have been used in performance assessment in Germany. Among the indicators available, dose and risk are regarded as the most fundamental to safety [ICRP, 1997]. Long-term consequences, evaluated in performance assessment, should give confidence that the performance of the repository will comply with acceptance guidelines.

Figure A2.1**: Practical aspects of assessing system performance**



Appendix 3

APPLICATION OF SAFETY INDICATORS IN GERMAN STUDIES

Site-specific safety indicators have been extensively used for confidence building in German studies for the planned Konrad and Gorleben repositories.

These two repositories are at present being developed for spent fuel, high-level and/or α-bearing wastes: one – since 1979 – in the Gorleben salt dome at depths of about 840 m to 1 200 m, in which all types of solid radioactive wastes are planned to be emplaced (total activity about 10^{21} Bq, α-activity about 10^{19} Bq), and another – since 1975 – in the disused Konrad iron ore mine, into which waste is to be emplaced which exerts a negligible thermal influence on the host rock (total activity 5 10^{18} Bq, α-activity 1.5 10^{17} Bq).

Tables A3.1 and 3.2 give some major examples of safety indicators and site specific phenomena used at the Konrad and Gorleben sites, respenctively. In the case of the Konrad repository, they were of utmost value in the licensing procedure, giving reasonable assurance that the performance assessment, which was based on observations from nature, does not lead to erroneous results. The time frames for performance assessment are about 1 % of those considered in the geological past of the site. Similar "model validations" have been applied to the Gorleben site. The present results are encouraging. The processes observed in the past again cover time periods at least two orders of magnitude longer than those necessary for performance assessment.

Table A3.1: **Safety indicators and site-specific observations used for the analysis of the Konrad site [HERRMANN & RÖTHEMEYER 1998].**

Safety Indicator	Supporting observations	Contribution to performance assessment
Timescales of processes, flux through barriers.	Age and salt concentration of natural deep groundwaters.	Age of groundwaters at least 10^7 years, possibly 1.5×10^8 years; the latter is the age of the geological formation. This indicates groundwater movements of less than about 1 cm in 10^3, years or even stagnating groundwater. Proof of a conservative groundwater model (groundwater travel time and dilution).
Flux through barriers.	Self-sealing effects of clay barriers (drillings, fracture zones).	Proof of adequate modelling of radionuclide transport.
Radiotoxicity.	Natural radiotoxicity of host rock.	Radiotoxicity of waste decreases to natural levels after about 3×10^5 years. Proof that longer consequences reflect natural risks.

Table A3.2: **Safety indicators and site-specific observations used for the analysis of the Gorleben site [HERRMANN & RÖTHEMEYER 1998].**

Safety Indicator	**Supporting observations**	**Contribution to performance assessment**
Flux through barriers, timescales of processes.	Normal and glacially influenced subrosion processes; the analysis of the highly soluble potash salt seams, of fluid inclusions and solutions (Gebirgslösungen) gave evidence of the depth down to which the salt dome was affected.	Modelling of an exponential mass change and of glacial processes indicating an isolation potential of the disposal system of millions of years. Proof of a past isolation period at disposal level of 2.5×10^{8} years, the age of the geologic formation.
Flux through barriers, timescales of processes.	Natural analogue studies revealed effects of high temperature on rock salt at depths of 700 - 800 m: basaltic melts with temperatures of around 1150°C intruded with mobile constituents into evaporites of Zechstein I of the Werra-Fulda mining district 15 to 25 million years ago. The mineral reactions and material transport observed can be attributed to fluid phases. They extended a few cm into the rock salt and up to and over 10 m into the K-Mg mineral association of the potash salt seams.	Even the stresses of the high temperatures and concentrated salt solutions neither lead to an extensive decomposition of the entire silicate rock, nor have they mobilised, e.g., lanthanides in vitrified components of the basalt or in insoluble silicate compounds of the rock salt. Not yet used in modelling.

Appendix 4

INDEX OF DEFINITIONS

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