REPORT ON THE EUROPEAN PILOT STUDY ON THE REGULATORY REVIEW OF A SAFETY CASE FOR GEOLOGICAL DISPOSAL OF RADIOACTIVE WASTE

EXECUTIVE SUMMARY

A number of countries are developing or considering developing geological disposal facilities for radioactive waste. Consistent approaches among countries to provide a high level of safety for such a facility would be beneficial. The IAEA and OECD/NEA have already developed internationally agreed standards, guidance and recommendations. A Working Party on Nuclear Safety (WPNS), within the European Union, has analyzed the extent to which EU Member States adopt a common approach to waste management. The Western European Nuclear Regulators Association (WENRA) has developed safety reference levels for radioactive waste and spent fuel storage, for decommissioning and more recently for disposals. France and Belgium have cooperated to develop common ideas and positions on the safety approach to geological disposal. The Franco-Belgian initiative generated valuable momentum amongst European regulators and international organizations.

The pilot study brought these together to share experience and opinions on the regulatory expectations from a safety case for geological disposal of radioactive waste and to develop a common view within the European Union. The pilot study sets out what the regulator expects from the safety case at each step of the project and how the regulator will evaluate the elements of the safety case. The pilot study involved regulatory bodies and technical support organizations from Belgium (FANC, Bel V), Finland (STUK), France (ASN, IRSN), Germany (GRS), Spain (CSN), Sweden (SSM), Switzerland (ENSI) and UK (EA) and representatives from the IAEA, OECD/NEA and EC.

A disposal facility and its safety case should be developed in a step-by-step manner with well-defined decision points. The degree to which a step-by-step process is legally implemented in regulations varies from country to country, and the responsibilities of the regulator at decision points also vary. Nevertheless, we can identify common themes, which we have drawn together in this study. A key common theme is the need to keep the regulator informed about the state of development and involved in the major decisions at each step in the development of a disposal facility from the beginning of the project.

The report addresses both operational and long-term safety. Long-term safety and associated performance assessments are the driving factors in design and development of geological repositories. Long-term safety thus holds a prominent place in safety cases presented to date, and significant discussion has been devoted to it in international projects and guidance. The IAEA safety requirements [2], for example, stress long-term protection as an overall optimization goal as well as a key consideration in site selection, in design of barriers and in performance assessment.

Safety during repository operation is obviously important in itself and there is a growing awareness that measures to ensure operational safety may have consequences on long-term safety. Depending on national regulations, operational and long-term aspects may be addressed under separate regulations and reviewed by different licensing bodies. If this is the case, the different regulatory bodies will need to liaise closely with one another since a balance needs to be found among their different requirements.

The report covers non-radiological impacts as well as radiological impact, which is consistent with recent international positions (ICRP, NEA). In this domain, and according to the national context, different licensing bodies may be concerned and the emphasis given to non-radiological impacts may depend on the licensing body. As a result, and according to the national regulatory framework, the requirements related to non-radiological aspects and the methodology used may vary substantially.

In the framework of a stepwise process the exact definition of the phases and decision-making points differ among national programmes. This report considers six phases describing broadly the progressive development of a repository (and its safety case) and identifies when certain information would generally be foreseen although national programmes may have different requirements. Regulatory reviews will govern the progression through the stepwise process. In nearly all programmes, formal decisions are expected at least from the point of repository construction and, in some countries, regulatory decisions will also be needed in earlier phases (conceptual and siting phases). Political decisions may also be required (i.e., legislative decisions, local referendum) in addition to regulatory actions.

The six key phases include:

1. The **conceptualization phase**, during which an implementer considers potential suitable sites and design options, establishes the safety strategy (approach to developing a disposal concept, approach to safety assessment and basis for the management system) and carries out preliminary assessments. Regulatory interaction at this stage should guide the implementer on the likelihood of achieving the necessary demonstration of safety and should help the implementer decide whether to commit resources to move to the next phase of the project.

2. The **siting phase**, during which the implementer confirm the suitability of potentially sites accordingly the safety strategy and characterizes these sites. A safety case is developed to the extent that a decision can be made on the preferred site.

3. The **reference design (and application for construction) phase**, during which the implementer adapts the conceptual design to the site properties, substantiates and finalises the design of the disposal facility, and develops the safety case, to support the implementer's application to construct, operate and close the facility. Based on the review of the safety case, the licensing body would decide whether to grant a licence for the implementer to construct the facility. This is a crucial milestone in the development of a repository.

4. The **construction (and application for operation) phase**, during which the implementer demonstrates that it has built the facility as planned in the safety case and in accordance with the conditions of the construction licence. Towards the end of this phase the implementer will present its final approach for operation and a concept for closing the facility. In preparing for operation, the implementer will need to demonstrate safety during operation and radiation protection of workers and members of the public.

5. The **operational phase**, during which the implementer emplaces waste packages in the disposal facility. During this phase, the implementer may build new disposal units, and backfill and possibly seal, either temporarily or permanently. During this phase, the implementer also develops an application to close and seal the facility, and prepares a plan for post-closure institutional controls, monitoring and surveillance. Towards the end of this phase the regulator will decide whether to grant a licence for the implementer to close and seal the facility. When the licence is granted the implementer proceeds to the closure of the facility.

6. The **post-closure phase**, at the start of which the implementer provides evidence to demonstrate that it has closed the disposal facility in accordance with safety requirements and presents a firm plan for institutional controls and continuing monitoring and surveillance as required by the national legal and regulatory framework.

The safety case evolves and matures throughout these phases, as new information, experience from practice, and results from research and safety assessments become available. At each step, the safety strategy is pursued, updated as necessary to remain consistent with current knowledge and expectations, the assessment basis augmented and the following aspects of the safety assessment are revisited:

- **Performance assessment**. The implementer has to assess the suitability of the host-rock, surrounding environment and engineering components in particular to demonstrate the feasibility, the performance and the robustness of the disposal system with regard to the safety functions. Features, events and processes that can affect the performance of the system and its components should be identified and effects on the system behaviour and robustness should be assessed. The implementer demonstrates that methods and materials of excavation and construction are feasible and reliable. In all these respects, the projected performance of the site and engineered components is expected to be confirmed and important uncertainties remaining at the particular stage of the project are identified and plans presented for managing them.

- **Impact assessment.** The implementer's objective is to show that people and the environment will be adequately protected from both radiological and non-radiological impacts during disposal facility operation and as the disposal system evolves over the long term, based on assessments using relevant data in appropriate models. These assessments should be shown to provide reasonably conservative estimates of impact relying on a representative set of evolution scenarios of the facility considering the features, events and processes cited above. The implementer will need to identify and assess the key dependencies on parameter values and assumptions, and to evaluate the effect of uncertainties. The degree of confidence in assessed radiological and non-radiological impacts should be appropriate to the stage of disposal facility development and to support the decision to move from one phase to the next phase in the stepwise procedure.

From the beginning of the project, the implementer should have a management system in place to assure an adequate level of quality for all safety-related aspects. This management system has to be adapted to the stage of disposal facility development. In particular the management system includes organizational arrangements for implementing and planning the project, for development of operational and control procedures, and for record keeping.

These elements are inter-related and together provide the necessary basis for demonstrating the safety of a disposal facility and for making regulatory decisions. They should be considered individually and in a structured, integrated manner through every phase of the step-by-step process. The implementer needs to assemble up-to-date information in a structured manner on each of these elements, covering all important aspects of the disposal system and including an updated safety assessment, in order to move from one phase to the next. For example, selecting a site is not only based on geological data. It typically requires a conceptual design, assessment of site and design compatibility, and an assessment of how the whole system would work together to achieve safety. It also requires the suitability of available techniques and materials for excavation and construction to be considered, to give confidence that the facility can be built as conceived. At every key decision point, the regulator will thoroughly review each aspect in the light of up-to-date information in order to decide whether to allow the implementer to move to the next step. All the information necessary to demonstrate the long-term safety fully and confidently may not be complete until a decision to close the facility is sought and it is subsequently confirmed that closure of the facility has been implemented appropriately.

During successive phases the regulatory body will assure itself that the implementer is achieving an adequate level of quality on safety-related aspects of the project and its implementation. It is recommended that, during the project, safety requirements are identified by the regulatory body and lead to targeted audits of the implementer's work.

The safety case should set out clear information on the design, construction and operational options considered and the key features on which safety relies. It should include a programme of work to acquire enough knowledge to demonstrate the safety of the disposal system. Assessing the soundness of the considered options is essential to enable the project to move forward from one phase to the next.

The safety case should acknowledge and accommodate uncertainties. Some uncertainties are unavoidable, and managing them is key when developing a disposal system and assessing its safety. Uncertainties and their management were examined in more detail in the frame of the pilot study and are presented in a companion report [1].

The pilot study group has reached a number of conclusions:

- Repository development should follow a stepwise process that includes: project conceptualization; site investigation; reference design; excavation and construction; operation and post-closure. Decision making processes – and regulatory review, where applicable – are often defined relative to these phases, although the exact definition of "phases" differs among countries.

- The regulatory process should evaluate systematically all the elements of safety and its assessment. There should be interactions between the regulator and the implementer from the earliest stages in the development of a disposal facility, even if initially the role of the regulator is less formal and its decisions or opinions may not be legally enforceable.

- The regulatory process requires the implementer to compile and present all safety arguments and their accompanying evidences , particularly where key decisions relating to progressing to the next phase of development must be made. These arguments and supporting evidence can be presented in a variety of documented formats, and collectively they are referred to as the safety case. The IAEA safety requirements [2] for geological disposal provide an adequate basis for developing the safety case.

- Demonstrating the safety of geological disposal is a process that needs to be undertaken systematically and through all phases of the development of a disposal facility. Safety arguments must be continuously refined and supporting safety assessments must be undertaken iteratively as the disposal facility is developed. The safety cases are expected to be consistent throughout the different phases.

- The safety strategy sets out the high-level approach for achieving safe disposal including the basis for an overall management system, a siting, design and implementation approach, and a safety assessment methodology. The safety strategy needs to be established from the beginning of the project.

- Elements of the safety assessment supporting the safety case may be distinguished between those related to: assessment of the robustness and performance the site and engineering of the facility; and assessment of impacts to people and the environment.

- The safety case must include an assessment of these individual elements and an integrated assessment of the overall disposal system. The manner and extent to which these elements are assessed during the process of developing and implementing the facility will vary with the phase reached.

- A systematic approach to managing uncertainties is key in demonstrating confidence in the safety of a disposal facility.

This pilot study provides an approach for demonstrating the safety of geological disposal, through the different stages of an evolving and maturing project. It focuses on regulatory review of the safety case and proposes a common set of regulatory expectations relating to safety issues that may provide the basis for the regulatory review of safety cases, in line with international emerging consensus. As disposal facility development progresses in various countries and experience from regulatory reviews of safety cases increases, this study could be revisited to take into account improved understanding and lessons learnt, and to take into account any new international standards and guidance.

CONTENTS

1. INTRODUCTION

1.1 BACKGROUND

Control and regulation of nuclear facilities involve many activities, including: establishing safety standards and related guidance; evaluating safety submissions (safety arguments and supporting assessments and evidence, collectively referred to as the safety case); establishing conditions of authorization; and assuring compliance. Considerable experience has been developed over the past few decades for most nuclear facilities, with the exception of geological disposal facilities for radioactive waste. Recent developments in a number of countries highlight the need to establish the processes required to regulate geological disposal facilities.

The IAEA and OECD/NEA have developed international standards, guidance, and recommendations on the subjects of nuclear, radiation, radioactive waste and transport safety, including specifically safety standards for geological disposal of radioactive waste.

At the beginning of the EPG project, within Europe, WENRA has published safety reference levels to assist in setting up a harmonized approach to demonstrating compliance with international safety standards in the fields of power reactor safety, decommissioning and waste storage safety. The safety reference levels are of a qualitative nature; they are intended to enable relatively straightforward auditing of compliance.

Some European countries and relevant international organizations with an interest in geological disposal are considering whether it is possible and sensible to develop a consistent approach to reviewing the demonstration of the safety of geological disposal facilities. The pilot study reported here is part of this work. The agreed approach is based on international safety standards, specifically the IAEA/NEA Safety Requirements for Geological Disposal [2]. A step by step approach to building confidence that the facility will meet the standards is adopted. We have aligned these steps with phases relating to major decision points required to move the development of a geological disposal facility from project conceptualization to site investigation, reference design, construction, operation, and post-closure phases. The process of formal regulatory approval to move between these phases may vary according to national regulations, but there is consensus that the overriding driver for regulatory purposes will be safety considerations.

The safety of geological disposal is achieved by a combination of site and engineered features designed to contain the radioactive waste and isolate it from the accessible biosphere for a very long time. The implementer of a geological disposal facility must carry out assessments and present these, together with all the necessary supporting evidence and safety arguments, to demonstrate that the proposed facility will perform these functions and meet the safety objective and criteria. Such assessments shall be performed for each phase in the development of the repository and shall require, for each phase, increasing information on the characteristics of the site, the facility engineering and the waste form, and an assessment of how these elements behave over time. Various uncertainties are associated with the assessments and the decision to proceed or not to the next phase must be made, based these assessments and the potential of the R&D programmes to manage these uncertainties. The extent and quality of knowledge about the facility and its behaviour will increase with time, which will clarify uncertainties and possibly reduce them. Managing these uncertainties (i.e. identifying them, evaluating their importance and identifying what has to be done to reduce or mitigate them) is crucial in developing confidence in the safety of the facility. In addition, arrangements to avoid or reduce radiation risks, radiological exposure of workers or public, non-radiological impacts to the environment, or feasible improvements of the robustness of the disposal system may be identified in the course of these assessments.

Therefore a systematic, structured, step-by-step approach is required to demonstrate the safety of a geological disposal system and to build confidence that it adequately meets the safety objective and criteria. In particular, this requires:

(a) Appropriate management systems to provide assurance to reach the safety objective of the disposal;
(b) Identification of the main geological and engineering features on which the safety of the disposal facility relies, together with technical arguments, evidence and assessments to demonstrate that these features will perform their safety functions adequately;
(c) Assessment of the performance and, radiological and non-radiological impacts on people and the environment, to demonstrate safety throughout the operational and post-closure periods taking into account normal and accident situations;
(d) Explicit consideration of uncertainties in assessments and identification of means, including R&D programmes, to manage them;

Together these elements provide the necessary basis for developing the safety case and for making decisions. They should be considered in a structured, integrated manner through every phase of the step-by-step process. The safety case will develop and mature as the project progresses. At any key decision-making step, the safety case must be sufficiently developed to provide the regulator that a sufficient level of safety has been reached to justify decision to proceed to the next stage.

1.2 OBJECTIVES

The pilot study focuses on regulatory review of the safety case and proposes a common set of regulatory expectations relating to safety issues that will provide the basis for this review. This report sets out what regulatory authorities may expect from the safety case at each step of the project and how the regulatory authorities may evaluate the elements of the safety case. In view of the importance of how uncertainties are managed, a detailed companion report on the subject has been prepared [1].

The safety objective and criteria are key to establishing the safety case for geological disposal. The manners in which these are set down vary somewhat between countries. However, those agreed in the international safety standards for geological disposal [2] are used as a point of reference and are set down in Chapter 3.

This report has been developed in two stages. The first version, available in March 2007, covered the first phases of development of a geological disposal facility. The present report, which builds on the first version, covers all phases of development.

This pilot study provides a framework for demonstrating the safety of geological disposal, through the different stages of an evolving and maturing project. It has broadly defined the regulatory expectations within this framework, which represents a currently emerging consensus. As disposal facility development progresses in various countries and experience from regulatory reviews increases, this study could be revisited to take into account improved understanding and lessons learnt, and to take into account any new international standards and guidance.

This report was developed by a group of experts. The report is intended to provide a common ground for participating countries on regulating radioactive waste disposal. It focuses on regulatory review of the safety case and proposes a common set of expectations relating to safety issues that may provide the basis for the regulatory review of a safety case. This report proposes what regulatory authorities could expect from the safety case at each step of the project and how the elements of the safety case may be evaluated. The intention is to support organizations involved in development or regulatory reviews of safety cases in the frame of radioactive waste disposal.

1.3 SCOPE

This report is the outcome of a volunteer effort by a dedicated group of experts as individuals working for regulatory bodies, technical support organisations or international organisations.

In 2004, the outcome of an early French-Belgium cooperation by means of a report on elements of a safety approach for radioactive waste disposal [3] was published. The French-Belgium initiative generated valuable momentum and a wider circle of countries decided to join the initiative and to expand on the collaboration within the so called European Pilot Group (EPG). A pilot study was implemented to share experience and opinions on the expectations of the regulatory bodies for the content of a safety case for geological disposal of radioactive waste at the different steps in a project to develop such a disposal facility. A first report on this pilot study was published in 2007 and covered the early development of the safety case, i.e. from the start of conceptualisation until a fully developed safety case is presented in support of a license application for the construction of a geological disposal facility.

The current report builds on the pilot study from 2007 and covers the entire lifecycle of a geological disposal project, i.e. from the start of conceptualisation until the disposal facility has been sealed and closed. A draft version of the report was sent for consultation in 2010 and the feedback from respondents has been integrated in the final version of this report. Due to the delay in finalisation, the newsworthiness of the finalised report is somewhat limited. Not least because other international initiatives has been developed in parallel, not least within the IAEA and the OECD/NEA, where members of the EPG has also participated. Thus, the intrinsic value of the work carried out within the EPG and the development of the pilot study as well as this report is not so much the resulting documents as such, but rather the process to develop the documents and the lessons learned in that process. Given this situation, the report should neither be considered to be exhaustive or represent the state-of-the-art. But it should all the same be considered a valuable contribution in support of organizations involved in development, or review, of safety cases for geological radioactive waste disposal.

2. STRUCTURE

The introduction sets out the background to the pilot study and how it has been carried out. Chapter 3 presents the safety objective and criteria based on the IAEA standards. It explains the structure and content of the safety case and how the regulator expects it to evolve as the project progresses. It addresses the various uses of the safety case and the approach to regulatory review of the contents and supporting assessments in relation to the decision making process. Chapter 4 discusses the regulator's expectations of the safety case throughout the lifecycle of a geological disposal facility, from conceptualization to post-closure. The chapter includes discussion of the role and content of the safety case, the evolution of the safety strategy, the assessment basis, the safety assessment, the management system and the integration of the various elements of the assessment, for each phase of the project. It also addresses aspects of regulatory review and decision making. Chapter 5 contains a discussion on uncertainties and their management and Chapter 6 presents the conclusions of the pilot study.

Throughout the report we refer, in parentheses, to the requirements set down in the IAEA document [2] in order to provide an easy reference.

3. THE SAFETY OBJECTIVE, CRITERIA AND THE SAFETY CASE. STRUCTURING AND PRESENTING THE SAFETY ARGUMENTS

The general safety objective and criteria, that geological disposal of radioactive waste must fulfil, as set down in SSR5 [2] are recalled below:

> (R.2.8) The primary goal is to ensure that radiation doses are as low as reasonably achievable and within the applicable system of dose limitation.
>
> (R.2.13) For a disposal facility, as for any other operational nuclear facility or facility where radioactive material is handled, used, stored or processed, an operational radiation protection programme, commensurate with the radiological hazards, is required to be put in place to ensure that doses to workers during normal operations are controlled and that the requirements for the limitation of radiation doses are met.
>
> (R 2.15) The safety objective and criteria for the protection of people and the environment after closure of a disposal facility are as follows:
> Safety objective: The safety objective is to site, design, construct, operate and close a disposal facility so that protection after its closure is optimized, social and economic factors being taken into account. A reasonable assurance also has to be provided that doses and risks to members of the public in the long term will not exceed the dose constraints or risk constraints that were used as design criteria.
> Criteria
>
> a) the dose limit for members of the public for doses from all planned exposure situations is an effective dose of 1 mSv in a year. This and its risk equivalent are considered criteria that are not to be exceeded in the future.
> b) To comply with this dose limit, a disposal facility (considered as a single source) is so designed that the calculated dose or risk to the representative person who might be exposed in the future as a result of possible natural processes3 affecting the disposal facility does not exceed a dose constraint of 0.3 mSv in a year or a risk constraint of the order of 10–5 per year.
> c) In relation to the effects of inadvertent human intrusion after closure, if such intrusion is expected to lead to an annual dose of less than 1 mSv to those living around the site, then efforts to reduce the probability of intrusion or to limit its consequences are not warranted.
> d) If human intrusion were expected to lead to a possible annual dose of more than 20 mSv to those living around the site, then alternative options for waste disposal are to be considered, for example, disposal of the waste below the surface, or separation of the radionuclide content giving rise to the higher dose.
> e) If annual doses in the range 1–20 mSv are indicated, then reasonable efforts are warranted at the stage of development of the facility to reduce the probability of intrusion or to limit its consequences by means of optimization of the facility's design.
> f) Similar considerations apply where the relevant thresholds for deterministic effects in organs may be exceeded.

The implementer of a geological disposal facility must assemble arguments and evidence to provide reasonable assurance that the above objective and criteria will be met, and to demonstrate that the disposal facility is safe throughout the different phases of a disposal programme. These arguments and evidence are usually referred to as a safety case, which may be one document or a series of documents. Requirements on the safety case are as follows (from [2]):

> (Requirement 3): Responsibilities of the operator
> The operator of a disposal facility for radioactive waste shall be responsible for its safety. The operator shall carry out safety assessment and develop and maintain a safety case, and shall carry out all the necessary activities for site selection and evaluation, design, construction, operation, closure and, if necessary, surveillance after closure, in accordance with national strategy, in compliance with the regulatory requirements and within the legal and regulatory infrastructure.
>
> (Requirement 12): Preparation, approval and use of the safety case and safety assessment for a disposal facility
> A safety case and supporting safety assessment shall be prepared and updated by the operator, as necessary, at each step in the development of a disposal facility, in operation and after closure. The safety case and supporting safety assessment shall be submitted to the regulatory body for approval. The safety case and supporting safety assessment shall be sufficiently detailed and comprehensive to provide the necessary technical input for informing the regulatory body and for informing the decisions necessary at each step.
>
> (Requirement 13): Scope of the safety case and safety assessment
> The safety case for a disposal facility shall describe all safety relevant aspects of the site, the design of the facility and the managerial control measures and regulatory controls. The safety case and supporting safety assessment shall demonstrate the level of protection of people and the environment provided and shall provide assurance to the regulatory body and other interested parties that safety requirements will be met.
>
> (R3.13) The operator has to conduct or commission the research and development work necessary to ensure that the planned technical operations can be practically and safely accomplished, and to demonstrate this. The operator likewise has to conduct or commission the research work necessary to investigate, to understand and to support the understanding of the processes on which the safety of the disposal facility depends. The operator also has to carry out all the necessary investigations of sites and of materials and has to assess their suitability and obtain all the data necessary for the purposes of safety assessment.

The following sections describe the structure, evolution, use and content of the safety case throughout the different phases of a disposal programme.

3.1 STRUCTURE AND CONTENT OF THE SAFETY CASE

The purpose of the safety case is to present all the arguments, information and assessments that together support and demonstrate operational and long term safety of the disposal facility. In this respect, the safety case will have to demonstrate as key objectives:

a. For the operational period, that workers, members of the public and the environment will be adequately protected against radiological and non-radiological hazards, under normal and accident situations.

b. For the period after closure, that members of the public and the environment will be adequately protected against radiological and non-radiological hazards, under conditions of expected and less likely modes of evolution of the disposal system.

The safety case will evolve, and the supporting evidence and the safety assessment will become more extensive and better developed, as the project progresses. Significant uncertainties associated with the disposal system will be addressed and, where possible, reduced as the project progresses and their consideration will feature prominently in the evolving safety case.

The format for the safety case is not fixed or prescribed and is likely to be different in different countries. The format will also vary with the decision context of the safety case. The safety case may be presented as one set of collated documents, or in a series of reports presenting different aspects of the case. Whatever the format adopted it will nevertheless contain [4]:

- The safety strategy, which sets out the high-level approach for achieving safe disposal, including the siting and design approach, the strategy to manage the activities and the assessment methodology;

- The assessment basis, which sets out the information and analysis tools that support the safety assessment and describes the disposal system, the data and understanding relevant to the safety assessment and the methods, models and computer codes for analyzing system performance and radiological impact;

- The safety assessment which is the process of systematically analyzing the hazards associated with the facility and the ability of the site, the host-rock and the operational procedures to provide the safety functions and meet technical and safety requirements. It also includes additional evidence and analyses for safety and for confidence in safety;

- The management system which structures the overall approach for managing the activities conducted by the implementer;

- A synthesis of all the available evidence, arguments and analyses and conclusions regarding the safety of the disposal and the level of confidence reached by the implementer.

The safety strategy, assessment basis, safety assessment and management system are described in more detail in sections 3.2, 3.3, 3.4 and 3.5. Other key aspects of the safety case are addressed in section 3.6.

3.2 SAFETY STRATEGY

The implementer of the disposal facility is responsible for defining and describing the safety strategy.

The safety strategy sets out, at a high level, the approach for achieving safe disposal. The safety strategy should describe all the approaches, processes and methods that will ensure that the disposal facility meets the safety objective. . The safety strategy should remain consistent during the different phases of disposal facility development.

The safety strategy should be developed in accordance with the key objectives presented in 3.1. It will address the implementation of the radiation safety principles and safety design principles such as demonstrability , defence in depth (use of multiple safety functions) and the use of passive means.

The safety strategy will identify the safety functions of the disposal system (containment, isolation), as well as those allocated to its components. The main components of the safety strategy are:

- The approaches for selecting a site, developing a concept, implementing practical engineering solutions and a monitoring and surveillance programme. These design choices take into account arrangements to ensure the reversibility of disposal operations and the retrievability of waste packages during the operational phase and after depending on the country;
- The approach to optimization leading to the achievement of as high as reasonable level of protection under the prevailing circumstances;
- The safety assessment methodology that describes how safety assessments will be carried out. It defines the approach to evaluating evidence, analysing the evolution of the system in the context of an adequate set of defined and substantiated scenarios and the approach to treating uncertainties (i.e. ranking uncertainties and propagating them in the impact assessment);
- The overall approach for managing the various activities related to the disposal facility development and implementation (such as siting and design, safety assessment, site characterization, management of uncertainties, waste form characterization, R&D and long term information management). The management approach ensures that:
    - the work focuses on the safety objective,
    - adequate resources are available
    - activities are correctly carried out and co-ordinated.

The safety strategy is intended to define how high-level objectives and principles will be fulfilled under the overall project development. Fundamental aspects of the strategy are not, in general, expected to change over the course of the project; however, approaches may evolve to take into account experience, technical developments, societal inputs, and new national and international standards and guidance. To the extent possible, the implementer should identify those aspects that are not expected to change throughout the development of the project, for example the concept of complementarity and independence of barriers deriving from the principle of “defence in depth” and the concept of “demonstrability”, as distinct from specific choices that might evolve as the project progresses, for example the schedule for waste emplacement.

Constraints may be imposed by the prevailing circumstances (scientific and technical state of the art, socio-economic situation, national legislation). These constraints and their consequences on the safety strategy should be clearly identified. Within the stepwise process, the implementer will have to confirm that the safety strategy is adequate to meet the key objectives. As part of the safety strategy, the approach to optimization will be set out and developed. The objective of optimization, in principle, is to strive for the ‘optimal’ or ‘best’ combination of characteristics in terms of balancing imperatives of operational and post-closure safety, keeping in mind that the final objective is to optimize overall protection taking into account prevailing circumstances.

The optimization process is a judgmental process that is applied to decisions made during siting and during the development of the facility's design. This will include, for example, consideration of how alternative options (e.g. for siting and design) will be evaluated. The implementer assembles the qualitative and quantitative arguments that support the choices made (including the reasons why particular options were rejected). Optimization should primarily aim at optimizing performance of the disposal system concerning isolation, containment capacities, as well as robustness properties, taking into account prevailing circumstances. There are no specific recommendations on methods to balance operational and post-closure safety, however, when selecting design options, an optimization approach that references both periods may have to be adopted. Optimization implies that sound engineering and technical solutions are adopted and that sound principles of quality management are applied to all aspects and in all phases of repository development.

The optimization process should involve dialogue between implementer, regulator and other stakeholders as appropriate. Key aims of the process should be to record the decisions taken and the role that optimization had played in making them. The NEA report on optimization states: "Where optimization becomes a matter for the regulatory authority, the focus should not be on specific outcomes for a particular situation but rather on processes, procedures and judgements" [5]. Additional information can be found in the companion report addressing uncertainty management [1].

3.3 ASSESSMENT BASIS

The assessment basis sets out the information and analysis tools that support the safety assessment.

The assessment basis describes the disposal design, the layout of its components, the scientific and technical information and understanding as well as the assessment methods, models, computer codes and data bases. The disposal system includes the waste inventory, the engineered barriers, the host rock and the parts of the host environment whose properties and behaviour contribute to post-closure safety.

The data and scientific understanding should highlight evidence that the information base is consistent, well founded and adequate for the purposes of safety assessment. Any relevant uncertainties should, where possible, be quantified or bounded, including how uncertainties vary over time. Features, events and processes that are potentially important for the safety of the disposal system should be identified and characterised.

The assessment methods, models, computer codes and databases must be shown to be reliable following a qualification process. This means that their development follows a logical, clear and systematic approach that is appropriate to their intended use; that the mathematical models are based on well-established physical and chemical principles and are applicable in conditions (e. g. scales of space and time) relevant to the assessment and that computer codes are developed in the framework of QA procedures and benchmarked and correctly solve the equations of the mathematical models.

3.4 SAFETY ASSESSMENT

The safety assessment includes at least the following two elements to determine whether or not the disposal facility is regarded as safe:

- Assessing the suitability of the host-rock, surrounding environment and engineering components in particular to demonstrate
  - the feasibility,
  - and the performance and the robustness of the disposal system with regard to the safety functions;
- Assessing the radiological and non-radiological impacts on people and the environment;

The performances of the system and its components can be assessed through indicators such as radionuclide concentrations or radionuclide fluxes through barriers. Other indicators (often termed "safety function indicators") which are more directly linked to physico-chemical or technical properties can also be applied. These assessments assist in demonstrating the overall safety of the disposal system by propagating uncertainties and evaluating a.o. the safety significance of the individual system components and their performance, robustness and complementarity.

The radiological impact is assessed against radiological criteria, most often in terms of radiation dose, risk or some combination of both. Non-radiological impacts on people and the environment may also be assessed against relevant criteria.

Radiological impact assessment entails the need to assess, with a sufficient level of confidence, exposures that might arise during the operational period and from the long term evolution of the facility. Non-radiological impact assessment entails a similar need. Both require a clear substantiation that the assessment of selected scenarios provides a conservative estimate of the impact. They also require a sensitivity analyses to identify key dependencies on parameter values and assumptions, together with evaluating the effect of uncertainties.

The safety assessment includes both quantitative and qualitative elements and multiple lines of reasoning. Safety assessments involve data selection and modelling.

As noted earlier, the safety case includes a description of the management system to assure an adequate level of quality in respect of all safety related aspects of the project (see section 3.5). Certain aspects of the management system – for example, assurance that models, codes and data are fit for purpose and are correctly applied – will relate specifically to the assessment basis and the safety assessment.

3.5 MANAGEMENT SYSTEM

The implementer should establish, document, maintain, assess and continuously update a management system during all the activities to be carried out from site characterization to closure of the facility and, as required by the regulator, post closure activities.

The management system which structures the overall approach for managing the activities has the aim of achieving and enhancing safety by:

- Bringing together in a coherent manner all the requirements for managing the organization;
- Describing and implementing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;
- Ensuring that other demands on the implementer (e.g.: health, environmental, security, quality and economic requirements) are not considered separately from safety requirements, to help preclude any unacceptable negative impact on safety.

More specifically the management system should ensure that:

- the implementer has set up an appropriate organization (including staffing, skills, experience and knowledge) and processes to address any requirement or recommendation resulting from the regulations, from regulatory assessment of the project and/or from peer review
- the implementer competently undertakes all relevant activities required to be implemented and to ensure the quality of the deliverables;
- R&D programmes are appropriately focussed on safety-relevant issues and adequate for the management of uncertainties;
- international feedback from similar facilities elsewhere is taken into account;
- key information, data and their provenance are recorded and preserved.

As the safety case is expected to summarize the output from many projects, results and substantiations, the management system should ensure that all the appropriate information is made available to the regulator in order to support regulatory decision-making. Furthermore, the management system should allow for information and lines of reasoning to be readily traceable through the safety case.

The safety case should contain information about the implementation of the management system with particular emphasis on considerations about long timescales and the iterative nature of the project. In particular, the implementer will be expected to present activities to be carried out and targets to be reached prior moving to the next step.

As part of quality management, quality audits are needed, for example to provide:

- assurance that models, computer codes and data are fit-for-purpose and correctly applied;
- assurance that scientific understanding within the assessment basis is state-of-the-art;
- assurance that characteristics and processes of the engineered barriers, the host rock and the surrounding geoenvironment and their evolution are comprehensive, confident and consistent;
- assurance that uncertainties are being managed;
- assurance that the facility has been constructed as designed and that the impacts from any deviation have been assessed for their effects on safety and incorporated in the safety case;
- confidence in the adequacy and quality of the records of the wastes disposed of (waste inventory and emplacement records); and demonstrate compliance with waste acceptance criteria.

Evidence of quality audits will form part of long-term information management and record-keeping.

The implementer’s management system needs progressively to improve and adapt so that it is suitable for each stage when that stage is reached. The implementer should substantiate that the allocation of appropriate resources is being updated and that needs for the next phase will be satisfied. In order to ensure that this is achieved, necessary adaptations need to be formulated in advance.

3.6 OTHER SPECIFIC ISSUES

Some elements of the safety case, such as the management of uncertainties, the basis for integration of safety arguments, and objectives for specific activities initiated during construction such as monitoring and surveillance, should be defined at the start of the project. These will evolve to take into account experience, technical developments and societal inputs as the project progresses, but they rely on principles that will remain the same in successive phases.

3.6.1 Management of uncertainties

In the safety case, the implementer needs to identify key uncertainties that may influence safety and the specific measures or actions needed to address them, especially with regard to the R&D programme. At the earliest stages of the project, there may be many unresolved issues and uncertainties. The safety case should present a methodology for addressing and managing those that might undermine safety, and demonstrate that there are good prospects for dealing adequately with them in future stages.

By the time a safety case is presented as part of an application for a licence to build the disposal facility, any uncertainties and open questions that might undermine safety should have been addressed adequately to support the necessary decisions, and this will be reflected in the statement of confidence. Uncertainties will inevitably remain (a host rock, for example, cannot be fully characterized without, in the process, perturbing its characteristics), but it should be demonstrated that these uncertainties do not undermine safety arguments.

The methodology for implementing this approach is presented in chapter 5 and the management of uncertainties is examined in more detail in a companion report [1]. For example, at the start of the project, it may be possible to reduce or avoid some key sources of uncertainty, or mitigate their effects, by modifying the location or design of the disposal facility.

Uncertainty and safety strategy

Management of uncertainties needs to be integrated within the safety strategy. Accounting explicitly for uncertainties and analysing their possible consequences are an essential part of any safety assessment for a radioactive waste disposal facility. Information about uncertainties and how they can be managed forms an important input for the decisions to be taken at each step in the development of the facility. The approach for managing uncertainties should define a management process for identifying, assessing and, where appropriate, avoiding, mitigating or reducing them. A register of significant uncertainties should be provided.

Uncertainty and assessment basis

In many cases, steps can be taken to avoid, mitigate or reduce uncertainties linked to the level of understanding of the processes governing the evolution of the repository system. This can apply whether or not the uncertainty concerned is amenable to quantification.

As the project progresses, effort should focus increasingly on key safety-relevant uncertainties and the data and measurements needed to address them. Uncertainties can be sometimes reduced by acquiring more data from, for example, site characterization (including host-rock) and laboratory tests. In some cases, uncertainties can be managed by identifying and assembling multiple lines of evidence that support assessment assumptions or parameters, including, for example, evidence from natural analogues to support the longevity of engineered materials.

Models may need to be simplified in order to carry out the safety assessment. Where this is necessary, the implementer should give the reasons and substantiate the validity of the simplifications with respect to its intended use. However, all the relevant basic data must be made accessible as part of the safety case. The provenance and quality of these data need to be demonstrated.

Uncertainty and performance assessment

One part of safety assessments is to deal with the identification, description and analysis of residual uncertainties that are relevant to safety, and investigation of their effects. These include uncertainties about whether all the relevant features, events and processes have been considered, uncertainties over how they are described and should be modeled, and uncertainties about the data used in analyses. Safety assessment, whose role is to assess the performance of the system or subsystems using performance indicators, is a valuable tool for identifying where further work should be directed to avoid, mitigate or reduce uncertainties. This is a means by which the link between safety assessment and safety strategy is maintained.

Irreducible uncertainties

Some uncertainties are difficult to quantify or bound, and are less amenable to the above methods, particularly in cases where the range of possibilities is very wide or uncertain. The evolution of the biosphere and the nature and timing of future human actions, for example, become highly speculative even over relatively short timeframes. Where such uncertainties may be considered to have a significant effect on the safety case, measures to investigate, address and mitigate these uncertainties as well as evaluate their impact on safety should be implemented. Such measures might be, for example, the use of safety and performance indicators complementary to dose and risk, and the use of stylised approaches that are broadly conservative with respect to any consequences for safety or the environment.

3.6.2 Integration of the safety arguments and evidence, statement on level of confidence

The implementer is responsible for developing the safety case to provide increasing confidence that a safe disposal system can be achieved, and to support the regulatory and other decisions for the project to progress to the next stage. An overall integration of the safety arguments and evidence from the assessments above will be progressively developed in the different phases of the project and presented in the safety case.

The implementer should argue, at each stage of the project, that a level of confidence has been reached sufficient to proceed to the next stage, based on the evidence, analyses and arguments presented in the safety case. If the evidence, analyses and arguments do not provide sufficient confidence to the regulator to support the proposed decisions because of the magnitude of the uncertainties, then the implementer will need to revise it (e.g. by reconsidering the site, by revising the design, by improving or modifying the assessment basis, or by utilising more of the information available in the assessment basis).

The safety case should demonstrate that all relevant data and information have been considered, all models have been tested adequately and a rational assessment procedure has been followed. It should include a verification of the consistency and completeness against regulatory expectations.

The safety case should also identify and consider the limitations of the currently available evidence, arguments and analyses, identify where knowledge is lacking or uncertainties are high, and the work needed in the next step. It should highlight the principal arguments that the implementer has considered in making its decision on continuing to develop the project. More particularly, it must demonstrate that there are good prospects for dealing adequately with uncertainties and unresolved questions in future stages.

Integrating the safety arguments and evidence is not an automatic process, but needs to be managed by the implementer. The evidence will accumulate over time and assumptions that seemed appropriate at a given stage may need to be revised later in the light of new and more relevant evidence. The implementer should consider the different possible interpretations of the evidence. In some cases the evidence may be so compelling that there is a clear scientific consensus or weight of evidence. In other cases, however, the evidence will be more equivocal and the safety case should address the likelihood and consequences of the different possible interpretations. This approach is essential to build confidence in the safety case and should not be seen as an endeavour to weaken it.

3.6.3 Monitoring and surveillance

The implementer should provide a description of the baseline (geological, hydrogeological, radiological, chemical …) conditions inside and around the disposal system. He should define a monitoring and surveillance programme appropriate to the different phases of disposal facility development and implementation, up to post-closure. The baseline must be monitored sufficiently early before the start of underground construction to allow representative data to be collected.

The monitoring and surveillance programme should meet the following general objectives [6]:

- To demonstrate compliance with regulatory requirements and with the licence conditions;
- To verify that the disposal system is performing as expected, as set out in the safety case. This means that the components of the disposal system are carrying out their functions as identified in the safety assessment.
- To verify that the key assumptions made and models used to assess safety are consistent with actual conditions;
- To establish a database of information on the disposal facility, the site and its surroundings to support future decisions;
    - when proceeding from siting to construction, operation, closure and the period after closure.
    - relating to updating concepts and procedures for monitoring and surveillance.
- To provide information for the public.

Throughout all phases of the project the implementer should identify the parameters to be monitored, the way the data will be analysed and how the results of analysis will be taken into account (for example, the implementer should specify the criteria for monitored parameters that, if violated, will require some response, ranging from undertaking further R&D to implementing corrective actions).

Monitoring and surveillance will take place at different locations in and around the disposal facility. The implementer should demonstrate that implementing the long-term monitoring and surveillance programme is feasible, and that the benefits of the monitoring and surveillance programme and its individual components are sufficient to outweigh any of its adverse impacts on the performance of the system and on long-term safety.

In developing an approach for monitoring and surveillance, the following possible detriments will be duly considered while developing the approach:

- formation of pathways through the barriers by the installation of monitoring and surveillance equipment, leading to increased potential for radionuclide migration within or around the disposal facility ;
- an increased likelihood of human intrusion especially if the underground structure remains open and institutional control is no longer continued;
- formation of pathways through the barrier system e.g. leading to flooding.

3.7 EVOLUTION OF THE SAFETY CASE WITH THE PROJECT

(Requirement 11): Step by step development and evaluation of disposal facilities
Disposal facilities for radioactive waste shall be developed, operated and closed in a series of steps. Each of these steps shall be supported, as necessary, by iterative evaluations of the site, of the options for design, construction, operation and management, and of the performance and safety of the disposal system.

(Requirement 14): Documentation of the safety case and safety assessment
The safety case and supporting safety assessment for a disposal facility shall be documented to a level of detail and quality sufficient to inform and support the decision to be made at each step and to allow for independent review of the safety case and supporting safety assessment.

3.7.1 Stepwise approach

It is agreed internationally that developing a geological disposal facility must be carried out in a series of phases, with work undertaken to ensure that enough is known about the safety of the facility before proceeding from one phase to the next. In this study, we identify these phases in terms of moving the project along from conceptualization, through siting, design, construction and operation, and finally to closure. Many activities will continue from one phase to the next, and, as noted previously, the exact “phases” and their definition will differ among national programmes. The phases defined in this document – and especially the transitions between phases – represent typical key decision-making points for the regulator (especially at later stages). The implementer will have additional hold points of its own associated with key decisions it must make. However this report focuses on the regulatory process and is aligned with the major phases identified above.

The safety case will provide the information needed to make these key regulatory decisions. The safety arguments will develop and mature as the project progresses and the supporting information and assessments will become more substantial. It will be important to maintain a historical record of the developing safety arguments so that how and why they have changed can be traced and understood.

3.7.2 Revision of the safety case

The implementer should update the safety case progressively to incorporate information gained during the different phases of the project. This will include:

- The growing body of data about the environment of the disposal facility;
- Information about the facility as actually built and the waste as actually emplaced;
- New developments and operating practices, such as emplacement techniques and materials of encapsulation, buffer materials or construction materials;
- New waste streams

In particular, the safety case will need to take into account experience and information derived from handling and emplacing waste packages and any construction activities continuing in parallel with operation of the facility.
If new information arises that is potentially significant in terms of its effect on safety, the implementer should review, and if necessary revise, the safety case to take the new information into account. It should be recognized that the design may evolve to some extent

during the development of the disposal facility (e.g. new construction or waste package materials, new engineering techniques, and any new emplacement plant and systems). The significance of any changes to the reference design will need to be identified and assessed. The implementer should carry out sensitivity analyses to assist in directing and updating the research programme and in developing the facility design. Any substantial change to the disposal system design motivated by feedback from operational activities or monitoring and surveillance should be documented in the safety case

The implementer will need to develop a process, and to maintain a dialogue with the regulator, to identify which modifications has to be submitted for approval.

If there are any unexpected events of significance to safety during the construction, operational and closure periods, the safety case should identify these and account for any consequences that they, and any changes made to operating practices as a result of them, may have on the safety arguments.

3.8 USE OF THE SAFETY CASE

(Requirement 6): Understanding of a disposal facility and confidence in safety: The operator of a disposal facility shall develop an adequate understanding of the features of the facility and its host environment and of the factors that influence its safety after closure over suitably long time periods, so that a sufficient level of confidence in safety can be achieved.

(Requirement 4): Importance of safety in the process of development and operation of a disposal facility: Throughout the process of development and operation of a disposal facility for radioactive waste, an understanding of the relevance and the implications for safety of the available options for the facility shall be developed by the operator. This is for the purpose of providing an optimized level of safety in the operational stage and after closure.

The main objective of the safety case is to demonstrate that it is possible to construct, operate and close safely a disposal facility by demonstrating that the aspects that have an impact on safety (in operation and after closure) have been analysed, understood, assessed and managed (or will be). As a consequence, a fundamental use of the safety case will be to enable the project to move from one phase to the next and to provide the arguments, assessments and information on which the regulatory process will be based. In this respect, the safety case should allow for an independent appraisal of the level of safety.

The safety case will be used as a reference of the implementation of the disposal facility. In the early phases, the safety case will be used to guide the site investigation and characterization work required in the next phases. It will also be used to plan research and development.

The safety case must address all the aspects of the disposal system that have an effect on its safety. The safety case should as well support the design and development process by providing substantiation based on assessments and information obtained during the earlier phases of the project.

The information provided in the safety case should be collected, analyzed and presented in a logical, coherent, systematic and structured manner.

The safety case will also form the basis for providing information to stakeholders. However, the weight given to different aspects of the case and their hierarchy, the detail provided, how the material is presented will be tailored to meet the needs of particular audiences (see section 3.10).

The level of detail of the safety case should be consistent with the current phase of the project. There will be a great deal of material available to support the assessment. It should be recognized that more information/material does not necessarily make a stronger or better safety case/assessment. However, a decision to disregard or discard irrelevant or non-essential information/material should be substantiated by clearly establishing the relevance of material/information from the assessment basis, to the safety assessment.

3.9 REGULATORY ROLE. GUIDANCE TO REVIEW THE SAFETY CASE

> (Requirement 1): Government responsibilities
> The government is required to establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities shall be clearly allocated for disposal facilities for radioactive waste to be sited, designed, constructed, operated and closed. This shall include: confirmation at a national level of the need for disposal facilities of different types; specification of the steps in development and licensing of facilities of different types; and clear allocation of responsibilities, securing of financial and other resources, and provision of independent regulatory functions relating to a planned disposal facility.
>
> (Requirement 2): Responsibilities of the regulatory body
> The regulatory body shall establish regulatory requirements for the development of different types of disposal facility for radioactive waste and shall set out the procedures for meeting the requirements for the various stages of the licensing process. It shall also set conditions for the development, operation and closure of each individual disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met.

In addition to developing the regulation and guidance related to geological disposal the regulator will have a continuing role to review the safety case and provide feedback to the implementer throughout the whole process of developing and implementing a geological disposal facility. Consideration is given in this report to the regulatory process and how this will be conducted throughout the project.

In the early stages the regulator should be ensured that the implementer will allocate and commit appropriate resources to the project. The long timescale for the process requires confidence in the stability of the implementing organization such that the safety strategy and safety relevant information will be preserved irrespective of potential future changes in organizations or responsibilities. The latter is often influenced by government decision and is generally outside the control of the regulator. Nevertheless, the regulator is in a good position to advise the government in this regard.

From the beginning of the project, the regulator should define and implement an appropriate organization to ensure allocation of sufficient resources for the review of the safety case at all the stages of the development of the repository. In particular, the regulator will need to establish and develop its resources and identify the need for research and development to be conducted in support of its expertise and ensure that the results are available in due time. R&D work is essential for regulators as it allows maintaining and improving their scientific and technical skills, contributes to their independence and helps to build public confidence in the regulatory system. The regulator will provide guidance and recommendation to the implementer. It may be called upon to advise government and interact with other stakeholders. Much of this will be concerned with the structure and content of the safety case. At these early stages the regulator may also have a more formal role in, for example, representation on advisory bodies and providing input to legislation.

As the project progresses and depending on the country, the regulator will be increasingly called upon to review the safety case and supporting assessments and information, and to provide feedback to the implementer. The regulator will need to ensure that important decisions are not made prematurely.

In the advanced phases of the project, the regulator will have to make decisions and go through defined formal legal processes. Such decisions may involve granting an authorization for the implementer to proceed to the next phase of facility development. The regulator will establish and issue any necessary conditions of the authorization, for example to impose specific requirements on the implementer, in order to move to the next phase in the development of the facility.

In reviewing the safety case the regulator may call upon specialist advisers for assistance. The regulator should ensure that its advisers are suitably independent from the implementer and have not contributed to aspects of the safety case on which they are being asked to provide advice. The regulator may also obtain (or require the implementer to obtain) independent peer review of particular aspects of the safety case.

Aspects of the work supporting the safety case will be subject to audit and inspection by the regulator. Such audits and inspections will be conducted according to a formal programme and established procedures. In the event of serious concerns or non-compliance, the regulator will take formal action. Other, less significant issues or concerns may be discussed with the implementer, or may be formally identified in writing, in order to move to the next phase in the development, on the understanding that they are addressed to the satisfaction of the regulator in a timely manner.

Throughout the project the regulator will document its activities and maintain a record of its decisions and the basis for those decisions. The regulator is expected to issue reports as necessary to inform stakeholders.

3.10 INTERACTION WITH STAKEHOLDERS

It should be borne in mind that both the implementer and the regulator will need to maintain a dialogue with stakeholders. The regulator will have to engage with a range of interested parties through, for example, formal or informal stakeholder dialogue processes and statutory consultation processes, as determined by national legislation or custom, or as circumstances require.

Key stakeholders will need to be kept up-to-date with the safety case as it progressively develops. A sound safety strategy is hence crucial to maintaining a broad consensus among stakeholders.

4. MAIN EXPECTATIONS OF CONTENT OF THE SAFETY CASE DURING EACH PHASE OF THE PROJECT

> (Requirement 11) Step by step development and evaluation of disposal facilities
> Disposal facilities for radioactive waste shall be developed, operated and closed in a series of steps. Each of these steps shall be supported, as necessary, by iterative evaluations of the site, of the options for design, construction, operation and management, and of the performance and safety of the disposal system.

Geological disposal facilities will be developed in a number of discrete phases and the safety case will support the decision making process for moving from one phase to the next. For the purposes of the pilot study all phases up to the post-closure phase are considered.

The various phases represent a logical chain of events leading through clearly defined milestones towards the implementation, operation, and closure of the disposal facility. In the succeeding sections of this chapter, the phases covering conceptualization, site investigation and selection, reference design, construction, operation, post-closure are addressed.

4.1 THE CONCEPTUALIZATION PHASE

During the conceptualization phase the implementer considers potential sites and design options, establishes the safety strategy and carries out preliminary assessments. At this stage of development these assessments will be based on assumptions and generic data, and taking into account prognosis of waste characteristics to be disposed of.

4.1.1 Regulatory review and decision making

This initial stage in the process usually does not involve a formal licensing process or regulatory role. There is mutual benefit, however, if the regulator becomes involved early in the process. The regulator may have a formal obligation to advise government and therefore should be kept informed of all relevant developments.

The regulator will review the safety strategy and guide the implementer on the likelihood of achieving the necessary demonstration of safety to move to the next phase of the project.

It is important for the implementer to be aware whether the regulator endorses the direction the project is taking. The regulator should not avoid being involved in the process at this early stage out of any concern over being constrained or compromised in its ability to make any future regulatory decisions.

For a meaningful involvement both during the early stages of a project and later, the regulator must have sufficient overall competence and should develop its own capacity for the subsequent phases of the project.

4.1.2 Role and content of the safety case

At this stage of the project, the safety case will present the safety strategy and the way it will be met. The key aspects related to the safety strategy, namely to optimization and description of the design concept, need to be addressed.

At this stage it will not be possible to provide a detailed description and assessment of the facility. Consequently, it should be recognized that it will not be possible to provide the evidence necessary to demonstrate long-term safety, nor will it be possible to demonstrate the practicability of the design. However, at the end of this phase the implementer should demonstrate that the key factors important to safety have been identified and that the design concept integrates properties and characteristics of the host rock, engineered materials and waste.

The management system and the approach to performance assessment, radiological and non-radiological impact assessment, as well as uncertainty management should be set out and explained, even though these aspects are likely to evolve in subsequent phases of the project.

4.1.2.1 Safety strategy

During the conceptualization phase the implementer should define the basis of the safety strategy, which will address the approach for selecting a site and developing a safety concept.

The strategy will deal with radiation safety principles and safety design principles such as the requirement for passive systems, and the use of multiple safety functions, in relation to the containment and isolation properties of the disposal system. These design requirements, set out in the SSR5 document [2], were further previously developed in more details in the Franco-Belgian study [3]. The adoption of these concepts in the safety strategy ensures that they are guiding principles during further development of the disposal system.

The safety strategy will also include a description of the functions assigned to each component of the disposal system (both during operation and post-closure) and the expected evolution of each component with time. It should explain how the components will function together in a complementary manner to ensure multibarriers principle. Features, events and processes that are potentially important for the safety of the disposal system should also be identified.

The assessment strategy at this stage should outline the basic approaches and tools that are expected to be applied to model the individual components of the disposal system and the disposal system as a whole, and to demonstrate the safety of the system with reasonable assurance. In particular, the assessment strategy should provide an indication of how the different aspects of safety assessment will be conducted. In particular, the implementer will address:

- The proposed methodologies to be adopted;
- Approaches to scenario
- Model development;
- The treatment of uncertainties;
- The role of sensitivity analysis, through safety assessment.

4.1.2.2 Assessment basis

At this stage, the collection of information and analysis tools supporting the safety assessment and including an overall description of the disposal system is preliminary. The implementer will present a preliminary design and substantiate the main design choices.

4.1.2.3 Safety assessment

Performance assessment

A global evaluation of the design concept and of the overall compatibility of the system components must be performed. At this stage the approach will be largely generic.

The safety assessment should confirm that individually and collectively the components of the disposal system will ensure implementation of the safety strategy and that the components will fulfil their expected role under anticipated conditions, taking into account also possible perturbations from anticipated conditions that have been identified.

In this respect, effects of the situations and phenomena that may significantly affect system performance, both internal and external (heat, corrosion, radiolysis, mechanical stress, criticality, geodynamics, seismicity, climate change, etc.), are expected to be progressively quantified so as to assess the system behaviour and robustness.

The Performance assessment must also address the feasibility and reliability of the proposed construction methods and the technical feasibility of the proposed design options, identifying aspects that rely on already proven techniques and those that are new and need future confirmation through experimental tests. For the latter, the implementer will be expected to provide arguments confirming that technical feasibility can be demonstrated through a qualification programme that can reasonably be carried out within the time planned for project development. Where such arguments involve large uncertainties, the implementer will be expected to consider design alternatives, based on technical options that have been demonstrated on the basis of extensive feedback from industrial experience.

Considering all these aspects, the design and site performance will need to be substantiated and the uncertainties remaining at the particular stage of the project will need to be propagated through the assessment.

Radiological and non- radiological impact assessment

Though impact assessments can only be very preliminary at the conceptualization phase, it is nevertheless desirable to carry out such preliminary assessments in order to provide a broad order of magnitude estimate of possible impacts, based on generic considerations of site performance, and to begin to identify the features of the facility and its geological setting that are likely to be important to safety.

4.1.2.4 Management system

Amongst the topics related to the implementation of the management system, at this early stage, the following should be addressed in the safety case:

- The basis of a programme of planned activities to ensure that each activity will, in time, provide necessary and sufficient information, taking into account progress, and allowing the flexibility to accommodate unexpected developments and results from other activities;

- A description of the information that will be recorded and how it will be recorded. The information management system should enable investigations of options considered and results of these investigations to be traced through the process. This is particularly relevant for the iterative process during the early stages in project development;

- The substantiation that the organizational structure will provide the necessary resources to undertake the project giving appropriately high priority to safety and enabling integration of the different aspects of work to be undertaken in a coherent manner.

4.1.2.5 Integration of the safety arguments and evidence

At this stage only preliminary elements will be presented. The safety case should aim specifically to address the identification of areas where knowledge is lacking or uncertainties are high and the establishment of priorities for further work in the next phase as well as proposals for the preferred approaches and options to address the areas identified above, particularly in respect of the development of the design, research and data acquisition, scenario development and modelling. It should be shown that adequate host formations and sites with respect to the safety strategy are potentially available.

4.2 SITE INVESTIGATION AND SELECTION PHASE

During the siting phase, the implementer identifies and confirms potentially suitable host formations and sites that are compatible with the design concept and the safety strategy and characterizes these sites to the extent that a decision can be made on the preferred site. The safety case must contain an appropriate demonstration of safety that will enable one or more candidate sites, together with specific locations on those sites, to be selected for the disposal facility and to allow progression to the next phase of disposal facility development.

At this stage it is very important for the implementer to identify the key uncertainties and to establish as far as possible that they can be managed. Inability to manage the key uncertainties adequately once a site has been selected is a key risk for the project.

At the end of this stage, the implementer aims at establishing that at least one design option presents good prospects of feasibility, in the sense that it relies on proven and/or demonstrable features and is able to accommodate uncertainties related to the expected performance of the various components of the disposal system. This is an important condition to enable the large resources needed for moving to the next phase.

4.2.1 Regulatory review and decision making

It is expected that, at the end of this phase, formal regulatory approval will be sought for the selected site, based on a review of the information and assessments addressed in the safety case. Conditions attached to the approval are expected to address the further site characterization work to be undertaken, the research and development programme and the design process.

The approval should define the basis for regulatory interaction in the next phase of the project.

The regulator will expect the implementer to substantiate the selection of the site, based on a comparison of available geological formations and sites in term of safety and more particularly in terms of containment and isolation capabilities and long term stability. Consideration should be given to locating the facility away from known underground mineral, geothermal and water resources and from densely populated territories, so as to reduce the risk of human intrusion into the components of the disposal system contributing to containment, and of human activities in the surrounding area that may affect the facility.

4.2.2 Role and content of the safety case

The first objective at this stage is to confirm the expected properties of the host rock (e.g. isolation and containment) and their compatibility with the design concept developed in the conceptualization phase. The second objective is to adapt and refine the design concept taking into account the new data collected from investigation and characterization of the host rock and surrounding environment. The potential candidate sites must be appropriately investigated to allow for the selection of one or more preferred sites.

The safety case and its content will evolve as the project develops in terms of engineering and in terms of characterization of the different components (natural and engineered) of the future disposal system. At this stage, the safety assessment, considered as generic at the conceptualization phase, evolves to an indicative impact assessment consistent with the development of the design and the level of detail of the site characterization. Any uses of the results from the safety assessment must be balanced with the associated level of uncertainty.

4.2.2.1 Safety strategy

For the current site investigation and selection phase, the implementer should confirm or update the overall approach to safety assessment and the management approach.

The implementer will be expected to put forward approaches on how the technical feasibility of the disposal system will eventually be substantiated using the results of the qualification programme initially planned during the conceptualization phase.

. On the basis of siting requirements established by the regulatory body (or other government authority), the implementer should establish a list of attributes on which he will select the host formation and the site.

The safety strategy will consider the implementation of measures to reduce the likelihood and consequences of human intrusion after the facility is closed.

4.2.2.2 Assessment basis

In order to provide an assessment of the capacity of the host rock to accommodate the existing and expected future waste streams, the implementer must establish an inventory of the waste packages, with sufficient evidence that the data assembled cover with adequate margins the important features for designing the disposal facility and ensuring its safety (number and volume of waste packages, radionuclide inventories, dose rates, thermal output, chemical composition, toxic content, gas emission, etc.).

During the site investigation and selection phase, the implementer should determine the basic characteristics of the host rock and surrounding environment of the candidate sites, as well as those of the potential construction materials of the engineered components. The implementer is expected to propose design options in such a way that the safety functions and performance expected for each component will be achieved for the site(s) under consideration.

Amongst the characteristics of the host rock, the implementer should investigate, through an appropriate R&D programme, its geological, geochemical, physical (e.g. thermal), hydro-geological and mechanical properties. The implementer should present to the regulator this R&D programme and the proposed investigatory techniques, together with suitable substantiation of both. The R&D programme should be designed to confirm the expected properties of the site established during the conceptualization phase. As examples, the investigations might determine hydraulic heads, the characterization of transport processes (diffusive vs. advective, retention, sorption, …), regional and local scale characterization with identification of the outlets; relevant geochemical properties including the pore-water characteristics (composition, oxidation-reduction properties) and mineralogy. The volume of rock should be sufficient to accommodate the expected dimensions of the future facility.

Concerning the engineered components, the implementer should establish the state-of-the-art knowledge on the properties of component materials (generally metal, clay or concrete) important for the safety of the disposal facility.

4.2.2.3 Safety assessment

At this stage, it is important for the implementer to carry out an assessment in order to support decisions related to the selection of host formations and sites. The safety assessment should address:

- How the proposed methodologies adopted will be implemented;
- The performance indicators;
- The radiological criteria;
- Development of scenari
- The treatment of uncertainties and sensitivity analysis.

Performance assessment

The implementer must assess the ability of the disposal system and its components to fulfil its expected role.

This will primarily consist of identifying the perturbations that might affect the disposal system and its components, these being of internal (thermal, chemical, mechanical, radiological,...) or external (intrusion, climate change, seismicity, …) origin. This assessment is likely to be subject to large uncertainties, because site data, the engineering design and R&D results from *in situ* tests can only be partial at this stage. Enough quantification of the expected phenomena must nevertheless be made so as to bring sufficiently convincing evidence that the proposed disposal system can withstand these perturbations without unacceptable loss of its containment and isolation capability.

The implementer will also need to confirm the appropriateness of the disposal system by studies and simulations of the performance of components, especially the waste packages, backfill and sealing materials.

The implementer will need to provide confirmation of how the disposal system components taken together will play complementary and independently to ensure that safety is not unduly dependent on a single safety function. Safety assessment of the facility should demonstrate the compatibility of the system components and, among other things, evaluate the impact of potential human intrusions. The assessment will need to consider all identified potential disturbances relevant for safety and specific to the considered sites.

Considering the possible perturbations and their uncertainties, the implementer should carry out sensitivity analyses in order to assess the robustness of the system and its components, and to assist in directing and updating the research programme and in developing the facility design.

With regard to the proposed construction techniques (including excavation), the implementer should present a feasibility assessment, based on the known characteristics of the host rock, which gives consideration to the suitability and effectiveness of the techniques. More specifically, the implementer has to show that the techniques used for construction allow to keep the perturbations of the initial characteristics of the host rock acceptable in terms of containment and isolation.

Radiological and non-radiological impact assessment (Requirement 6)

Further developments of the radiological and non-radiological impact assessment are expected following the outcome of the conceptualization phase.

The impact assessment evolves from generic, in the previous conceptualization phase, to indicative in the current phase with the progressive collection of data and accumulation of knowledge about the site and the engineering components. Site-specific assessments should be performed for the candidate site or sites.

The modelling capability and the scenario definition process of the implementer must be such that the impact cannot be underestimated. In this respect, even if scenario selection and treatment are not exhaustive, the impact assessment should cover the anticipated normal evolution of the disposal system and take into account the main perturbations identified. The implementer should take into account uncertainties and should provide substantiation for the main assumptions and simplifications adopted.

4.2.2.4 Management system

The safety case should update information about the management system with emphasis on:

- The organizational structure and procedures that are in place to ensure the quality of data acquisition, especially site data and management of the impact assessment process;
- The overall planning of activities looking forward to the next phase, in particular R&D programmes concerning system components including waste packages, regulatory and other stakeholder involvement; and
- Implementation of the information management and record keeping system, especially in respect of data, evolution of the safety assessment and of important decisions.

The implementer should demonstrate at this stage that the allocation of appropriate resources is continuously being updated and will be adequate for the next phase.

4.2.2.5 Integration of the safety arguments and evidence

The implementer should provide an update on compliance with the safety strategy in respect of both the evolving design and the safety assessment approach. The safety case should provide an overall integration of the safety arguments and evidence from the assessments above. The safety case should specifically update the points from paragraph 4.1.2.5 addressed during the previous phase. The implementer is also specifically expected to present proposals for a programme of site and design qualification.

Although at this stage in the project it will not be possible to confirm all the properties of the system components necessary to support a full demonstration of safety, it must be shown that this will be possible through a reasonable R&D programme and with a reasonable amount of testing.

4.3 REFERENCE DESIGN AND APPLICATION FOR CONSTRUCTION PHASE

Development of geological disposal facilities

(R1.25) Moreover, the development of disposal facilities that incorporate provisions in design or operation to facilitate reversibility, including retrievability, is considered in several national programmes for waste management. In some States, post-closure retrievability is a legal requirement and constitutes a boundary condition on the options available, which must always satisfy the safety requirements for disposal. No relaxation of safety standards or requirements could be allowed on the grounds that waste retrieval may be possible or may be facilitated by a particular provision. It would have to be ensured that any such provision would not have an unacceptable adverse effect on safety or on the performance of the disposal system. This subject is not extensively dealt with in this Safety Requirements publication.

(R3.14) The operator has to establish technical specifications that are justified by safety assessment, to ensure that the disposal facility is developed in accordance with the safety case. This has to include waste acceptance criteria (see Requirement 20) and other controls and limits to be applied during construction, operation and closure.
Requirement 5: Passive means for the safety of the disposal facility
The operator shall evaluate the site and shall design, construct, operate and close the disposal facility in such a way that safety is ensured by passive means to the fullest extent possible and the need for actions to be taken after closure of the facility is minimized.
Requirement 6: Understanding of a disposal facility and confidence in safety
The operator of a disposal facility shall develop an adequate understanding of the features of the facility and its host environment and of the factors that influence its safety after closure over suitably long time periods, so that a sufficient level of confidence in safety can be achieved.

(Requirement 7) Multiple safety functions
The host environment shall be selected, the engineered barriers of the disposal facility shall be designed and the facility shall be operated to ensure that safety is provided by means of multiple safety functions. Containment and isolation of the waste shall be provided by means of a number of physical barriers of the disposal system. The performance of these physical barriers shall be achieved by means of diverse physical and chemical processes together with various operational controls. The capability of the individual barriers and controls together with that of the overall disposal system to perform as assumed in the safety case shall be demonstrated. The overall performance of the disposal system shall not be unduly dependent on a single safety function.

(Requirement 8) Containment of radioactive waste
The engineered barriers, including the waste form and packaging, shall be designed, and the host environment shall be selected, so as to provide containment of the radionuclides associated with the waste. Containment shall be provided until radioactive decay has significantly reduced the hazard posed by the waste. In addition, in the case of heat generating waste, containment shall be provided while the waste is still producing heat energy in amounts that could adversely affect the performance of the disposal system.

(Requirement 16) Design of a disposal facility
The disposal facility and its engineered barriers shall be designed to contain the waste with its associated hazard, to be physically and chemically compatible with the host geological formation and/or surface environment, and to provide safety features after closure that complement those features afforded by the host environment. The facility and its engineered barriers shall be designed to provide safety during the operational period.

Following site selection, the implementer carries out a complete, full-scale site characterization in order to determine the location and lay-out of underground and surface facilities. In preparation for the application for licensing the construction of the disposal facility, the implementer adapts the conceptual design to the site properties, specifies and substantiates the reference design of the disposal facility, sets out detailed techniques for excavation and construction.. The implementer also selects the main options for the operational phase and develops technical proposals for the closure of the facility.

The safety case presented by the implementer at this point should substantiate that all subsequent activities may be carried out such that the safety is not compromised, and will constitute the baseline for all subsequent activities and cover all subsequent steps.

4.3.1 Regulatory review and decision making

During this phase the regulatory process will usually include a formal licensing procedure leading to the authorization for construction of the geological disposal facility and surface facilities.

To deliver the authorization, the regulator will expect the implementer to present, as a reference solution, a complete design for the disposal facility (including design of the closure arrangements), which is shown to be safe. The regulator will expect the choices made in the design are optimized. The regulator will also expect the solution presented to be fully substantiated as feasible. If the techniques proposed are not commonly used under similar conditions in other industries, the substantiation is expected to be based on demonstration of these techniques under conditions representative of those the implementer expects to encounter during construction of the facility.

The formal regulatory decision will be based on the review of the documentation as described in chapter 4.3.2.

As part of the authorization process, the regulator should place conditions on the implementer for regulatory compliance during the construction phase. These conditions may specify hold points in the construction for regulatory involvement or interaction. They may also specify aspects of the regulatory procedure for subsequent phases such as requirements for documentation and substantiation to be provided to the regulator before authorization to operate the facility may be granted.

Meanwhile, if not already established in the regulatory framework, and depending on the national context, the regulator should define, in discussion with the government if appropriate, the detailed procedures and expected conditions for delivering the authorization for closure of the disposal facility.

As the subsequent construction phase is likely to span decades, the regulator may accept that, in the safety case for authorization for construction, the implementer should present detailed information for the first steps of the construction phase (early years of construction) but can present progressively less detail for later steps. If the regulator accepts such an approach, the implementer should clarify, through interactions with the regulator, the level of detail about the final disposal facility design that the regulator will expect before granting the authorization for construction.

4.3.2 Role and content of the safety case

At this stage, the implementer is expected to develop the safety case to demonstrate that the adopted design can be implemented and will provide assurance that the disposal system (disposal facility together with the host rock and its environment) will meet the safety requirements for a given site. The implementer should investigate operational and long-term safety and present the outcome in detail. The safety case should present that the disposal facility is optimized.

In order to substantiate that these goals have been achieved, the safety case should be based, in particular, on a mature assessment of the engineering and performance of the disposal facility as well as a detailed description and substantiation of the area where the disposal facility will be implemented. Residual uncertainties should be accounted for explicitly and the analyses of their possible consequences should be an essential part of the safety assessment. The safety case should provide an update on the management system and an assessment of its ongoing adequacy.

The safety case is expected to be developed more specifically to substantiate the following items:

- a zone presenting favourable geological properties for implementing a geological disposal facility; and the location of surface facilities;
- a detailed reference design for the facility and disposal units;
- detailed technical approaches for excavation and construction;
- preliminary operational safety analyses, for design implementation purposes.

4.3.2.1 Safety strategy

The implementer should consolidate the safety strategy developed during the previous phases. At this stage the safety strategy is largely fixed but allows for adjustments if needed be (for example to take into account evolution of science and techniques or improved knowledge of the disposal system behaviour such as knowledge of the host rock). The constraints imposed by the prevailing circumstances (scientific and technical state of the art, socio-economical situation) and their consequences on the safety strategy need to be identified. Any changes in the safety strategy with respect to the previous phase should be duly substantiated by the implementer. At this stage, the optimization process should be presented in detail. The qualitative and quantitative criteria that have been considered in order to select the design among alternative options should have been developed. The methodology to assure the quality of design and the traceability of data should also be described.

The implementer will need to confirm the safety functions assigned to each component of the disposal system, both during operation and post-closure. The design rules should contribute to ensuring that the likelihood of a component important for safety of the disposal system failing is low and that, in the event of degradation, the loss of a safety function of one component does not jeopardize the safety of the whole system, considering the normal evolution of the facility and disturbing events both reasonably anticipated and less likely.

From this stage onwards the safety strategy should also address the definition of timeframes for construction of the surface facilities and the general infrastructure of the underground facilities as well as the timeframes for construction, operation and closure of the individual disposal modules. The safety strategy should address the approach to managing possibly concurrent construction and operation activities in different parts of the facility.

4.3.2.2 Assessment basis

The evolution of the design to the selected reference option in the framework of an optimization process should be addressed and shown to be consistent with the safety strategy.

The implementer should present how the mathematical models and codes used in the safety assessment have been qualified.

At this stage, in addition to the site engineering description, the assessment basis should contain an initial description of operational issues. This initial description should progressively be developed through subsequent stages.

- **Site and engineering description**

The collection of information on the site, together with design and development of the analysis tools, is expected to be well advanced at this stage because a reference design solution should be demonstrated to be safe before the authorization for construction can be granted.

The implementer should also consolidate the reference design including the methods for sealing the disposal facility. This would include :

- an update of the waste package inventory and characteristics (radiological and non-radiological properties, main chemical forms, …). The different waste packages should be described, providing details of their geometrical features and their shielding properties. The source term (radionuclide release models, waste degradation mechanisms) and the definition of waste acceptance criteria should be presented;
- a full-scale site characterization based on a site description using up-to-date data, in order to confirm the suitability of the area selected for constructing the disposal facility, taking into account long-term safety and the feasibility of the construction work. This site characterization directed toward constructing the disposal facility should focus on all characteristics contributing to and affecting the containment and isolation safety functions. The list of situation and phenomena that can affect safety should be further developed. The implementer should substantiate the adequacy of the location of surface facilities and of the shafts and/or ramp to access the underground facility and the lay-out of the access tunnels. The long term and operational safety requirements for the facility should be considered, as well as the usual requirements for the location of nuclear facilities and the availability of transport routes.
- the main technical choices (layout of the disposal facility, excavation and construction techniques, waste emplacement, materials, safety functions complementarity, access to disposal, sealing and backfilling options …) and the feasibility of their implementation (including reversibility issues if required);
- the performance targets for the engineered components and the associated specifications (including the characteristics of materials used);

- R&D related to the performance of engineered components of the system, considering all envisaged forms of loading on these components (thermal load, mechanical load, chemical, radiation…) representative of the operational and post-closure periods;
- demonstration tests (for waste emplacement systems, sealing, EBS, …) including development of prototypes.

- **Operational issues (including commissioning and decommissioning)**

At this stage the implementer should define the operational issues and, more specifically, the description of facility operations, a preliminary operational safety analysis, including normal and accident conditions, and the preliminary plans for waste management activities during operation. The implementer should also set out preliminary plans for the decommissioning of surface facilities.

Different operational stages should be distinguished:

- The construction stage, which includes the activities of site preparation, construction of surface facilities, of shafts and/or ramps and of underground galleries. In principle, these activities are non-nuclear and therefore do not involve any potential exposure to ionizing radiation;
- The operational stage, which comprises the activities of transportation of conditioned waste from the surface facilities, through the designated shaft, and into the disposal gallery;
- The closure stage, which includes the activities related to the sealing of the repository, or sections of it, and the decommissioning activities.

It is recognized that activities relating to all three of these stages may overlap in time, i.e. they may be partly concurrent.

4.3.2.3 Safety assessment

The implementer should present a safety assessment including an analysis of the performance and robustness of the disposal system and the radiological and non-radiological impact assessment.

At this stage the safety case should contain information which demonstrates the quality of the assessment including substantiation of the adequacy of the scenarios to be used for assessment and the models chosen for use in connection with the site and facility design. The scenario selection and treatment should be exhaustive. The implementer should present the level of confidence in and conservatism of the assessment results.

- **Performance assessment**

The Performance assessment should include:

- an assessment of the performance of the components (waste packages, engineered barriers, host rock), their interactions and the system as a whole. The assessment should consider disturbances caused by interactions, unexpected events which can reasonably be anticipated and manufacturing defects. Sensitivity analyses should be performed as part of the assessment;

- a demonstration that it is feasible to perform the construction, waste package emplacement, and closure operations. This should be based on the proven ability of the implementer to develop practical and organizational operating procedures.

The performance assessment of the disposal system should focus on showing that the disposal system will meet the operational and long term safety requirements and should demonstrate a sufficient understanding of the behaviour of the components of the disposal system and surrounding environment based on phenomenological analysis, experiments and qualitative judgment. Factors to be taken into account include the effects of disposal facility excavation, construction, operation and sealing. The performance assessment should also be based on the up-to-date level of knowledge about the ability of each component to fulfil its expected role under the normal evolution of the facility and also where there are disturbing events both reasonably anticipated and less likely.

The implementer must demonstrate that monitoring and surveillance does not lead to unacceptable adverse impacts on the performance of the system and long term safety.

The assessment should include the propagation of uncertainties important to safety and will have to be managed them as part of the safety demonstration. The uncertainty ranges should be assessed and recorded.

- **Radiological and non-radiological impact assessments on people and environment**

Further developments of the radiological and non-radiological impact assessment are expected following the outcomes of the site investigation and selection phase.

The impact assessment should present a mature development ensuring a sufficient level of confidence. The safety assessments for operational and long term periods for normal evolution and perturbed scenarios, together with human intrusion scenarios, should demonstrate a sufficient knowledge of the behaviour (especially migration) of radionuclides and hazardous substances in the disposal system and its surrounding environment.

The implementer has to demonstrate that the uncertainties have been treated and managed adequately, and that the assessment contains a sufficient level of conservatism implying that the methodology followed cannot lead to an underestimate of the radiological and non-radiological impacts.

4.3.2.4 Monitoring and surveillance programme

The implementer should provide a description of the baseline conditions and define an adequate monitoring and surveillance programme through the successive phases of facility lifecycle. The monitoring and surveillance plans for the operational, closure and post-closure phases should also be described.

More specifically, the monitoring and surveillance programme accompanying the construction of the disposal facility should address:

- the rock, physical and chemical perturbations associated with excavation and construction and selection of associated equipment and experimental procedures;
- the perturbations to the surface and near-surface environment from excavation and construction of the disposal facility and selection of associated equipment;

4.3.2.5 Management system

As already identified, the management system should evolve as the project develops so as to adapt to the needs of successive phases. It should be substantiated that appropriate resources are being allocated.

In this phase, the safety case should update information about the management system with particular emphasis on:

- The organization and procedures in place to assure the quality of the design work performed, together with its linkages to the outcome of R&D activities, the site characterization work and the safety assessment work and ensure traceability and recording of these;
- The planning of activities;
- The arrangements for periodic assessments to confirm that implementation is correct;
- The QA procedures for construction.
    - The implementer should provide information on:long-term knowledge management and record-keeping procedures and provisions for maintaining institutional memory of the disposal facility (site, radioactive inventory, …);
    - a description of the safety and security provisions (safeguards, …) including those to prevent human intrusion;

4.3.2.6 Integration of the safety arguments and evidence

The implementer should make a thorough synthesis that integrates all the available evidence, arguments and analyses. The synthesis should show how all relevant data and information have been considered, all models have been tested adequately, and a rational assessment procedure has been followed. It should include a confirmation of the consistency, completeness and proper integration of the safety assessment (site, engineering, radiological impact management system) in accordance with regulatory expectations. More generally, the implementer should show that the implementation of the safety strategy has led to the identification, management and, where possible, avoidance or reduction of uncertainties. The synthesis should also consider the limitations of currently available evidence, arguments and analyses, and should identify areas where knowledge is lacking or uncertainties are high and where further work is needed for the next phase. It should therefore highlight the principal arguments on which the implementer has come to a judgement that the planning and development of the disposal system has reached a stage allowing the regulator to grant a licence for construction of the facility.

4.4 CONSTRUCTION PHASE AND APPLICATION FOR OPERATIONAL PHASE

Construction Phase and Preparation for the operational period

(R2.8) In radiation safety terms, the disposal facility is considered to be a source of radiation that is under regulatory control in a planned exposure situation. In the operational period, any radioactive release can be verified, exposures can be controlled and actions can be taken if necessary. The engineering means and practical means of achieving safety are well known, although their use in a disposal facility involves specific considerations. The primary goal is to ensure that radiation doses are as low as reasonably achievable and within the applicable system of dose limitation.

(R2.9) The optimization of protection (that is, the process of determining measures for protection and safety to make exposures, and the probability and magnitude of potential exposures, "as low as reasonably achievable, economic and social factors being taken into account") is considered in the design of the disposal facility and in the planning of all operations.

(R2.10) Relevant considerations in the optimization of measures for protection and safety include: the separation of mining and construction activities from waste emplacement activities; the use of remote handling equipment and shielded equipment for waste emplacement, where necessary; the control of the working environment so as to reduce the potential for accidents and their potential consequences; and the minimization of the need for maintenance in supervised areas and controlled areas. Contamination is required to be controlled and prevented to the extent possible.

This phase extends from the beginning of construction of the surface facilities, shafts and underground facilities up to the licensing of the disposal facility so that waste emplacement in the facility can begin. Subject to regulatory approval, construction of extensions to the disposal facility may continue after the operational licence has been granted.

At this stage, the implementer should describe the reference plan (design and technique) for closure of the disposal facility, since the application is for a licence that will allow for the first introduction of waste into the disposal facility. The reference plan may evolve during facility operation.

4.4.1 Regulatory review and decision making

During this phase the regulatory process should include a formal review of the safety case and granting a licence (authorization or formal regulatory approval based on national requirements) for operation of the geological disposal facility and surface facilities. The regulator will also organize audits and inspections of the implementer.

The regulator will expect the implementer to detail operating procedures as well as demonstration of safety during operations. All the methods for emplacing the waste (and, where appropriate, ensuring reversibility or retrievability) should be fully qualified. The methods for closure of disposal units should also be fully demonstrated and the technical feasibility of a detailed reference method for closure of the facility in the respect of the safety objectives should be demonstrated with sufficient confidence to allow the operational phase to be licensed.

Moreover, the implementer must justify that the facility has been constructed in accordance with the terms of the construction licence, which was granted during the previous phase.

The granting of the licence will be based on the review of the safety case based on the content defined in section 4.4.2.

4.4.2 Role and content of the safety case

For the application for operation, the safety case will be at its broadest (i.e. it will need to address in detail both operational and post-closure safety) and should demonstrate both for the operational period and the period after closure that the protection objectives will be achieved (see key objectives of safety case given in chapter 3).

The implementer is expected to develop the safety case to demonstrate especially that the facility, as constructed in accordance with the approved design, will meet the operational and long-term safety requirements. The safety case needs to be updated based on possible updated design, substantiation and more detailed information gained during construction and component fabrication, and from demonstration tests of appropriate duration. The safety case will provide assurance that design and safety principles developed in previous phases have been followed and that safety requirements are met. The implementer should address all the subsequent phases of geological disposal and as a minimum present:

1. The overall approach for operation, partial closure of the disposal units and final closure of the disposal facility (updated as appropriate based on construction experience).
2. A detailed description and substantiation of the suitability for safe operation of the operational facilities and structures, systems and components (SSCs), in the context of planned operations and the proposed management system (for example as part of these, operating rules and waste acceptance criteria, provisions for worker protection against both radiological and non-radiological hazards, description of the procedures and rules for proper response to an accident or emergency during waste emplacement operations, procedures for site security and safeguards controls, procedures for the monitoring and surveillance of the facility its surrounding surface environment);
3. The consolidation of the safety assessment (brought up to date based on construction and fabrication experience) focusing on safe facility operation. This assessment should confirm that the disposal facility as built meets applicable criteria ;
4. The detailed technical approaches for closure of disposal units and a reference method for closure of the facility.

All the activities associated with waste emplacement will need to be appropriately covered in the operational aspects of the safety case. They include receipt of the waste packages on site, handling and storage of the packages on the surface, transport of the packages underground and to the locations where they will be emplaced, as well as emplacement itself.

In order to substantiate that these goals have been achieved, the safety case should be founded, in particular, on a mature assessment of performance that is based on the as-built facility. The safety assessment needs to show that the safety significant uncertainties identified when the construction licence was issued have been reduced where possible and that residual uncertainties do not undermine long-term safety and can be managed. Uncertainties should be taken into account when preparing technical specifications (operational limit conditions) for disposal. The safety case should provide an update on the management system and an assessment of its adequacy.

4.4.2.1 Safety strategy

The implementer should review the safety strategy to ensure its continuing suitability.

The safety strategy should address the methodology for confirmation of safety during operation and how optimization should be carried forward during detailed level design work and into the operating phase.

An important transient element of the safety strategy will concern the safety management of parallel or sequential operational activities, including (a) waste emplacement, (b) construction work to extend the disposal facility and (c) backfilling and sealing of parts of the facility where waste emplacement has been completed. None of these activities must have unacceptable adverse effects on any of the others.

4.4.2.2 Assessment basis

At this stage the assessment basis should contain an update of the site and engineering description needed for entering the operational phase. Emphasis is given to information necessary for assessment of operational safety.

Site and engineering description

The implementer should update the site and engineering description. This should include an update of information regarding :

- the waste inventory, source term and waste packages design and performance (based on information from demonstration tests and fabrication and possible confirmatory results from long-term demonstration tests).

- the host rock and surrounding environment. This information should be based on the monitoring and surveillance program including information gained from construction of the underground facility (more detailed near-field information).;

- the facility SSCs;

- the underground facility and disposal units including:
    - a detailed description of the as-built facility design;
    - in the case of continuing construction activities, acceptance criteria for construction (or rock suitability criteria), based on construction experience. Also updated rules for construction activities in the host rock;
    - techniques and design for emplacement of waste in disposal units, based on experience from fabrication and demonstration tests; if required, a description of demonstrating the feasibility of reversibility or retrievability;
    - techniques and design for sealing of the units based on experience from fabrication and demonstration tests including closure acceptance criteria.

In case of design modifications, they should be recorded and substantiated according to the licensing conditions (subject to approval or information).

The implementer should provide plans for corrective action to deal with foreseeable geological or geotechnical problems which might arise during construction and operation of the facility.

Operational issues (including commissioning and decommissioning)

The assessment basis should include a detailed description of operation including all safety relevant operational stages (commissioning, operation, termination of operation). The assessment basis should include information needed to analyse operational safety including accident conditions (for example fire, flooding, package drop).

In particular, the implementer will need to provide information on the underground facility, surface facilities and SSCs:

- a detailed description of the as-built facility and SSC properties relevant to the assessment of operational safety;
- a description of normal operation and accident conditions as a basis for the operational safety assessment;
- a description of the plans for monitoring and surveillance of SSCs to address ageing of facility components taking into account the long period of facility operation.

The implementer should prepare operating rules that describe as a minimum:

- waste acceptance criteria;
- operational limit conditions which form the basis for the safety analysis of normal operation;
- procedures for operational disturbances and accident conditions;
- procedures for concurrent construction and waste emplacement (if planned);
- radiation safety procedures for workers;
- information and records management procedures and measures to document and retain institutional memory.

Specific provisions should be made by the implementer for possible waste retrieval (i.e. in case of a waste package defect) in which case a dedicated safety assessment should be established. This could include, for example, provisions to ensure that the disposal facility has enough temporary storage capacity to retrieve more than one package (i.e. in case of fire for example) and to allow for safe temporary stoppage of waste emplacement.

During the construction phase the implementer should prepare a description of facility commissioning that will be performed to confirm that systems function as designed. The regulator may require the implementer to conduct demonstrations or trials before waste handling and emplacement begins on a regular basis. The trials might initially be with non-radioactive dummy waste packages, then moving on to trial handling and emplacement of a limited number of radioactive packages. Assuming no major problems, the rate of handling and emplacement of waste packages would progressively be increased to the intended operational rate.

4.4.2.3 Safety assessment

The implementer should present a safety assessment including the disposal system performance and robustness analysis, the operational safety assessment and the long term radiological and non-radiological impact assessment.

(Requirement 8) Containment of radioactive waste
The engineered barriers, including the waste form and packaging, shall be designed, and the host environment shall be selected, so as to provide containment of the radionuclides associated with the waste. Containment shall be provided until radioactive decay has significantly reduced the hazard posed by the waste. In addition, in the case of heat generating waste, containment shall be provided while the waste is still producing heat energy in amounts that could adversely affect the performance of the disposal system.

(R4.15) The safety case for a disposal facility has to address safety both in operation and after closure. It may also address safety in transport … All aspects of operation relevant to safety are considered, including surface and underground excavation, construction and mining work, waste emplacement, and backfilling, sealing and closing operations. Consideration has to be given to both occupational exposure and public exposure resulting from conditions of normal operation and anticipated operational occurrences over the operating lifetime of the disposal facility.

Performance assessment

The implementer should confirm the performance of SSCs providing safety functions relating to the design basis, based on experience from construction and component fabrication and on the acquisition of new data. The substantiation that the design basis/safety requirements/rules have been met should be presented.

The implementer should update the performance assessment to demonstrate that the as-built underground disposal units, facility systems and EBS components meet the design basis and safety requirements presented in previous phases with respect to operational and long term safety.

The site assessment should for example include an analysis, based on the results of the monitoring and surveillance program, showing that construction has not adversely changed the host rock properties to an unacceptable extent with respect to the safety case. If there will be continuing construction of disposal units, the assessment should also update the assessment of suitability of the site at a detailed level. The operational safety assessment should show that facility will meet the safety requirements for normal operation and in accident conditions. It should be updated based on the updated design of the disposal facility and the modes of operation for waste handling.

The assessment should review uncertainties important for safety to ensure that in this respect it is acceptable to start the operating phase and should demonstrate that remaining uncertainties important to safety (e.g. regarding rock mechanical stability, gas generation, feasibility of closure, …) have been taken into account in the facility's operational design specifications.

Radiological and non-radiological impact assessment

The impact assessments should include both operational and long-term safety analysis.

The long-term radiological and non-radiological impact assessments should be updated based on information gained during the construction phase. Possible changes of facility design or different understanding of parameters relevant to safety assessment that have occurred during the construction phase should be re-analysed.

4.4.2.4 Monitoring and surveillance programme

During this phase, the implementer should have a monitoring and surveillance programme and systems developed to monitor the evolution of the components important for safety. The monitoring and surveillance programme should be brought up to date based on experience from site characterization and from construction.

The implementer should provide a description of the monitoring and surveillance programme for the operational phase including the continued monitoring of host rock disturbances due to construction and operation, confirmation of barrier system performance (type of parameters measured and how they are related to the performance of components that provide the safety functions) as well as radiation monitoring for operational safety. A description of the environmental monitoring programme should also be presented.

4.4.2.5 Management system

As in the previous phase a demonstration should be provided that the allocation of appropriate resources is continuously updated and will be adequate for the next phase.

The implementer should provide planning information including time schedules for construction, operation and closure of individual disposal units as well as for closure of the disposal facility as a whole.

The implementer should develop the management system to support the safe operation of the disposal facility. The description of the management system provided as part of the safety case should be completed by :

- the organizational arrangements for disposal operations including the training of personnel;
- the procedures that are in place to assure the quality of construction and disposal operations;
- the information management and record-keeping for facility operation, especially related to the inventory of waste already disposed of and its location in the disposal facility;
- the arrangements for physical protection, for the safeguards control system and for emergency preparedness;
- measures related to institutional memory.

The management system should provide assurance that all the appropriate information will be available to support decision-making. Furthermore, the information and lines of reasoning should be readily traceable through the safety case to the supporting evidence.

Provisions for institutional control (legal, financial, technical) described in the previous phase should be updated.

4.4.2.6 Integration of the safety arguments and evidence

The implementer should update the demonstration showing that the implementation of the safety strategy has led to the identification, management and, where possible, avoidance or reduction of uncertainties.

The integration work should, at this stage, provide a synthesis of all assessments and should enable all the information to be assembled in a manner that allows independent appraisal of the level of safety that the as-built facility will achieve in operation. This forms the basis for the licence application for operation of the facility.

The implementer should confirm that the safety case contains all updated information about the disposal system, based on knowledge and new data gained during the construction phase.

The implementer should demonstrate that uncertainties related to new elements identified during the construction phase can be managed in the next phases.

4.5 OPERATIONAL PHASE

This chapter is divided into two main sections dealing respectively with waste emplacement and authorization for final closure and sealing of the facility.

Section 4.5.2 (Operational Phase: Waste Emplacement) deals with the major part of the operational phase.

Section 4.5.3 (**Authorization for Final Closure and Sealing of the Facility)** deals with the much shorter period at the end of the operational phase, when waste emplacement is complete and the implementer seeks authorization from the regulator for decommissioning and removal of operational equipment and final closure and sealing of the facility.

4.5.1 Operational Phase : Waste emplacement

Radiological protection during the operational period

(R 2.7) The radiation safety requirements and the related safety criteria for the operational period of a disposal facility are the same as those for any nuclear facility or activity involving radioactive material and are established in the International Basic Safety Standards. Disposal facilities receiving waste from nuclear fuel cycle facilities will generally be licensed nuclear facilities and have to operate under the terms of a facility licence. Disposal facilities for small quantities of waste (e.g. borehole facilities) may not be regarded as nuclear facilities in some States but have to be subject to an appropriate regulatory process and have to be licensed accordingly.

(R 2.8) In radiation safety terms, the disposal facility is considered to be a source of radiation that is under regulatory control in a planned exposure situation. In the operational period, any radioactive release can be verified, exposures can be controlled and actions can be taken if necessary. The engineering means and practical means of achieving safety are well known, although their use in a disposal facility involves specific considerations. The primary goal is to ensure that radiation doses are as low as reasonably achievable and within the applicable system of dose limitation.

(R2.9) The optimization of protection (that is, the process of determining measures for protection and safety to make exposures, and the probability and magnitude of potential exposures, “as low as reasonably achievable, economic and social factors being taken into account”) is considered in the design of the disposal facility and in the planning of all operations.

(R2.11) No releases of radionuclides, or only very minor releases (such as small amounts of gaseous radionuclides), may be expected during the normal operation of a radioactive waste disposal facility and hence there will not be any significant doses to members of the public. Even in the event of an accident involving the breach of a waste package on the site of a disposal facility, releases are unlikely to have any radiological consequences outside the facility.

(R2.12) The absence of radiological consequences of any significance outside the facility would be confirmed by means of safety assessment (see the requirements concerning the safety case and safety assessment, Requirements 12–14). Relevant considerations include the waste form (i.e. the packaging and the radionuclide content of the waste), the control of contamination on waste packages and equipment, and the monitoring and control of drainage water from the disposal facility, where applicable, and of the ventilation exhaust air from underground disposal facilities.

Requirements for geological disposal facility operation

(R2.13) For a disposal facility, as for any other operational nuclear facility or facility where radioactive material is handled, used, stored or processed, an operational radiation protection programme, commensurate with the radiological hazards, is required to be put in place to ensure that doses to workers during normal operations are controlled and that the requirements for the limitation of radiation doses are met. In addition, emergency plans are required to be put in place for dealing with accidents and other incidents, and for ensuring that any consequent radiation doses are controlled to the extent possible, with due regard for the relevant emergency action levels [16].

(R2.14) The doses and risks associated with the transport of radioactive waste through public areas to a disposal facility are required to be managed in the same way as the doses and risks associated with the transport of other radioactive material. The transport of radioactive waste is subject to the requirements of the IAEA's Regulations for the Safe Transport of Radioactive Material [17].

(Requirement 18) Operation of a disposal facility
The disposal facility shall be operated in accordance with the conditions of the licence and the relevant regulatory requirements so as to maintain safety during the operational period and in such a manner as to preserve the safety functions assumed in the safety case that are important to safety after closure.

(R4.35) All operations and activities important to the safety of a disposal facility have to be subjected to limitations and controls and emergency plans have to be put in place. The various procedures and plans have to be documented and the documentation has to be subject to appropriate control procedures. The safety case has to address and justify both the design and the operational management arrangements that are used to ensure that the safety objective and criteria set out in Section 2 are met. Additional, facility specific criteria may be established by the regulatory body or by the operator.

(R4.36) The safety case also has to demonstrate that hazards and other radiation risks to workers and to members of the public under conditions of normal operation and anticipated operational occurrences have been reduced as low as reasonably achievable. Active control of safety has to be maintained for as long as the disposal facility remains unsealed, and this may include an extended period after the emplacement of waste and before the final closure of the facility.

(R4.37) Fissile material, when present, has to be managed and has to be emplaced in the disposal facility in a configuration that will remain subcritical. This may be achieved by various means, including the appropriate distribution of fissile material during the conditioning of the waste and the proper design of the waste packages. Assessments have to be undertaken of the possible evolution of the criticality hazard after waste emplacement, including after closure.

This period marks the beginning of waste emplacement and continues up to (but not including) the time when the facility is full and decisions are made on when and how finally to close and seal the facility. During this period the implementer may be carrying out the following main types of activity:

a. Emplacing waste, including all the associated activities such as receipt of the waste packages on site, handling and storage of the packages on the surface, and transport of the packages underground and to the locations where they will be emplaced;

b. Constructing extensions to the facility, in the form of new disposal units (tunnels, vaults and shafts) for waste emplacement, together with the associated access ways;

c. Backfilling and possibly sealing, either temporarily or permanently, parts of the disposal facility where waste emplacement has been completed;

d Developing an approach and detailed plans for finally closing and sealing the facility.

The operational period may be protracted, typically extending over several decades.

While waste is being emplaced in some parts of the disposal facility, activities such as the construction of additional disposal units for waste emplacement and the associated access ways may be continuing in other parts of the facility. At the same time, backfilling and possibly sealing of parts of the facility where waste emplacement has been completed may also be taking place.

Data about the geological environment of the disposal facility and about the facility as actually built and the waste as actually emplaced, as opposed to the prior intent, will be gathered progressively during this period. In addition, there is the potential for significant improvements over the period, both to the practical techniques used by the implementer and to the methods used for establishing the safety case. New information gathered over this period will be used to improve the safety case and update it periodically.

The implementer will be developing the closure scheme and possibly to some extent implementing it (by backfilling, and possibly sealing, parts of the facility where waste emplacement has been completed).

During this period plans will be fully developed to close and seal the facility safely and in accordance with any national strategy and the facility design concept.

4.5.1.1 Regulatory review and decision making

During this period the regulator needs to ensure that the facility is being operated in accordance with the conditions of the licence, which was granted at the previous phase. This should involve periodic regulatory audit of compliance against licence conditions. One of the conditions of the operating licence is likely to be (based on the national context) a requirement for the implementer to update the safety case regularly. Throughout the period, the regulator should ensure that the implementer provides submissions at appropriate intervals confirming that the safety case continues to provide assurance that the overall safety objective is being met.

There is likely to be a need for the implementer to update, and for the regulator to review, the safety case:

i. Before the implementer embarks on any substantial new programme of disposal facility development work, or implements any modifications to operational practices that may impinge on the safety case; and also

ii. At regular intervals, to ensure that the safety case is kept properly up-to-date and that the requirements it imposes continue to be properly reflected in the conditions of the licence.

The objective of the regulatory review of the safety case before the implementer embarks on any substantial new programme of disposal facility development work is to provide the basis for a regulatory decision on whether the new programme of work should begin and, if so, under what conditions.

Disposal facility development work potentially includes (a) disposal of a new waste stream, (b) disposal of waste in a new part of the facility, (c) construction of a new part of the facility and (d) backfilling and possibly sealing part of the facility once emplacement of waste in that part is complete.

Through the change control procedure, the implementer should also keep the regulator informed of modifications to operational practices that may impinge on the safety case, such as for example new waste forms or waste containers, new or improved practices and techniques identified as a result of experience gained during waste emplacement.

The objective of regulatory reviews of the safety case at regular intervals is to confirm that the safety case continues to be acceptable, to identify any additional work that the implementer needs to commission in order to improve or confirm the safety case, and to ensure the facility continues to be operated in accordance with the safety case.

In practice, the implementer should submit an up-to-date safety case that enables the regulator to combine these objectives.

The outcome of a regulatory review might be to identify a requirement for a further revision of the safety case, or specific parts of it (for example, the need to address new information), and to determine any necessary changes to the licence conditions. Some countries may have statutory requirements controlling the periodicity for regulatory review of the safety case, over a timespan of many decades or indeed centuries. In countries where there is no such legal requirement, the implementer and regulator should define an agreed programme of review. A regulatory review should in any case follow any significant revision of the safety case.

Moreover the start of operation signals a major change from all previous stages of disposal facility development, since it is at this stage that radioactive waste will begin to be handled at the facility, entailing a whole new set of operational safety requirements.

4.5.1.2 Role and content of the safety case

Requirements on the scope of the safety case and safety assessment

(Requirement 13) Scope of the safety case and safety assessment
The safety case for a disposal facility shall describe all safety relevant aspects of the site, the design of the facility and the managerial control measures and regulatory controls. The safety case and supporting safety assessment shall demonstrate the level of protection of people and the environment provided and shall provide assurance to the regulatory body and other interested parties that safety requirements will be met.

(4.15) The safety case for a disposal facility has to address safety both in operation and after closure. It may also address safety in transport, … . All aspects of operation relevant to safety are considered, including surface and underground excavation, construction and mining work, waste emplacement, and backfilling, sealing and closing operations. Consideration has to be given to both occupational exposure and public exposure resulting from conditions of normal operation and anticipated operational occurrences over the operating lifetime of the disposal facility.

(4.16) Accidents of a lesser frequency, but with significant radiological consequences (i.e. possible accidents that could give rise to radiation doses over the short term in excess of annual dose limits), have to be considered with regard to both their likelihood of occurrence and the magnitude of possible radiation doses. The adequacy of the design and of the operational features also has to be evaluated.

The implementer should update the safety case progressively to incorporate information gained during operation. This will include:

- The growing body of data about the geological environment of the disposal facility
- Information about the facility as actually built and the waste as actually emplaced, as opposed to the prior intent
- New developments and operating practices, such as emplacement techniques and materials of encapsulation, buffer materials or construction materials
- Any other advances in understanding

All the activities associated with waste emplacement will need to be appropriately covered in the operational aspects of the safety case when it is updated. They include receipt of the waste packages on site, handling and storage of the packages on the surface, transport of the packages underground and to the locations where they will be emplaced, as well as emplacement itself.

Where specific provision is made for possible waste retrieval, the safety case will need to demonstrate that any potential effects of measures adopted to provide for waste retrieval will not unacceptably compromise short-term (operational) and long-term (post-closure) safety. In order to support this provision, the implementer will need periodically to review and demonstrate (over a period covering potentially many decades or more than a century) the ability to retrieve wastes, and to consider fully the practicability, the implications and the safety of retrieval operations, for all the wastes covered by the provision.

Any substantial change to the disposal system design motivated by feedback from operational activities or monitoring and surveillance should be documented in the safety case and submitted to the regulator for approval. These could include new engineering or packaging materials, emplacement techniques or configurations.

If there are any unexpected events of significance to safety during the operational period, the safety case should identify these and account for any consequences that they, and any changes made to operating practices as a result of them, may have on the safety arguments.

The implementer should identify how decisions already taken before and during operation have contributed to optimization of the disposal system.

Based on the content of the safety case and the outcome of the regulatory review, conditions for licensing the extended operational phase and/or closure of different parts of the disposal facility will be defined.

4.5.1.2.1 Safety strategy

The safety strategy will be updated to incorporate feedback from operations. By the end of the operational period, knowledge about key uncertainties needs to be in a final state for the purpose of making the safety case for the period after closure.

An important transient element of the safety strategy will concern an update of the safety management of parallel or sequential operational activities, including (a) waste emplacement, (b) construction work to extend the disposal facility and (c) backfilling and sealing of parts of the facility where waste emplacement has been completed. None of these activities must have unacceptable adverse effects on any of the others.

The safety strategy should include schedules and proposals for closure of individual disposal modules and the facility as a whole. It should indicate in outline how the proposals for closure have been optimized and should present the way to ensure and verify that closure will be performed as planned. During the operational period the safety strategy should present and discuss plans for post-closure monitoring and surveillance (if any), markers and controls.

4.5.1.2.2 Assessment basis

Throughout operation, the regulator will expect the implementer to complete the assessment basis with new information from the monitoring and surveillance programme and the facility as actually built (i.e. confirm that it corresponds to the geological environment of the disposal facility as it is found to be).

- **Site and engineering description**

The implementer will need to update the site and engineering description. The significance of any changes to the reference design from the previous phase introduced during operation will need to be addressed (e.g. new construction or waste package materials, new engineering techniques, and any new emplacement plant and systems).

The site and engineering description will include updates on the following:

- The waste inventory and waste acceptance criteria;
- Waste package evolution (radionuclide decay, radionuclide release, heat generation, package degradation such as microbial, chemical or radiolytic action leading to gas generation, etc.);
- Detailed techniques for waste package emplacement;
- Any inputs from outside sources, such as experience and information from the operation of other disposal facilities either nationally or internationally;
- The results of monitoring and surveillance both within the disposal facility and at various distances in various directions from it (for example: measurements of disturbances associated with desaturation of the rock or changes in chemical conditions, evolution of temperatures and rock mechanical conditions);
- The detailed plans for closing the facility, including technical/engineering methods for closure, materials for backfilling and sealing, and demonstration of optimization within the constraints of previous decisions.

The implementer should provide plans for corrective action to deal with foreseeable geological or geotechnical problems which might arise during operation or closure of the facility.

- **Operational issues**

Arrangements for operation will need to be clear and agreed as appropriate with the regulator before the start of the operational period. The arrangements will include written rules, instructions and procedures to ensure safety of the facility and protection of workers, of members of the public and of the environment.

The rules, instructions and procedures will need to cover both the operation and the maintenance of relevant equipment. They will also need to cover the commissioning and decommissioning of the equipment. Operating staff will need to be trained to act in accordance with the written rules, instructions and procedures. The written rules, instructions and procedures will need to be updated whenever there are relevant changes to the underlying requirements and in any case should be subject to regular review.

If the implementer intends dissimilar activities (e.g. waste emplacement, continuing construction work, and backfilling and sealing of sections already filled with waste) to take place simultaneously or sequentially in the facility, the arrangements for operation will need to provide for this.

4.5.1.2.3 Safety Assessment

In each case, the assessment needs to be updated whenever during the operating period there is a significant development or change either to the safety strategy or to the assessment basis. The implementer also needs to review the safety assessment periodically to ensure that it is up-to-date.

- **Performance assessment**

As the operating period progresses, information about the disposal system as it actually is (e.g. the disposal facility as actually constructed, the waste as actually emplaced, the closure and sealing of the facility as they are specifically intended to take place and the geological setting as it is increasingly understood) will increasingly become available. Updated performance assessments of individual components of the disposal facility should be carried out taking into account this new information.

- **Radiological and non-radiological impact assessment on people and the environment**

In order to develop the impact assessment models, the implementer will need to pursue or commission investigations in parallel to operational activities. As a result of these investigations, there may be adjustments and improvements to the way in which site and engineering information is represented in assessment models. There should thus be a progressive improvement in the quality both of assessment models and of assessment data during the operational period.

As well as assessments of long-term safety, operational safety assessments, covering both normal operation and fault or accident conditions may also be conducted.

4.5.1.2.4 Monitoring and surveillance programme

At the start of the operational period, the implementer's monitoring and surveillance programme, both within and surrounding the disposal facility, will need to be extended to include radiation monitoring and sampling for the presence of radioactive substances. In other respects, the monitoring and surveillance programme will need to be brought up to date. Parts of the monitoring and surveillance programme will be to demonstrate compliance with licence conditions (for example, with respect to any limits on radioactive discharges to water or air) and assurance of radiological protection for facility workers, members of the public and the environment. The monitoring and surveillance programme will need to be agreed as appropriate with the regulator.

The monitoring and surveillance of rock and engineered barriers during operation will be needed to assess the effects of construction and operation on the characteristics of the disposal system components, and to demonstrate that any such effects are taken into account and do not unacceptably compromise safety.

Where specific provision is made for possible waste retrieval, monitoring and surveillance during the operational period will be needed to contribute to decisions as to whether to retrieve waste or to move towards closure.

During the operational period, the implementer will need to develop the programme for monitoring and surveillance while closure of the disposal facility is taking place. During this period, the programme of monitoring and surveillance after closure, if there is to be any, will also need to be developed. If there is to be such a programme, substantiation will be needed for the timescale for which it will continue.

4.5.1.2.4 Management system

The management system should adapt to new situations arising from the creation of new disposal units or the existence of new developments. During the operating period, the implementer will be expected to formulate the management system needed for closure and the management system needed after closure. During this period, the implementer also needs to formulate suitable quality management arrangements for the disposal facility closure stage and for the post-closure period.

The detailed provisions potentially needed as part of the management arrangements for the post-closure period include control of access to the site, monitoring and surveillance, nuclear safeguards, maintaining a long-term institutional memory and making the necessary financial provisions for these activities.

4.5.1.2.5 Integration of the safety arguments and evidence

The implementer should update the demonstration that the implementation of the safety strategy has led to the identification, management and, where possible, avoidance or reduction of uncertainties.

By the end of the operational phase the integration of the safety arguments and evidence will need to be acceptably complete.

4.5.2 Authorization for Final Closure and Sealing of the Facility

> Requirements for geological disposal facility closure
>
> (Requirement 19) Closure of a disposal facility
> A disposal facility shall be closed in a way that provides for those safety functions that have been shown by the safety case to be important after closure. Plans for closure, including the transition from active management of the facility, shall be well defined and practicable, so that closure can be carried out safely at an appropriate time.
>
> (R4.38) The safety of a disposal facility after closure will depend on a number of activities and design features, which can include the backfilling and sealing or capping of the disposal facility. Closure has to be considered in the initial design of the facility, and plans for closure and seal or cap designs have to be updated as the design of the facility is developed. Before construction activities commence, there has to be sufficient evidence that the performance of the backfilling, sealing and capping will function as intended to meet the design requirements.
>
> (R4.39) The disposal facility has to be closed in accordance with the conditions set for closure by the regulatory body in the facility's authorization, with particular consideration given to any changes in responsibility that may occur at this stage. Consistent with this, the installation of closure features may be performed in parallel with waste emplacement operations.
>
> (R4.40) Backfilling and the placement of seals or caps may be delayed for a period after the completion of waste emplacement, for example, to allow for monitoring to assess aspects relating to safety after closure or for reasons relating to public acceptability. If such features are not to be put in place for a period of time after the completion of waste emplacement, then the implications for safety during operation and after closure have to be considered in the safety case.
>
> (R4.41) Availability of the necessary technical and financial resources to achieve closure has to be assured ….

At this point, waste emplacement is complete and the only further engineering steps directly concerned with the disposal facility itself are to decommission and remove any remaining operational equipment within the facility and finally to close and seal the facility.

Although closing and sealing the facility might in principle be reversed, this would be by design a practical step of such difficulty that it is highly undesirable.

4.5.2.1 Regulatory review and decision making

Subject to an acceptable safety case, the regulator needs to take the decision to permit the disposal facility to be closed and sealed without undue delay. The process should include a formal review of the safety case and granting of regulatory approval.

It is essential that, before regulatory approval for closure and sealing of the facility is given, all relevant documentation is in place and in an acceptable state. The regulator will focus its attention on the approaches (design, techniques, …) to be adopted by the implementer during the final closure operations and on the confirmation of the performance of these approaches.

The regulator will also expect the safety case to substantiate that the construction, operation and closure of disposal units have been implemented in accordance with the approved procedures and that wherever deviations have been identified their impact on safety has been assessed and it has been demonstrated that the safety requirements are still met.

Moreover, to support the decision of the regulator and enhance its confidence in the overall demonstration of the safety of the disposal as designed, constructed and operated, the regulator may require the safety case to review and summarize any element likely to enhance this confidence.

Based on the safety case, the closure phase will be implemented. As this phase is crucial with regard to long term safety issues it is highly recommended that the regulatory body audits the quality of the work being performed and the compliance of the closure operations with safety requirements.

In addition, there will be a need to define future legal, financial and technical responsibilities although, depending on the country, this may not be a matter for the disposal facility regulator.

4.5.2.2 Role and content of the safety case

Both the implementer and the regulator must at this stage assume that the safety case is in its final form. This means that, apart from subsequent confirmation that closure and sealing have taken place as intended, nothing further must remain to be confirmed. It is possible that there might subsequently be changes or developments to the safety case, but this cannot be assumed.

The key objectives of the safety case will include:

a. To confirm that the disposal system has been optimised, that every operations has been done as expected, that the disposal system behaves as expected based on monitoring and surveillance, and that remaining uncertainties can be managed.

b. To describe the intended method of closing and sealing the disposal facility, to confirm that the method is feasible and to show that it provides a result of acceptable integrity with respect to long term safety.

c. To show that any radiological and non-radiological risks to workers and members of the public are acceptably low using the intended method of closing and sealing the facility.

d. To consider any contingencies that might arise during closure and sealing of the disposal facility and to identify acceptable methods of dealing with these.

e. For any period after the facility has been closed and sealed, to demonstrate that members of the public and the environment are adequately protected against radiological and non-radiological hazards, under normal and accident situations.

4.5.2.2.1 Safety strategy

The safety strategy will be updated presenting the final approach to closing and sealing the disposal facility and showing in the safety assessment that it provides a result of acceptable integrity with respect to long term safety and with respect to any radiological and non-radiological risks to workers and members of the public.

It will also be updated to provide further detail about the approach for post-closure monitoring, surveillance and controls.

4.5.2.2.2 Assessment basis

The assessment basis must be complete. It should be updated based on monitoring and surveillance of the evolution of rock properties in the excavation disturbed zones (EDZ) in shafts and access drifts and experience feedback from in situ closure tests.

In line with the objectives, the safety case shall at least include descriptions of the following key elements:

- Records of the disposal facility as actually constructed
- The waste acceptance criteria as actually implemented
- Records of waste emplacement as actually implemented
- Records of backfilling and sealing of sections of the disposal facility as actually implemented up to the present time
- Detailed technical proposals for all remaining backfilling and sealing operations, including those associated with closure of the facility as a whole
- Evidence regarding the state and expected evolution of the disposal system as a whole (i.e. the disposal facility in its geological setting) based on disposal as actually built, operated and on the planned approach for final closure
- Management arrangements for closure, including radiological protection and safety rules
- Detailed technical proposals for the decommissioning and removal of any remaining operational equipment from the facility
- Plans for monitoring and surveillance post-closure if any
- Plans for site security and nuclear safeguards post-closure

4.5.2.2.3 Safety Assessment

The implementer should present a confirmation of disposal system performance. This should be based on an updated and integrated overview of the level of knowledge about the ability of each component of the disposal system and of the overall system itself to fulfil their expected roles accounting for the perturbations already encountered and any further ones foreseen. The implementer will be expected to provide a qualitative and quantitative assessment of the overall performance of the system with respect to the isolation and confinement of the radionuclides and hazardous substances contained in the waste.

The implementer will need to provide final substantiation of the models used for calculation, and full assessment of the remaining uncertainties and of the residual margins in the calculations based on information already presented in the previous safety case, updated as necessary.

The implementer will have to confirm that the assessment contains a sufficient level of conservatism implying that the methodology followed cannot lead to an underestimate of the radiological and non-radiological impacts.

The implementer will also need to confirm that throughout the whole process (including closure of the disposal facility), the objective of “optimization” has been adequately achieved and that the relevant uncertainties have been reduced or otherwise addressed to provide confidence in the safety assessment and its results.

Radiological and non-radiological impact assessment on people and environment

At this step, the safety case should confirm compliance with the national regulations in terms of levels of dose or risk. To meet this objective the impact assessment should be updated from the previous safety case as necessary to take into account the up-to-date information gathered from the monitoring and surveillance programme and the expected effects of closure operations.

4.5.2.2.4 Management system

The management system should include processes and procedure for sealing access routes and final closure.

The implementer will need to update the chapter on management system assessment to demonstrate that the whole process has been conducted under a sound and reliable management system.

The update will particularly emphasize the description of the organization and management structure that will be implemented during the post-closure phase (until license release) with regard to disposal and environmental monitoring and surveillance, periodic safety reviews and health surveys when required by the regulatory framework.

The safety case will need to be updated to present the arrangements (legal, financial, technical) for :

- Installing and maintaining physical markers intended for the long-term
- maintaining a long-term institutional memory, including information management and record keeping (site, radioactive inventory, …), and providing accessibility to future generations
- safety and security to prevent human intrusion or human action that would interfere with the passive safety design of the closed disposal facility (safeguards, institutional controls…)
- implementing the monitoring and surveillance programme and health survey when required by national regulations

Such arrangements should be developed in dialog with the regulator.

4.5.2.2.5 Integration of the safety arguments and evidence

The integration of the safety arguments and evidence must have reached a final state and should at this stage enable all the useful information and evidence to be assembled in a comprehensive manner that allows independent appraisal of the level of safety that the facility has reached so that a decision can be made to close the disposal facility.

4.6 POST-CLOSURE PHASE

The post closure phase begins at the time when all access routes from the surface are sealed.

Moving towards a post-closure phase means that safety is only ensured by passive means inherent in the characteristics of the site, the engineered barriers and the waste packages. However this does not necessarily mean that regulatory control will be suspended.

Maintaining institutional memory of the site can be achieved by two means:

- passive means (mainly records) to keep information of the disposal facility as long as possible or required by future generations or by the regulator;
- more active means: monitoring and surveillance activities and institutional controls may continue for an undefined period, for there may be an intention to maintain controls on the site.

> Requirements for geological disposal facility after closure
>
> (Requirement 22) The period after closure and institutional controls
> Plans shall be prepared for the period after closure to address institutional control and the arrangements for maintaining the availability of information on the disposal facility. These plans shall be consistent with passive safety features and shall form part of the safety case on which authorization to close the facility is granted.
>
> (R5.13) …. Consideration has to be given to: local land use controls; site restrictions or surveillance and monitoring; local, national and international records; and the use of durable surface and/or subsurface markers. Arrangements have to be made to be able to pass on information about the disposal facility and its contents to future generations to enable any future decisions on the disposal facility and its safety to be made.
>
> (Requirement 23) Consideration of the State system of accounting for, and control of, nuclear material
> In the design and operation of disposal facilities subject to agreements on accounting for, and control of, nuclear material, consideration shall be given to ensuring that safety is not compromised by the measures required under the system of accounting for, and control of, nuclear material.

As closure of the disposal facility is a key step in meeting the safety objectives, it will be necessary to confirm that the facility has been closed in accordance with safety requirements, which implies that the regulator has conducted a review of the safety case after closure of the repository. Moreover, it should also be confirmed that remediation actions from decommissioning of surface facilities have been completed. This should be confirmed by a formal regulatory approval.

As the disposal system is intended to be passively safe, the safety objective should be achievable even in the absence of active institutional controls. For political or societal reasons some arrangements for institutional control and continuance of monitoring and surveillance programme may be defined and applied for an extended period.

Depending on the regulator’s responsibilities during this phase, the regulator may find it useful:

- To define and regulate legal, technical and financial responsibilities for the post-closure arrangements;
- To decide whether additional measures should be taken by the organization in charge of monitoring and surveillance to improve environmental and health surveys as well as providing arrangements for maintaining memory of the repository;
- To seek periodic reporting on results from monitoring and surveillance, and the environmental and health surveys;
- To define some possible restricted use of land or any other institutional arrangement to ensure control of the site.

Regulatory or political choices may also concern specific arrangements with regard to transfer of responsibility to an organization other than the implementer.

4.6.1 Role and Content of the safety case

To confirm that the level of safety stated prior to closure has been achieved the implementer will update the safety case for the geological disposal facility to take into account data and information gathered during facility closure. The implementer will demonstrate that facility closure has been implemented according to conditions of approval for closure. The intent will be to provide the assurance that the safety objective of the disposal facility is complied with and that regulatory requirements for long term safety are met.

This post-closure safety case will need to confirm that no more corrective actions are necessary to ensure safety. The confirmation of the safety of the disposal facility will not refer to any reliance on any positive future human action, other than possible action through institutional control to prevent disturbance of the site.

The implementer will also have to demonstrate that the final state after remediation of surface facilities meets the requirements set by the regulator and the objectives defined in the plan for decommissioning and remediation.

This implies that the implementer must ensure that the safety case is up to date with respect to the following elements:

- Confirmation that the disposal facility has been correctly closed and sealed in accordance with the requirements and the safety assessment developed in the earlier safety case. The implementer is expected to demonstrate that, taking into account the experience feedback from closure of the facility, no non-conformity or unexpected event is likely to affect compliance with the safety criteria;
- Assessment of the performance of the disposal system and its safety functions after closure taking into account the total radioactive inventory disposed of to the facility;
- Environmental and radiological impact assessment of the disposal facility;
- Results of environmental and health surveys conducted during the previous stages;
- Description of a programme (including the management system) for post-closure monitoring and surveillance and nuclear safeguards, their implementation and provisions to maintain them as long as possible (or as required by the legal system or by Government policy);
- Description of the arrangements for maintaining a long-term institutional memory, including information management and record-keeping. This should demonstrate that the techniques and methods used to provide for the long-term conservation of institutional and societal memory are adequate, so that the existence of the disposal facility will not be forgotten for a long period of time. The nature, amount and quality of information documented should be shown to be sufficient for future generations to take any foreseeable decision they might wish to take regarding the disposal facility.

The last two elements of the safety case will be updated from the safety case for the previous phase to take into account any new expectations from the regulator or the public. Attention should be paid to institutional arrangements in order to avoid as far as possible abandonment of the site in an uncontrolled manner.

4.6.1.1 Safety strategy

The implementer should, if required, present its updated approach for post closure monitoring, surveillance and controls.

4.6.1.2 Assessment basis

The assessment basis should be completed with the as-built description of the sealing of the disposal facility.

It is recognized that properly designed disposal facilities (especially geological disposal facilities) are not expected to give rise to significant releases to the biosphere during any reasonable period of monitoring and surveillance. However, for political or societal reasons some arrangements for a monitoring and surveillance programme may be defined.

The implementer will, if required, present the finalized post-closure monitoring and surveillance programme which should aim at:

- to the extent possible, confirming the ability of the disposal system to behave as predicted and isolate the wastes properly after closure;
- being able to assess periodically any potential impacts on the public and environment that could be attributed to releases from the disposal facility.

This programme will more specifically aim at demonstrating that radiological and non-radiological impacts of the disposal system on people and the environment comply with statutory and regulatory requirements. To the extent possible, it will also allow detection of any abnormal situation liable to have a negative impact on the performance of the disposal system. Monitoring and surveillance of the disposal facility should also facilitate the prevention of site intrusion.

4.6.1.3 Safety assessment

The objective will be to confirm the safety assessment results and the compliance with the regulatory criteria after closure.

This confirmation will more particularly aim at confirming the absence of any conditions (especially due to the closure phase) that could reduce the post-closure safety of the facility as assessed in previous phases. It will be based on confirming that all the activities (especially closure) have been performed following the planned requirements.

The implementer should update the safety assessment established in the previous stage on the basis of feedback from closure operations and analysis of the data gained during closure (from in situ monitoring and surveillance of the disposal system).

The implementer should present a confirmation of the expected performance of the disposal system. This will be based on an updated and integrated overview of the level of knowledge about the ability of each component of the disposal system and the ability of the overall system itself to fulfil their expected roles accounting for any perturbations already encountered and any further ones foreseen. The implementer will be expected to provide a qualitative and quantitative assessment of the overall performance of the system regarding isolation and confinement of the radionuclides and hazardous substances contained in the waste.

Radiological and non-radiological impact assessment on people and environment

The radiological impact assessment should be updated from the previous safety case as necessary to take into account feedback from closure operations.

Regarding the surface facilities, the implementer should demonstrate that decommissioning has proceeded in accordance with national regulations and should assess the impact on people and the environment. The implementer should report the results of the decommissioning and remedial actions undertaken with respect to auxiliary facilities and should provide substantiation of the absence of residual impact on the environment.

4.6.1.4 Management system

The implementer should ensure that the chapter on management system assessment demonstrates that the whole process (including closure) has been conducted under a sound and reliable management system. The chapter should describe the organization and management structure that will be implemented during the post-closure phase with regard to disposal system monitoring and surveillance, together with environmental and health surveys when required by the regulatory framework.

Specific attention should be paid to the definition and assessment of the management system dedicated to maintaining institutional memory.

5. MANAGEMENT OF UNCERTAINTIES

Uncertainties associated with the safety of disposal facilities are unavoidable due to the complexity of the phenomena involved and the scales in time and space under consideration. Management of uncertainties is essential when developing a disposal facility and assessing its safety. For this reason, the issue of uncertainties and their management has been chosen for a more detailed examination as part of the pilot study, in order to identify the level of commonality on this subject among the participating countries, to understand differences better, and to propose some common grounds for guidance. The resulting outcome, which is detailed in a companion report [1], focuses on management of uncertainties in the context of the adopted safety strategy within the safety assessments and assessing compliance with safety requirements.

There are two broad types of uncertainties, namely uncertainties that can be quantified because data exist or can be acquired to support quantification, and uncertainties that are much less amenable to quantification because no relevant data can be made available. Uncertainties related on natural variability belong to the first type (capable of being assessed statistically) while problems of data relevance, lack of understanding of processes, or uncertainty about future human behaviour belong to the second type. Uncertainties of the second type are no less real and important than those of the first type.

The approach to the management of uncertainties is a part of the safety strategy. Accounting explicitly for uncertainties and analysing their possible consequences are an essential part of any safety assessment for a radioactive waste disposal facility. Within a step-by-step approach to disposal facility development, information about uncertainties and perspectives on how they can be managed form an important input for the decisions to be taken at each step. How much uncertainty can be accepted at a given step depends on the decisions to be taken at that step. A key issue in the safety case is inclusion of a register of significant uncertainties and a management process for assessing and, where appropriate, avoiding, mitigating or reducing them.

Regarding the effect of uncertainties on the safety assessment, emphasis is placed on:

- the approach to scenario development;
- the role of probabilistic and deterministic approaches; and
- the role of best estimate, conservative and pessimistic approaches.

Identifying and substantiating a set of illustrative scenarios helps to structure the safety case and is a valuable tool to identify where further work should be directed to avoid, mitigate or reduce uncertainties and to evaluate their effect. By this means, the link between safety assessment and safety strategy is maintained. A radiological impact assessment should include a representative number of different scenarios that can account for the range of possible outcomes. These scenarios could be assessed through probabilistic or deterministic approaches, each having benefits and limitations as outlined in more detail in the companion report.

The safety case is expected to include a conservative estimate of the impact of the disposal system on people and the environment based on a best estimate description of the likely evolution of the system. This provides a starting point for developing the management of uncertainties. This process is expected to lead to the definition of categories of scenarios of similar likelihood of occurrence leading to the development of information needed for deciding whether a sufficient level of safety has been reached.

Probabilistic and deterministic assessments have important but different contributions to make. A mixed analysis approach combining both probabilistic and deterministic assessments could be considered.

A distinction is usually made between "best estimate / best belief" and "conservative" choices of modelling assumptions and parameter values. Sometimes, a third category is introduced, namely "pessimistic / penalising" choices. More specifically, the three categories distinguish between choices which:

- are considered likely to reflect the real system as well as possible to the best knowledge of the modeller, without any reference to the calculated consequences ("best estimate / best belief");
- are considered less likely to do so but are still within the range of conceivable possibilities, thereby being deliberately chosen so as to lead to an upper estimate of consequences ("conservative"); and
- are considered to bound all conceivable, including very unlikely possibilities and lead to calculated consequences more severe than any that could actually be realised ("pessimistic / penalising").

A key objective of the safety case is to obtain a thorough knowledge of the processes likely to take place in the disposal system and an adequate understanding of its long term behaviour. This entails investigating the most likely performance of the system, leading towards a best estimate approach.

However, for compliance with regulatory requirements it is usually necessary to show that the estimates of radiation dose or risk from the possible migration of radionuclides from a disposal facility are below or consistent with some reference criteria. It is then sufficient to demonstrate that an upper estimate of the release lies below the target value. Such considerations lead towards a conservative approach.

A pessimistic approach may use a model or set of parameter values that do not refer to phenomenological knowledge, chosen to lead with certainty to an impact greater than anything possible. For example, a parameter value may be chosen that corresponds to a physical limit. The motivation for using such an approach might be to test the overall robustness of the disposal facility concept or to handle with certain processes that are poorly understood.

It should be recognised that there are limitations to making exclusive use of an overall best estimate approach and that some conservative assumptions leading to simplifications will always be necessary for some parts of the system (e.g. due to limitations of site investigations). In particular, where uncertainties are large the concept of a best estimate may have little meaning. In the framework of the step by step approach there is a need for dialogue between the regulator and the implementer to clarify expectations on the matter at each decision step.

The approach for assessing compliance differs considerably depending on the country. However a common theme is that many uncertainties in the post-closure safety case cannot be quantified reliably. Calculated doses or risks can only be regarded as broadly conservative indicators , and accordingly, the post-closure safety case needs to be based on all the relevant arguments and evidence that provide a reasonable assurance of compliance with safety requirements.

6. CONCLUSIONS

A number of countries in Europe interested in geological disposal of radioactive waste, recognising the potential benefits of a common approach, have been collaborating for some years on approaches to demonstrating the safety of facilities based on this broad disposal concept. Mindful of these benefits, but also of the potential difficulties, a pilot study group was established together with observers from the EC, IAEA and NEA to investigate the regulatory review of a safety case for geological disposal of radioactive waste. The main objective of the pilot study was to develop a consensus advisory document on the expectations of the regulator regarding the progressive evolution of a safety case and its constituent elements at different stages in the development of such a project. The scope of the study was broad enough to demonstrate the emergence of common views held by the participating organizations.

The conclusions reached by the group are as follows:

- The regulatory process requires the implementer to compile and present all safety arguments and their accompanying evidences, particularly where key decisions relating to progressing to the next phase of development must be made. These arguments and supporting evidence can be presented in a variety of documented formats, and collectively they are referred to as the safety case. The IAEA safety guidance [2] for geological disposal provides an adequate basis for developing the safety case.

- Demonstrating the safety of geological disposal is a process that needs to be undertaken systematically and through all phases of the development of a disposal facility. Safety arguments must be continuously refined and supporting safety assessments must be undertaken iteratively as the disposal facility is developed. The structure of the assessments must be consistent throughout.

- The regulatory process needs systematically to evaluate all the elements of safety and its assessment. The regulatory process should begin at the earliest stages in the development of a disposal facility, even if initially the process is less formal and decisions or opinions of the regulator may not be legally enforceable.

- Elements of the safety assessments supporting the safety case are separated into those related to: feasibility and performance assessment of the site and design of the facility; assessments of impact to people and the environment; and assessments of the management system.

- The safety case must include an assessment of these individual elements and an integrated assessment of the overall disposal system. The manner and extent to which these elements are assessed during the process of developing and implementing the facility will vary with the phase reached.

- From a regulatory perspective, the phases that need to be addressed are: conceptualization; site selection (including the selection of the host formation); design; construction; operation; and post-closure.

- An overall safety strategy which sets out the high-level approach for achieving safe disposal, and includes an overall management system (including an approach to optimization), a siting and design approach and a safety assessment methodology, needs to be established from the beginning of the project.

- A systematic approach to managing uncertainties is key in demonstrating confidence in the safety of a disposal facility.
- This pilot study has determined a framework for demonstrating the safety of geological disposal, through the different stages of an evolving and maturing project. It has broadly defined the regulatory expectations within this framework, which represents a currently emerging consensus. As disposal facility development progresses in various countries and experience from regulatory reviews increases, this study could be revisited to take into account improved understanding and lessons learnt, and to take into account any new international standards and guidance.

7. GLOSSARY

Assessment

Assessment is aimed at demonstrating that something is satisfactory with regard to requirements. In this respect sufficient information should be available to support the basis of a decision. Various kinds of *analysis* may be used as tools in doing this.

Impact assessment. *Assessment* of the radiological consequences (e.g. *doses*, *activity concentrations*) and the non-radiological consequences (e. g. concentrations of chemically toxic elements in waters) of *normal operation* and possible *accidents*, associated with the operation of a disposal or part thereof *as well as of* normal evolution, altered scenarios and human intrusion scenarios. Impact assessment is a synonym of consequence assessment and related to exposure assessment.

Performance assessment. Assessment of the performance and robustness of the disposal system or subsystem and its implications for protection and safety.

Assessment basis

The assessment basis is the collection of information and analysis tools supporting the safety assessment. [NEA - 3679 - Post closure safety case 2004]

Authorization

The granting by a regulatory body or other governmental body of a written permission for an implementer to perform specified activities.

- Authorization could include, for example, licensing, certification or registration.
- The term authorization is also sometimes used to describe the document granting such as permission.
- Authorization is normally a more formal process than approval.

[IAEA Safety Glossary, Terminology Used In Nuclear Safety and Radiation Protection, 2007 Edition]

Closure

The completion of all *operations* at some time after the emplacement of *spent fuel* or *radioactive waste* in a *disposal facility*. This includes the final engineering or other work required to bring the *facility* to a condition that will be safe in the long term.] [Joint convention – 1997].
The post-closure period begins at the time when all the engineered containment and isolation features have been put in place, operational buildings and supporting services have been decommissioned and the facility is in its final configuration. After closure, the safety of the disposal facility is provided for by passive means inherent in the characteristics of the site and the facility. [IAEA draft safety requirements DS 354 section 1.18]

Control

The function or power or (usually as *controls*) means of directing, regulating or restraining. *'Control'* typically implies not only checking or *monitoring* something but also ensuring that corrective or *enforcement* measures are taken if the results of the checking or *monitoring* indicate such a need. [IAEA Safety Glossary, Terminology Used In Nuclear Safety and Radiation Protection, 2007 Edition]

Decommissioning

"Decommissioning" means all steps leading to the release of a nuclear facility, other than a disposal facility, from regulatory control. These steps include the processes of decontamination and dismantling. [IAEA Safety Glossary, Terminology Used In Nuclear Safety and Radiation Protection, 2007 Edition]

Defence in depth

For nuclear installations, the defence in depth principle leads to the implementation of successive lines of defence which are capable of preventing the appearance of or, if appropriate, limiting the consequences of technical, human or organisational faults which are likely to result in accident situations which could affect the protection of people and the environment.

Demonstrability

Capability of being demonstrated. The implication is that the demonstration will be either (1) by logical proof (QED), or (2) by practical means such as observation or experiment and supported by a large weight of evidence, such as to put it beyond reasonable doubt.

Demonstration of safety

Providing reasonable assurance that the safety objective and criteria will be met. [IAEA Safety Glossary, Terminology Used In Nuclear Safety and Radiation Protection, 2007 Edition]

Design

Design basis**.** Principles for the design of the disposal facility established by the implementer in accordance with the safety strategy.

Design options. General principles and basis for the design established by the implementer as for instance the allocation of safety functions to individual components.

Design requirements**.** Safety requirements for the design established by the regulator (e.g. minimum depth for the disposal facility).

Design rules or specifications. Specifications of components defined by the implementer which may be controlled by demonstration tests.

Safety design principles. Principles for the design of the disposal established by the regulator and/or the implementer.

Engineered barrier system (EBS)

In geological disposal systems, the barriers include the natural geological barrier and the engineered barrier system (EBS). The EBS may itself comprise a variety of sub-systems or components, such as the waste form, canister, buffer, backfill, seals, and plugs. The purpose of an EBS as a whole is to prevent and/or delay the release of radionuclides from the waste to the disposal facility host rock.

Institutional control

Most commonly used to describe controls over a disposal facility after closure or a facility undergoing decommissioning. Institutional controls refer to control of a radioactive waste site by an authority or institution designated under the laws of a State. This control may be active (monitoring, surveillance, remedial) or passive (land use control) and may be an important component ensuring the safety of some types of disposal facilities (e.g. near surface facility). Also refers to the controls placed on a site that has been released from regulatory control under the condition of observing specified restrictions on its future use to ensure that these restrictions are complied with.
[Derived from IAEA Safety Glossary, Terminology Used In Nuclear Safety and Radiation Protection, 2007 Edition]

Proposed classification :
Active institutional control *: monitoring, surveillance, restricted access*
Passive institutional control : *land use control, archives, markers*

Impact assessment (see assessment)

Implementer

The organization responsible to develop a concept for geological disposal of radioactive waste, applying for authorization or authorized.

Isolation

Isolation means designing to keep the waste and its associated hazard away from the accessible biosphere. It also means designing to minimize the influence of factors that could reduce the integrity of the disposal facility such as avoiding sites and locations with higher hydraulic conductivities and making human access to the waste difficult. [IAEA - DS 354]

Licensing

A "licence" means any authorization, permission or certification granted by a regulator to carry out any activity related to management of spent fuel or of radioactive waste (equivalent to authorization).

Management system

A set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an effective and efficient manner. The component parts of the management system include the organizational structure, resources and organizational processes. [IAEA Safety Glossary, Terminology Used In Nuclear Safety and Radiation Protection, 2007 Edition]

Monitoring, surveillance

The purpose of the monitoring and surveillance programme is to collect and update the information needed to confirm the conditions necessary for the safety of workers and members of the public and the protection of the environment during the construction, operation and closure of the facility and to confirm the absence of any conditions that could unacceptably reduce the post-closure safety of the facility.

Optimization[1]

The optimization for a geological disposal facility is a judgmental process that is applied to the decisions made during the development of the facility's design. Most important is that sound engineering and technical solutions are adopted and sound principles of safety and quality management are applied throughout the development, operation and closure of the geological disposal facility. [2]

Radiation protection objectives (see radiation safety principles)

Radiation safety principles

Radiation safety principles are principles applicable to providing radiation safety. Such principles have been formulated by the International Commission on Radiological Protection (ICRP), most recently in its Publication 103 (2007), under the headings justification, optimization and limitation (of radiation risks). Reference in the present report to 'radiation safety principles' means either the ICRP principles themselves or principles derived from them that are adapted for application to a geological disposal facility. Radiation safety principles are the basis for the definition of radiation protection objectives.

Reversibility

Reversibility is defined as the possibility of reversing one or a series of steps in repository planning or development at any stage of the programme" (managerial concept) (NEA-3140).

Reversibility is an approach to decision making whereby at each time a decision to go forward is to be made, the question is also asked: should we change course or go back?

Retrievability

Retrievability is defined as the possibility of reversing the action of waste emplacement (technical concept) (NEA-3140).

Safety assessment

The safety assessment is the process of systematically analysing the hazards associated with the facility and the ability of the site, designs and operational procedures to provide the safety functions and meet technical and safety requirements. [IAEA safety requirements SSR5] Performance assessment is part of safety assessment (see performance assessment).

Post-closure safety assessment. The process of analysing the performance of a disposal facility and showing, with an appropriate degree of confidence, that it will remain safe over a prolonged period, beyond the time when active control of the facility can be relied on. [NEA - 3679 - Post closure safety case 2004]

[1] Another definition for optimization of protection (and safety), as given by the International Commission on Radiological Protection System of Radiological Protection, is «the process of determining what level of protection and safety makes exposures, and the probability and magnitude of potential exposures, "as low as reasonably achievable, economic and social factors being taken into account" » (ALARA).

Safety case

A collection of arguments and evidence in support of the safety of a facility or activity. This will normally include the findings of a safety assessment and a statement of confidence in these findings. For a repository, the safety case may relate to a given stage of development. In such cases, the safety case should acknowledge the existence of any unresolved issues and should provide guidance for work to resolve these issues in future development stages. [IAEA glossary _2007]

Safety strategy

The safety strategy is the high-level approach adopted for achieving safe disposal, and includes the basis of an overall management system, a siting and design approach, an approach for operating the facility and an assessment methodology. (NEA - 3679 - Post closure safety case 2004)

Performance assessment. (see assessment)

Structures, systems and components (SSCs)

A general term encompassing all of the elements (items) of a *facility* or *activity* which contribute to *protection and safety*, except *human factors*.
Structures are the passive elements: buildings, vessels, shielding, etc. A ***system*** comprises several *components*, assembled in such a way as to perform a specific (active) function. A ***component*** is a discrete element of a *system*.

8. REFERENCES

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