PAMINA
Performance Assessment Methodologies in Application to Guide the Development of the Safety Case
(Contract Number: FP6-036404)

The Treatment of Uncertainty in Performance Assessment and Safety Case Development:
Synthesis of PAMINA RTDC-2
DELEGERABLE (D-N°: D2.3.1)

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<table>
<thead>
<tr>
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<td>PU</td>
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<tr>
<td>RE</td>
<td>Restricted to a group specified by the partners of the [PAMINA] project</td>
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<tr>
<td>CO</td>
<td>Confidential, only for partners of the [PAMINA] project</td>
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Dissemination Level: PU, RE, CO

Compliance with the E fucking
Foreword

The work presented in this report was developed within the Integrated Project PAMINA: Performance Assessment Methodologies IN Application to Guide the Development of the Safety Case. This project is part of the Sixth Framework Programme of the European Commission. It brings together 25 organisations from ten European countries and one EC Joint Research Centre in order to improve and harmonise methodologies and tools for demonstrating the safety of deep geological disposal of long-lived radioactive waste for different waste types, repository designs and geological environments. The results will be of interest to national waste management organisations, regulators and lay stakeholders.

The work is organised in four Research and Technology Development Components (RTDCs) and one additional component dealing with knowledge management and dissemination of knowledge:

- In RTDC 1 the aim is to evaluate the state of the art of methodologies and approaches needed for assessing the safety of deep geological disposal, on the basis of comprehensive review of international practice. This work includes the identification of any deficiencies in methods and tools.

- In RTDC 2 the aim is to establish a framework and methodology for the treatment of uncertainty during PA and safety case development. Guidance on, and examples of, good practice will be provided on the communication and treatment of different types of uncertainty, spatial variability, the development of probabilistic safety assessment tools, and techniques for sensitivity and uncertainty analysis.

- In RTDC 3 the aim is to develop methodologies and tools for integrated PA for various geological disposal concepts. This work includes the development of PA scenarios, of the PA approach to gas migration processes, of the PA approach to radionuclide source term modelling, and of safety and performance indicators.

- In RTDC 4 the aim is to conduct several benchmark exercises on specific processes, in which quantitative comparisons are made between approaches that rely on simplifying assumptions and models, and those that rely on complex models that take into account a more complete process conceptualization in space and time.

The work presented in this report was performed in the scope of RTDC 2.

All PAMINA reports can be downloaded from http://www.ip-pamina.eu.
The Treatment of Uncertainty in Performance Assessment and Safety Case Development: Synthesis of PAMINA RTDC-2

Report History

This document has been prepared by Galson Sciences Limited (GSL) as part of the European Commission Project PAMINA FP6-036404. GSL gratefully acknowledges cofunding received from NDA, ONDRAF/NIRAS and NAGRA.

Draft 1 was issued on 31 October 2009 and distributed to PAMINA participants for comment. This version addresses the comments received, and includes details of several PAMINA deliverables completed after the production of Draft 1.

| The Treatment of Uncertainty in Performance Assessment and Safety Case Development: Synthesis of PAMINA RTDC-2 |
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| Version: D2.3.1 Version 1 | Date: 31 Dec 2009 | Main Author: M.B. Crawford | Reviewed by: D.A. Galson | Approved by: D.A. Galson |
Executive Summary

The European Commission’s PAMINA Project (Performance Assessment Methodologies in Application to Guide the Development of the Safety Case) ran from 2006 to 2009 with the aim of improving and developing a common understanding of integrated performance assessment methodologies for disposal concepts for spent fuel and other long-lived radioactive wastes in a range of geological environments.

Galson Sciences Ltd was responsible for co-ordination and integration of the Research and Technology Development Component “RTDC-2” of the PAMINA Project. The objective of RTDC-2 was to allow development of a common understanding of different approaches to the treatment of uncertainty in PA, and to provide guidance on, and examples of, good practice on how to treat different types of uncertainty in the context of the development of a post-closure safety case, both as a whole and in specific areas. Guidance on the development of work in RTDC-2 came from an initial review of key drivers and methodologies for the treatment of uncertainty, conducted in RTDC-1 as Work Package 1.2 (WP1.2).

RTDC-2 was organised in three work packages:

- WP2.1 researched key drivers and methodologies for the treatment of uncertainty, addressing regulatory compliance, the communication of uncertainty, approaches to system PA, and techniques for sensitivity analysis.

- WP2.2 proceeded in parallel with WP2.1 and tested and developed the framework outlined in WP1.2 by undertaking a series of exercises to provide examples of uncertainty treatment from different European programmes at different stages of development. The work was divided into tasks that considered the main types of uncertainties (scenario, model, parameter), the treatment of spatial variability, and the development of probabilistic safety assessment tools.

- WP2.3 was a synthesis task pulling together the WP1.2 review, and research on the treatment of uncertainty under WP2.1 and the testing and development work under WP2.2 to arrive at final guidance on approaches for the treatment of uncertainty during PA and safety case development that contains state-of-the-art examples from the PAMINA project for a range of key areas.

This report comprises the synthesis (WP2.3) of the treatment of uncertainty in PA and safety case development. It includes cross references to work on the treatment of uncertainty elsewhere in the PAMINA project, within RTDC1 (review of PA methodologies), RTDC3 (other methodological advances in PA) and RTDC4 (relevance of sophisticated PA approaches to practical cases). It is complementary to the main project deliverable, the Handbook of PA Methodologies.

This report:

- Discusses radioactive waste management programmes and how they go about demonstrating the safety of geological disposal.
• Summarises the sources of uncertainty in the radioactive waste management process and how programmes go about managing uncertainty, focusing on the management of uncertainty in PA.

• Discusses the PA process and how uncertainties are addressed within this process.

• Outlines how different types of uncertainty are categorised and treated in PA.

• Reviews the different calculational approaches that can be used in PA to handle the different types of uncertainty and to display the results.

• Reviews methods for the presentation and communication of uncertainty in PA results.

• Considers the approach to the treatment of uncertainty in regulations and regulatory guidance, and how regulators review the treatment of uncertainty in PAs.

• Discusses how uncertainties are taken into account in programme development and forward planning.

There is a high level of awareness of the importance of treating uncertainties in PA and the safety case, and treatments of varying degrees of sophistication have been implemented in all national programmes. This report summarises the contribution made by the PAMINA project to evaluation and further development of methods for the treatment of uncertainty.
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1 Introduction

1.1 Project Context

Spent nuclear fuel and long-lived radioactive waste from nuclear power generation must be isolated from humans and the environment for many thousands of years. Disposal of spent nuclear fuel and long-lived radioactive waste in engineered facilities or repositories located underground in suitable geological formations is the waste management strategy - termed geological disposal - that is currently being investigated in most countries. This strategy can provide long-term security and safety in a manner that does not require active monitoring, maintenance and institutional control once the repositories are closed and sealed.

A repository is considered to be safe if it meets the relevant safety standards that are recommended internationally or that are specified by the responsible national regulator. Within the European Union, however, differences exist in methodologies to demonstrate the safety of a repository. These differences are due to specific national regulations and the geological and technical boundary conditions. These differences include the terminology employed, the features and processes that are accounted for and the different codes and models used.

With funding from the European Commission (EC), 27 European organisations are participating in project PAMINA: Performance Assessment (PA) Methodologies IN Application to Guide the Development of the Safety Case. The overall objective of PAMINA is to improve and harmonise PA methodologies and tools for geological disposal concepts for long-lived radioactive wastes.

PAMINA consists of four Research, Technology, and Demonstration Components (RTDCs), and a fifth Component concerned with training, knowledge management and dissemination. The four RTDCs are:

- RTDC-1: Review of PA methodologies in participating organisations.
- RTDC-2: Treatment of uncertainty in safety case development.
- RTDC-3: Other methodological advancements in PA.
- RTDC-4: Relevance of sophisticated PA approaches to practical cases.

The treatment and management of uncertainties are integral parts of PA and safety case development because there are significant uncertainties present in long-term
assessments of repository safety. For this reason, a large part of PAMINA is concerned with establishing best practice with respect to treating uncertainties, and is being conducted via four interlinked Work Packages (WPs):

- An initial review task to establish the state-of-the-art with regard to approaches to the treatment of uncertainty in recent safety cases in Europe and worldwide (WP1.2).


- Research focused on further development and testing of the concepts for treating uncertainty (WP2.2). This component of RTDC-2 comprises five tasks: 2.2.A Parameter uncertainty; 2.2.B Conceptual model uncertainty; 2.2.C Scenario uncertainty; 2.2.D Spatial variability; 2.2.E Fully probabilistic safety assessment.

- A task pulling together the initial review and the research conducted into a final guidance document on approaches for the treatment of uncertainty in PA and safety case development, and containing a set of state-of-the-art examples for a range of key areas (WP2.3) - this document.

PAMINA has run for three years from 1 October 2006 to 30 September 2009. This document represents the conclusion of PAMINA RTDC-2 and forms the WP2.3 deliverable.

1.2 Objectives

The objective of RTDC-2 Work Package 2.3 (WP2.3) is to develop a guidance report describing methodologies for the treatment of uncertainty in PA and safety case development, and containing a compendium of state-of-the-art examples for a range of key areas. The guidance is developed from the initial guidance developed in WP1.2 and draws on the results of the work performed under RTDC-2. The guidance is intended to provide a key international reference point for performance assessor and safety case developers.

The focus of work within PAMINA RTDC-2 is on the treatment of uncertainties within PA and safety cases. Therefore, issues of uncertainty management (e.g., designing out uncertainty, relationship between PA and R&D), though touched upon in this report, do not form part of the R&D work within RTDC-2 and are not central to this report.
1.3 Report Inputs

This section provides a summary of the work undertaken in PAMINA that has been used to develop this report.

WP1.2 of PAMINA involved the development of initial guidance for the management of uncertainty – the precursor to this report. This task gathered together for PAMINA RTDC-2 an initial database of information on the management of uncertainty, including examples from previous relevant PAs and safety cases. A questionnaire was circulated to radioactive waste management organisations, and the results are reproduced in Appendix 1 and summarised in [Galson and Khursheed 2007]. The results are used throughout this report. The remainder of the work under PAMINA RTDC-2 was focused on developing and extending the WP1.2 database and addressing key gaps.

Tasks under WP2.1 were focused on researching key drivers and methodologies for the management of uncertainty:

- **Task 2.1.A: Regulatory compliance.** This task focused on how the treatment of uncertainty in PA impacts upon regulatory compliance. A facilitated workshop was attended by regulators and regulatory support organisations from different European countries with different approaches to regulation of radioactive waste disposal. The workshop considered the advantages and disadvantages of detailed, prescriptive regulation for geological disposal and treatment of uncertainty and the relationship to a stepwise approach to licensing. A workshop report was produced [Hooker and Wilmot 2008] and this is a key input to Section 8 of this report.

- **Task 2.1.B: Communication of uncertainty.** This task assessed the effectiveness of different methods for communicating disposal system performance, communicating how it has been determined, and communicating the uncertainty associated with the determination and its significance, to both lay and technical audiences. A high-level stakeholder panel consultation concerning the communication of uncertainty was undertaken [Hooker and Greulich-Smith 2008], followed by an activity designed to test specific communication materials on a wider audience [Hooker et al. 2009], and these are key inputs to Section 7 of this report. A template for consistent presentation of the main characteristics of PA results and/or performance indicators to the technical community is reported by [Bolado and Badea 2009], and is an input to Sections 6 and 7 of this report.

- **Task 2.1.C: Approaches to system PA.** This task examined the relative advantages and disadvantages of different approaches to the quantification of uncertainties in system-wide PA calculations. A summary is provided in [Galson et al. 2009d]. Four topics were covered:
  
  - Topic 1: Deterministic assessments versus probabilistic assessments. This is discussed in [Galson et al. 2009a] and is a primary input to Section 5.5.
Topic 2: Levels of conservatism and realism in performance assessments. This is discussed in [Galson et al. 2009b] and is a primary input to Section 5.6.

Topic 3: Exploration of the potential of hybrid stochastic-subjective approaches to the treatment of uncertainty. This is discussed in [Vetešník 2008] and is a primary input to Section 5.3 and Section 6.2.

Topic 4: Alternative approaches for presentation of results from safety analysis / uncertainty analysis in the form of graphical outputs. The presentation of the results of probabilistic analyses is discussed in [Iooss and Devictor 2008] and is an input to Section 7 of this report.

Task 2.1.D: Techniques for sensitivity and uncertainty analyses. This task involved review, analysis and testing of the methods of sensitivity and uncertainty analysis applied to PA calculations. A summary of this task is provided by [Becker et al. 2009a]. The work proceeded through parallel topics undertaken by different groups:

Topic 1: A review of the main techniques for sensitivity analyses in use, their strengths and weaknesses. This is reported in [Badea and Bolado 2008] and is a key input to Section 6 of this report.

Topics 2-5: Application of the sensitivity analysis methods highlighted by the Topic 1 review in a series of test cases drawn from the national programmes of participating organisations. The calculations covered a range of repository types and host rock formations. The results are summarised in [Becker et al. 2009a] and Section 6 of this report.

Topics 6-7: Testing of sensitivity analysis methods on generic complex and CPU-intensive models. The testing is reported in [Iooss and Marrel 2008] and is an input to Section 6 of this report.

Topic 8: A benchmark study involving all participants in Task 2.1D aimed at testing a wide range of sensitivity analysis methods on analytic and synthetic test cases. This is reported in [Plischke et al. 2009] and is also an input to Section 6 of this report.
WP2.2 proceeded in parallel with WP2.1 and was aimed at testing and developing the guidance from WP1.2 by undertaking a series of exercises to provide examples of uncertainty treatment, divided into tasks that consider the main types of uncertainties:

- **Task 2.2.A: Parameter uncertainty.** This task researched the development of practical recommendations for the reliable and defensible derivation of Probability Density Functions (PDFs) for key parameters used in PA calculations. The work is summarised in [Becker et al. 2009b] and proceeded through parallel studies undertaken by different groups, as follows:
  
  - Topics 1-2: Developing guidance on methods to construct PDFs. A protocol for defining parameter uncertainty is proposed by [Becker et al. 2008] and is discussed in Section 5.3 of this report. Use of fuzzy set theory to define parameter values is discussed by [Vetešník 2009] and is an input to Sections 5.3 and 6.2 of this report.
  
  - Topics 3-4: Developing guidance on methods for determining PDF type (shape). This is reported in [Destin and Smidts 2009] and is an input to Section 5.3 of this report.
  
  - Topic 5: Developing guidance on the use of formal expert judgement to derive PDFs. A review of the use of expert judgement is provided by [Bolado et al. 2009a] and a protocol is trialled in [Bolado et al. 2009b]. These reports are inputs to Section 5.3 of this report.
  
  - Topic 6: Evaluation of parameter uncertainty in the context of the KBS-3 disposal concept. This is reported in [Nordman 2009] and is an input to Section 5.3 of this report.

- **Task 2.2.B: Model uncertainty.** This task evaluated methods for treating uncertainties in PA calculations arising from the representation of physical processes by models, at both conceptual and practical levels. The task was divided into three topics, with a general report also being added. The reports are key inputs to Section 5.4 of this report:
  
  - Topic 1: Models for assessing risk from the groundwater pathway, reported in [Poole 2009].
  
  - Topic 2: Models for assessing the consequences of gas generation, reported in [Norris 2008].
  
  - Topic 3: Reactive chemistry modelling for a tube filled with a mixture of crushed rock and bentonite, reported in [Luukkonen and Nordman 2008].
  
  - General guidance on the treatment of model uncertainty within the context of a performance assessment for a geologic repository, reported in [Hansen 2009].
• Task 2.2.C: Scenario uncertainty. This task evaluated the uncertainties attached to scenarios. The work is summarised in [Galson et al. 2009e] and was divided into three topics. The reports are key inputs to Section 5.5 of this report:

➢ Topic 1: Review of scenario development methodologies with respect to treatment of uncertainty, reported in [Bassi and Devictor 2008].

➢ Topic 2: Quantifying probabilities for scenarios, reported in [Galson et al. 2009c].

➢ Topic 3: Trial of formal use of expert judgement for scenario conceptualisation, reported in [Grupa 2009].

• Task 2.2.D: Spatial variability. This task considered approaches to treating uncertainties in PA calculations that arise from the spatial variability of facies, materials, and material properties inherent in the geosphere. This task involved review and testing of techniques for upscaling (Topic 1 [Rodrigo-Illarri and Gómez-Hernández 2007]), and review of the use of geostatistical techniques in PA (Topic 2 [Plischke and Röhlig 2008]; [Iooss 2008]). The results are brought together in [Rodrigo-Illarri et al. 2008]. The work is summarised in Section 6.2 of this report.

• Task 2.2.E: Fully probabilistic assessment approach. This task involved the development and testing of an integrated, fully probabilistic safety assessment (PSA) approach incorporating scenario, model and parameter uncertainty [NAGRA 2010]. [ENRESA 2009] undertook complementary PSA calculations using Goldsim. [Röhlig and Plischke 2009] provided a regulatory view of the use of the PSA approach. The work is discussed in Section 6.4 of this report.

Some of the work conducted under the components of PAMINA other than RTDC-2 also has a bearing on, or provides examples of, the treatment of uncertainty in PA and safety case development:

• Under RTDC-1, WP1.1 reviewed methods and approaches in safety case development used in the main geological disposal development programmes. The review was structured around 11 topics, and of particular relevance to the treatment of uncertainty are the topics covering the definition and assessment of scenarios [Marivoet et al. 2008], uncertainty management and uncertainty analysis [Marivoet et al. 2008] (this review is complementary to that undertaken for WP1.2 [Galson and Khursheed 2007]), modelling strategy [Capouet et al. 2009], and sensitivity analyses [Capouet et al. 2009]. The WP1.1 reviews are referenced as examples in the relevant parts of this report.

• RTDC-3 was focused on developing the methodologies and tools for integrated PA for various geological disposal concepts. Of most interest to the discussion in this report are the work on scenarios (identification of scenarios on the basis of safety functions and development of stylised scenarios), as
summarised in [Beuth et al. 2009], and the application of performance and safety indicators, as summarised in [Becker et al. 2009c].

- RTDC-4 evaluated the use of more complex and more realistic modelling approaches in PA, particularly with regard to demonstrating comprehension, providing added value, and including processes not yet fully accounted for in PA. As such, this work is mainly relevant to Section 5.4 in this report on the treatment of modelling uncertainty.

1.4 Report Structure

This report is structured as follows:

- Section 2 discusses radioactive waste management programmes and how they go about demonstrating the safety of geological disposal.

- Section 3 summarises the sources of uncertainty in the radioactive waste management process and how programmes go about managing uncertainty. This report is focused on the subset of the management of uncertainty in the assessment of the performance of the disposal system.

- Section 4 discusses the PA process and how uncertainties are addressed within this process.

- Section 5 outlines how different types of uncertainty are categorised and treated in PA.

- Section 6 reviews the different calculational approaches that can be used in PA to handle the different types of uncertainty and to display the results.

- Section 7 reviews methods for the presentation and communication of uncertainty in PA results.

- Section 8 considers the approach to the treatment of uncertainty in regulations and regulatory guidance, and how regulators review the treatment of uncertainty in PAs.

- Section 9 discusses how uncertainties are taken into account in programme development and forward planning.

- Section 10 contains references.

Responses to the questionnaire circulated as part of the WP1.2 review are included with only relatively minor formatting changes in Appendix A.
2 Demonstrating Safety

2.1 Stages in Development of Waste Management Strategy

The state of development of a radioactive waste disposal programme will have a strong influence on the type of PA that is performed in that programme, and consequently how uncertainties in the assessments are treated and presented to stakeholders. Though there is some variation between countries, for the purposes of this report, the main stages in the development of a typical radioactive waste disposal programme can be described as:

1. Conceptual development, where principal design elements are established.
2. Feasibility studies aimed at establishing the technical viability and inherent safety of designs.
3. Site selection and characterisation.
4. Adoption/licensing by national and local government(s).
5. Construction.
6. Pilot operation/advanced operational testing.
7. Full-scale operation.

There is the potential for considerable overlap between stages - for example, site characterisation may proceed from the initial stages of conceptualisation through to construction and operation. Design will continue throughout the programme. Also, there will be a need for public consultation and regulatory dialogue at several points, possibly throughout all of the stages. A summary of the current status of programmes covered in PAMINA is given in Table 1 (adapted from [Galson and Khursheed 2007]).
Table 1: Status as of 2009 of programmes to develop geological disposal facilities (HLW = high-level waste, SF = spent fuel, ILW = intermediate-level waste, and LLW = low-level waste).

<table>
<thead>
<tr>
<th>Country</th>
<th>Waste type(s)</th>
<th>Site</th>
<th>Host rock(s) considered</th>
<th>Programme status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>HLW, SF</td>
<td>None</td>
<td>Clay</td>
<td>Feasibility studies.</td>
</tr>
<tr>
<td>Canada</td>
<td>ILW, LLW SF</td>
<td>Bruce site, Kincardine, Ontario None</td>
<td>Argillaceous limestone</td>
<td>Site characterisation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Undecided</td>
<td>Setting process for site selection.</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>SF</td>
<td>Six potential sites</td>
<td>Undecided</td>
<td>Site selection work has been subject to delays.</td>
</tr>
<tr>
<td>Finland</td>
<td>SF</td>
<td>Olkiluoto, municipality of Eurajoki</td>
<td>Crystalline rock</td>
<td>Detailed characterisation and construction.</td>
</tr>
<tr>
<td>France</td>
<td>HLW, SF, ILW</td>
<td>Bure</td>
<td>Clay</td>
<td>Feasibility study published – detailed site characterisation underway.</td>
</tr>
<tr>
<td>Germany</td>
<td>LLW, ILW</td>
<td>Morsleben</td>
<td>Salt</td>
<td>Closure.</td>
</tr>
<tr>
<td></td>
<td>LLW, ILW</td>
<td>Konrad</td>
<td>Limestone</td>
<td>Licensed. Under construction. Site characterisation.</td>
</tr>
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<td></td>
<td>HLW</td>
<td>Gorleben</td>
<td>Salt dome</td>
<td></td>
</tr>
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<td>Japan</td>
<td>HLW</td>
<td>None</td>
<td>Undecided</td>
<td>Feasibility studies.</td>
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<td>The Netherlands</td>
<td>HLW</td>
<td>None</td>
<td>Salt dome</td>
<td>Concept development.</td>
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<td></td>
<td></td>
<td></td>
<td>Clay</td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>SF, ILW</td>
<td>None</td>
<td>Crystalline rock/clay</td>
<td>Feasibility studies.</td>
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<tr>
<td>Sweden</td>
<td>SF</td>
<td>Forsmark, Osthammar</td>
<td>Crystalline rock</td>
<td>Site selection completed. License application being prepared.</td>
</tr>
<tr>
<td>Switzerland</td>
<td>SF, HLW, ILW</td>
<td>None</td>
<td>Clay preferred</td>
<td>Feasibility studies completed. Site selection to commence.</td>
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<tr>
<td></td>
<td>L/ILW</td>
<td></td>
<td>Undecided</td>
<td></td>
</tr>
<tr>
<td>United Kingdom</td>
<td>HLW, ILW, LLW</td>
<td>None</td>
<td>Undecided</td>
<td>Concept development. Stage 1 of site selection.</td>
</tr>
</tbody>
</table>
2.2 Assessing Safety

Disposal facilities are designed to ensure both operational safety and post-closure safety. In geological disposal facilities, operational safety is provided by means of engineered features and operational controls, and post-closure safety is provided by means of engineered and geological barriers. While monitoring and institutional control might continue after closure, facilities are designed to be passively safe post-closure [IAEA 2006a].

A radioactive waste disposal facility can be considered safe, from a technical point of view, if it meets the relevant safety standards specified by the responsible national regulator. Quantitative safety standards are discussed in Section 2.3 below, and there are also a range of qualitative standards such as use of multiple barriers and demonstration of optimisation.

The safety of a disposal facility is usually documented in a safety case (e.g., [NEA 2004a]; [IAEA 2006a]). Within the safety case, the performance of the facility against the quantitative safety standards is evaluated using a PA or, as it is termed in this context, a safety assessment. For assessment of the post-closure performance of the facility, the PA involves developing an understanding of how, and under what circumstances, radionuclides and chemotoxic substances might be released from the repository, how likely such releases are, and what the radiological or other consequences of such releases could be to humans and the environment. Importantly, it is necessary to understand how the geological characteristics of the site and the components of the design will evolve and function, and document the uncertainties associated with the assessment and their potential consequences. In light of the uncertainties over the long timescales being considered, a broad range of evidence and arguments must be included in the safety case / PA to complement and build confidence in the reliability of the results of the quantitative analyses [NEA 1999; 2004a]. This range of evidence is discussed further in Section 2.4.

2.3 Primary Performance Measures

The majority of regulatory regimes adopt dose to an individual member of a ‘critical group’ or a ‘potentially exposed group’ as a primary quantity for assessing the long-term radiological consequences of a geological disposal facility, most commonly through the imposition of an annual exposure limit on effective dose from all sources, and dose constraints that apply to individual sources. As doses are being calculated for hypothetical individuals in the far future, the calculations can ever only be illustrative in nature.

The dose limit for members of the public from all practices is usually set to the International Commission on Radiological Protection (ICRP)-recommended level of 1 mSv/yr, and the source-related constraint (e.g. for a single repository) is typically in the range 0.1 to 0.5 mSv/y. The use of a ‘critical group’ dose concept takes account of variability in a population with regard to habits that determine exposure, for example diet and occupancy rates within buildings or at defined locations, and
enables illustrative calculations to be made of potential doses received by hypothetical individuals that could comprise the most exposed part of a future population.

Annual ‘risk’ to an individual member of a potentially exposed group is also frequently used as a primary regulatory quantity. The use of risk has the advantage that it allows the probability of occurrence of unlikely events and processes to be explicitly accounted for in evaluating compliance. On the other hand, in practice it can prove extremely difficult to estimate probabilities of occurrence for unlikely events and processes. Like calculated individual doses, calculated individual risks in the far future are also only ever considered to be illustrative.

The quantity of ‘risk’ has a closer relationship to potential health impact than dose, in the sense that dose limits are derived from a back calculation from an assumed tolerable level of risk (typically that which would be considered negligible by most individuals). Therefore, the use of individual risk as a regulatory performance measure avoids making the regulations themselves dependent on the complex relationship between radiation dose and health impacts, which in the past has been subject to revision through changes in scientific advice. However, it places a burden on the safety case developer to remain aware of any changes in the dose-to-risk conversion factor and to calculate risks accordingly.

A different approach is used in regulations for the WIPP in the US, where the fundamental regulated quantity for long-term PA is the cumulative amount of radionuclides that can be released to the accessible environment over 10,000 years. Limits on cumulative releases were derived by the regulator based on back calculation from dose for a range of conceptual HLW repositories. This is akin to the total activity limits placed on radioactive discharges from conventional nuclear sites, but with a modification to deal with the extended time span of the release.

Because of the illustrative nature of dose and risk calculations, some countries have also considered establishing alternative primary performance measures. A range of alternative safety and performance indicators have been discussed in [IAEA 2003] and evaluated in the EC SPIN project [Becker *et al.* 2003] and in PAMINA WP3.4 [Becker *et al.* 2009c]. In discussions about the development of safety requirements in Germany, an approach based on demonstration of the confinement of radionuclides has been proposed. Most of the proposed indicators - namely the fraction of released amount of substance, the concentration of released U and Th, the contribution of released radionuclides to power density in groundwater, and the contribution to radiotoxicity flux in groundwater - are located in the vicinity of the so-called “isolating rock zone”, rather than in the accessible environment. The function of the isolating rock zone is, together with the engineered barriers, to ensure the confinement of the waste for a defined isolation period during normal evolution of the repository. As far as possible, indicators are relied upon that can be calculated based on modelling of system components that are relevant for safety and the evolution of which can be forecast over the assessment timeframe, rather than on largely hypothetical considerations of biosphere evolution and possible exposures to individual members of future human populations.
Following development of a conceptual dosimetric framework for wildlife and the environment by ICRP [ICRP 2003], and EC-funded research in this area [Larsson 2004], it is anticipated that dose to non-human biota will be included as a performance measure in some regulatory regimes. Recently formulated guidance in Canada [CNSC 2006] and the UK [EA and NIEA 2009] already incorporates such provisions.

2.4 Building Confidence

A claim that compliance has been demonstrated must be supported by evidence for the reliability of the analyses and the adequate treatment of uncertainty [NEA 2004a]. With regard to the PA calculations themselves, this can be approached through discussion of the:

- Management of uncertainty and adoption of a cautious or conservative approach where needed.

- Quality and reliability of the science and design work that underlies the PA, including the adequacy of the range of scenarios (calculations) considered, and the adequacy of quality of the models, computer codes and databases used to analyse them.

- Quality management requirements for performing the PA calculations.

- Peer review of the PA and comparison with similar studies / assessments.

There is also another aspect to building confidence in PAs, which is to refer to evidence for the robustness and reliability of the geological environment and the engineered barriers over prolonged periods (Table 2). This semi-quantitative evidence then supports the PA models that simulate the performance of the disposal system barriers over long timescales.
Table 2: Examples of the types of evidence that can be used to support arguments for the robustness and other favourable characteristics of a geological disposal facility [NEA 2004a].

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

The term “uncertainty” covers a broad range of concepts. Its dictionary definition is simply the condition or fact of not certainly knowing. Within the context of a PA, uncertainty can generally be considered to arise from imperfect knowledge of the disposal system and its evolution. This is exacerbated by the very long timescales over which PAs are run, the uncertainties about the future and how the system and its component will evolve over these timescales, the randomness or unpredictability of certain events, and the natural variability of geological media. Over and above these uncertainties, however, there are also uncertainties about the radioactive waste management programme itself, for example with regard to decisions that have yet to be made (e.g., siting, inventory, regulatory criteria, resources) and decisions that have been made but that might be changed in the future (e.g., those based on stakeholder value judgements or economic priorities that may change). Some of these programme uncertainties might be addressed within a PA through boundary conditions or alternative calculations, and some might be considered outside the scope of PA. The treatment of uncertainties included within a PA is the principal subject of this report. However, the overall approach to uncertainty management within radioactive waste management programmes is considered first here.

Example – Uncertainty Management
Under PAMINA WP1.1, [Marivoet et al. 2008] summarised the responses of radioactive waste management organisations regarding uncertainty management. Management features include:

- Stepwise development process of the disposal programme: at each step the uncertainties are identified, analysed and ranked: priorities are defined to systematically reduce and/or address remaining uncertainties.
- Openness and participation of multiple stakeholders in the development process. Independence of the Regulatory Authority.
- Long timescales of the project, from the initial planning phase to the closure of the repository, which provides opportunity for (i) multiple stages for re-assessment of the acceptability of the repository and (ii) the involvement of different individuals.
- Robust repository concept (i.e. low sensitivity to uncertainties), for example the use of sound principles, the multi-barrier / multi-function system, passive safety.
- Flexibility of the repository development programme: (i) to accommodate changes in the amounts and quantities of waste, (ii) to deal with new site data, and (iii) to take decisions (in particular on technological issues) when sufficient knowledge is available, keeping alternative options available until a decision is needed.
- Intrinsically sound repository components (e.g. use of reliable materials and technologies for engineered barriers, excellence of site characteristics).
- Specific design provisions to avoid or mitigate certain sources of uncertainty, and margins to counter their effects (e.g. avoiding problematic materials, durable containers, limiting temperatures, compartmentalisation of the repository into zones to prevent interactions.)
Uncertainties due to lack of knowledge can be reduced by research investment, e.g., site characterisation, design studies, fabrication and other demonstration tests, and experiments both in the laboratory and in underground test facilities. Alternatively, uncertainties can be avoided or their impact reduced through siting, and/or design, and/or construction investment. As a programme matures, studies will increasingly focus on key safety-relevant uncertainties and the specific data and measurements needed to resolve these. Needs-driven forward programmes based on uncertainty analyses are discussed further in Section 9. In some cases, uncertainty can be managed by seeking multiple lines of evidence for particular assessment assumptions or parameters, including, for example, evidence from natural analogues to support the longevity of engineered materials. In other cases, it may be preferable to avoid the sources of uncertainty or mitigate their effects by modifications to the location or design of the repository. For instance, if there are important uncertainties over the corrosion processes affecting a waste container, then the material or thickness specification might be changed.

In addition to the PA uncertainty analysis and links to the forward programme, uncertainties in the broader sense can be managed in radioactive waste management programmes using the standard project management good practice of maintaining a project risk register. Key uncertainties can be formulated in terms of risks and associated likelihoods and, where appropriate, this can be linked to PA calculations, e.g., inclusion of a new waste stream in a facility creates an associated long-term radiological impact. Mitigation measures can then be developed to reduce potentially significant risks.

Finally, one objective of radioactive waste management programmes, on the basis of ICRP recommendations, is to demonstrate that the programme solution is optimised. In terms of decision-making theory or policy-making, the process of optimisation can be thought of as (after [Morgan and Henrion 1990]):

\[
\begin{align*}
\text{MEU} &= \max \{ f(X, M, V, MEU) \} \\
\text{MEU} &= \max \{ f(X, M, V') \}
\end{align*}
\]

Where \( f \) is a functional model or relationship that relates the inputs to the outputs, \( X \) represents the input variables, \( M \) represents the model dimension variables, \( V \) shows the value variables, i.e., those variables that reflect preferences such as the degree of risk aversion, \( MEU \) is the maximised expected utility, e.g., risk, that is achieved as an output when the decision variables, \( D \), are optimised. In the optimisation process, the model \( f \) is used to determine the decision \( D \) determined by variables \( X' \) or values \( V' \) over the range of \( X' \) and \( V' \) and, thereby, to select the optimum decision. In terms of uncertainties, \( X \) represents quantities whose uncertainty might be represented by a probability distribution and is related to a factor such as statistical variation, subjective judgement, variability, randomness, approximation, or ambiguity (disagreement between experts). Assuming that the model dimensions and value judgements can be specified for an assessment, these inputs might be considered certain. However, the functional model itself is also subject to uncertainty. As will be seen in the following sections, uncertainty in models (\( f \)) and parameters (\( X \)) are the
cornerstones of the PA uncertainty analyses, with parameter uncertainty being split between scenarios and parameters depending on the nature and source of the uncertainty.
4 The PA Process

The development of a PA involves a series of iterative steps. Figure 1 illustrates a generic PA process developed by the IAEA project for Improving long-term Safety Assessment Methodologies for near-surface radioactive waste disposal facilities (ISAM) [IAEA 2004]. Each waste management programme, be it for geological disposal or near-surface disposal, tends to adopt its own PA process – see example box. However, each national-specific process is built around similar components (albeit sometimes varying in terminology) and, for the purposes of this report, these components are illustrated in Figure 1.

![PA Process Diagram](image)

**Figure 1:** The IAEA ISAM PA process [IAEA 2004]. See Section 4.3 of Part 5 of [Capouet et al. 2009] from PAMINA WP1.1 for discussion of this diagram. A key feature missing from this diagram is the process of iterative feedback between the safety assessment and research and design studies.
Examples – PA methodology

For examples of PA process diagrams and the associated treatment of uncertainty in recent PAs, see Figure 2.1 of [SKB 2006a], Figure 3.7-2 of [NAGRA 2002a], Block Diagram 1-1 of [ANDRA 2005], and Section 4.3 of Part 5 of [Capouet et al. 2009]

With regard to the treatment of uncertainty, the following steps in the generic PA process are relevant:

- **Assessment context.** All PAs start with definition of objectives, setting of scope (i.e., what is in and what is out of the assessment), and specification of boundary conditions (e.g., inventories to be considered, timescales). At this point, the overall philosophy to the treatment of uncertainty might be set out. For example, a decision might be taken to adopt cautious or conservative assumptions throughout, rather than a more realistic approach – see Section 5.6. The relevant regulations (see Section 8) and the intended audiences and the consequent style of presentation (see Section 7) will also be identified at this point.

- **System description.** All PAs will include some sort of system description, describing the system to be modelled as it is now or when built and how it will evolve in the future. Uncertainties in the characteristics of the system and uncertainties in how it will evolve should be identified and, possibly, prioritised.

- **Scenario development.** This term is used here as a catch-all in the PA process where the nature of the main calculation cases to be analysed is determined. It is at this point that uncertainties in the assessment are generally categorised (see Section 5.1). This might be done in a number of ways, as discussed in Section 5, including a formal analysis of features, events and processes (FEPs) that are potentially relevant to the disposal system, expert elicitation of a list of uncertainties, or through a fault analysis.

- **Model development.** This involves the formulation of conceptual models and the approximation of these models in terms of implementation as equations and parameter values in computer codes. Therefore, model development introduces additional uncertainties to the PA concerning the nature of the system and its modelling representation.

- **Run analyses.** Within the framework of conducting the PA calculations and managing the runs, Section 6 of this report discusses the analytical methods for conducting uncertainty and sensitivity analyses.

- **Interpret results.** PA results may be used for a wide variety of purposes, such as comparison to standards, analysis of system and sub-system performance, and optimisation. Section 7 of this report discusses the communication of results and their associated uncertainty, and Sections 8 and 9 discuss the use of PA results in decision-making and planning of forward programmes.
5 Treatment of Uncertainty in PA

This section reviews how different types of uncertainties are categorised in PA (Sections 5.1 and 5.2) and treated through the specification of scenarios for calculation, alternative models and modelling assumptions, and parameter values (Sections 5.3 to 5.5). The merits of adopting a cautious or conservative approach to deal with uncertainty are discussed in Section 5.6, and methods for building confidence in the PA and its treatment of uncertainty are reviewed in Section 5.7.

5.1 Categorisation of Uncertainties Considered in PA

There is a high level of consensus on both how uncertainties considered in PA should be classified and the nature of uncertainties, although this is masked by variations in terminology and differences in how uncertainties are treated in programmes. Uncertainties can be classified as follows:

1. Uncertainties arising from an incomplete knowledge or lack of understanding of the behaviour of engineered systems, physical processes, site characteristics and their representation using simplified models and computer codes. This type of uncertainty is often called “model” uncertainty. It includes uncertainties that arise from the modelling process, including assumptions associated with the reduction of complex “process” models to simplified or stylised conceptual models for PA purposes, assumptions associated with the representation of conceptual models in mathematical form, and the inexact implementation of mathematical models in numerical form and in computer codes.

2. Uncertainties associated with the values of the parameters that are used in the implemented models. They are variously termed “parameter”, or “data” uncertainties. They arise mainly from the following sources:

   (a) The parameter values cannot be determined exactly because:

      i. The parameter values cannot be measured accurately;

      ii. The model requires parameter values applicable to scales for which values are not measurable, and the values have thus to be transferred, averaged or “upscaled” from values available for a different measurement scale (e.g., the use of laboratory-derived measurements to estimate in situ values); and/or

      iii. The parameter is a simplified representation of a more complex phenomenon, which is not fully understood and/or characterised, or is too difficult to model within a PA (e.g., bulk sorption is a simplified representation of many processes).

   (b) The models use single (or spatially averaged) values for parameters, derived from measurements at discrete locations, whereas in reality
there is continuous variation in parameter values over space - as well as over time (variability).

3. Uncertainties associated with significant changes that may occur within the engineered systems, physical processes and site over time. These are often referred to as “scenario” or “system” uncertainties.

All three classes of uncertainty are related to each other, and particular uncertainties can be handled in different ways, such that they might be dealt with in one class or another for any single iteration of a PA/safety case, depending on programmatic decisions (e.g., on how to best communicate results) and practical limitations (e.g., on funding or timescales). For example, uncertainties associated with future climate change are dealt with in some PAs as a “scenario” uncertainty, via the establishment of separate scenarios for different possible climate futures, and in other PAs as a “parameter” uncertainty within a single scenario, via theoretical consideration of possible climate variability and the establishment of appropriate probability distribution functions (PDFs) for groundwater flow models and radionuclide transfer factors in biosphere models.

The classification system for uncertainties given above essentially arises from the way PA is implemented, and says little about the nature of the uncertainties. With respect to nature, a useful distinction can be made between epistemic and aleatory uncertainties. Epistemic uncertainties are knowledge-based and, therefore, reducible by nature. Aleatory uncertainties, on the other hand, are random in nature and are irreducible. These two types of uncertainties have also been termed in some studies as subjective and stochastic, respectively, although these terms are not in frequent use.

All three classes of uncertainty contain elements that are epistemic and aleatory, although it may be generally true that “scenario” uncertainties contain a larger element of aleatory uncertainty than the other two groups. To take an example, typically “parameter” uncertainties may arise for the following reasons, as noted above:

- The parameter values have not been determined exactly. This type of uncertainty is largely epistemic in quality, and can be reduced with further effort.
- The models use single values for parameters, whereas in reality there is variation in parameter values over space and time. This type of uncertainty is partly aleatory in quality and cannot be reduced by further effort.

This system of describing the classification and nature of uncertainties is summarised in Figure 2.

An issue of interest is how to best explain and present the increasing level of uncertainty in a PA with time. Some assessments are now being conducted and presented using a “timeframes” approach, whereby safety functions are assigned to different parts (barriers) of the disposal system, and these barriers are expected to provide a certain level of performance over a certain period.
5.2 Example of different types of uncertainties

The following idealised example illustrates the three classes of uncertainty that occur in PA. Consider a radionuclide flux from a repository borne by groundwater through fractured rock, such as would occur if a repository were situated in crystalline bedrock. PA receptors are situated at ground level above the repository, and a very simple PA model represents transport of radionuclides by vertical advection through a homogenous rock layer to a well from which water is drunk by a member of the public. Radionuclide transport from the repository to the well is described as a single, fixed, upward flow rate for groundwater $f_1$ (y$^{-1}$m$^{-2}$) and a single, fixed, downward flow rate for infiltration $f_2$ (y$^{-1}$m$^{-2}$). Retardation of radionuclide species is modelled using a bulk sorption coefficient, $K_d$, for each radionuclide species.
Considering the parameter $K_d$, there are uncertainties that arise from:

1. Representation of the fractured multilayer rock medium by a homogenous, single layer.
2. Representation of complex, non-linear, reactive chemical processes, which may not be fully understood, by the simple linear sorption model represented by the bulk sorption coefficient $K_d$.
3. Assumptions about the chemical forms of the radionuclide species.
4. Time-dependent changes that affect groundwater chemistry.

In this case, given the choice of $K_d$ to represent uncertainty, these could all be considered examples of “parameter” uncertainty. The difficulties in quantifying these uncertainties in terms of a parameter range are compounded by the fact that, as a parameter in a highly stylised, simplified model, $K_d$ cannot be directly mapped to a single measurable quantity.

The relationship between “parameter” and “model” uncertainties is illustrated if the very simple model is replaced by a more complex model that simulates transport through a series of rock fractures. In this model, sorption occurs at the fracture surfaces, leading to a change in the way that sorption is specified: the $K_d$ parameter, if retained, would have a modified range in the new formulation.

The characteristics of “model” uncertainties are illustrated by representing the problem with increasing levels of detail such as fracture structure and connectivity, and alternative formulations for describing physical processes such as flow through fractures, diffusion and reactive chemistry. For the purpose of assessing the potential impact of “model” uncertainties, several stylised concepts may be developed that represent the range of model conceptualisations in terms of PA outcomes.

“Scenario” uncertainties are illustrated by considering the occurrence of events or gradual changes over time that may significantly influence outcomes at the receptor level. A large number of these can be identified, but two simple cases would be:

1. Changing climate may significantly change groundwater flow pathways and properties over time, necessitating fundamental changes to the groundwater flow model or the introduction of new flow parameters.
2. Future human activity, from say drilling into the host rock, may accelerate transport of the radionuclides to surface layers, requiring specific models and new parameters to be introduced.

5.3 Parameter Uncertainty

Uncertainties associated with model parameters can be treated conveniently within most computational schemes. All of the programmes included in Appendix A contain
measures to treat parameter uncertainties in the formal quantitative PA. Common approaches to treating parameter uncertainty are:

1. Setting PDFs for parameters, which are sampled during the course of a probabilistic assessment.

2. Repeat deterministic calculations where individual parameter values are varied across a range of likely or possible values, including deterministic calculations using values representing the best understanding available ("best estimate") in order to better understand the system, e.g. with regard to sensitivities.

3. Deterministic calculations where deliberately pessimistic values of parameters are taken, producing a “conservative” estimate of the value of receptor quantities in order to demonstrate compliance with limits.

Surveying the practices in Appendix A, a simplistic summary of the current situation might place programmes in two camps: those that rely primarily on the probabilistic approach described in (1) and those that primarily use deterministic approaches (2) and (3). In the first camp, programmes in the US are notable champions. However, this is, increasingly, an over-simplified summary.

While a probabilistic approach may be preferred, it is often supplemented by deterministic calculations (e.g., in Germany, the Netherlands, Spain, and the UK). The reasons for the preference is generally the ease with which probabilistic calculations are done and completeness in terms of describing the whole system from source to receptor. The programme in Sweden uses probabilistic calculations to supplement deterministic ones, mostly for the more complete treatment of parameter uncertainty that the probabilistic calculations afford and because of the new risk-based regulation in Sweden. Programmes in Belgium, Finland, France, Japan and Switzerland favour largely deterministic approaches, but probabilistic approaches have been or are being considered in these countries to supplement the deterministic calculations. There seems to be a view that a deterministic approach has advantages where there are very large uncertainties in the PA, and where the use of deterministic approaches allows a more transparent treatment of uncertainty. As discussed in Section 8, regulation can play an important role in determining which approaches to PA are adopted for compliance calculations.

5.3.1 Probabilistic approach to treating parameter uncertainties

Whether a probabilistic approach is used for a small component of a PA, or the whole system, many of the issues with respect to treating uncertainty are common. The total system approach is supported by the increasing availability of user-friendly software (e.g., GoldSim) that allows the near field, far field and biosphere to be modelled in a single implementation of the whole system, and the performance of many calculations in a short time. The greater part of the effort is taken up with determining PDFs for uncertain parameters. Performing the calculations themselves is relatively quick with modern software and is becoming quicker still through the continuing increase in computing power.
The following issues are associated with this approach:

- It is not necessarily straightforward to derive meaningful PDFs from available data for uncertain parameters, and inappropriate choices could bias the results.

- Possible couplings (correlations) between parameter values need to be identified and incorporated into sampling schemes.

- Care is needed to ensure sufficient sampling of parameter space for PDFs that have long tails. However, balanced against this issue is that only a probabilistic approach explores the full parameter space.

- Care is needed to identify and avoid “risk dilution”, whereby an increase in parameter uncertainty results in a decrease in calculated mean annual individual dose or risk. This effect can be identified by comparing the peak of the calculated mean with the mean of the individual peaks from each model run.

- There may be a lack of transparency in implementing a single model that aggregates all outcomes.

At worst, the probabilistic approach can foster a false sense of confidence that all uncertainties have been included in the assessment, and may lead to focus excessively on total system inputs and outputs and so detract from understanding the underpinning causes of the behaviour of the repository system.

**Example – Probabilistic assessment and treatment of parameter uncertainty**

PA calculations for the WIPP project involve using the results from a set of deterministic, process-level models to construct response surfaces that are subsequently used by a probabilistic, process-level code (CCDFGF) to estimate potential releases [USDOE 1996]. Uncertainty in the process-level models is considered epistemic and is associated with the lack of knowledge about the precise values of the model parameters. This uncertainty is represented by sampling 300 sets of parameter values (using Latin Hypercube Sampling) for the parameters and running the models for each set. PDFs for each parameter are derived from data, where available, and/or by using subjective methodologies. The level of information on which to base the assignment of the distributions of possible values varies greatly among the parameters. The level of knowledge is an important consideration in assigning both the shape and the variance of a distribution. When knowledge about parameters is small and these parameters have been identified by the regulator or modellers as potentially significant to the performance of the disposal system, a conservative approach is sometimes taken. Bounding assumptions have been made in these instances.

As noted above, the quantification of parameter uncertainties to feed into a probabilistic assessment is not a simple task, and protocols for systematically deriving PDFs have not been established internationally.
Example – Derivation of PDFs for parameter uncertainties

Under PAMINA WP2.2A, [Becker et al. 2009b] propose a three-step protocol for assessing the uncertainty of parameters on the basis of available data:

1. Identification of the parameters that need to be considered.
2. Selection of a suitable knowledge base to be used for deriving the PDFs.
3. Derivation of the PDF for each parameter to be considered following the general scheme set out in [Becker et al. 2009b].

Quality levels are assigned to data sets according to whether they are based on measurements (highest level), models, analogies, or plausibility (lowest level). The combination of data sets of different levels to derive PDFs leads to one of six possible “cases” with associated quality that impact on the chosen PDF-shape (see figure).
Example – Probability distributions
Description of the various types of distributions that can be applied to characterise uncertainties can be found in many statistical textbooks (e.g., Chapter 5 of [Morgan and Henrion 1990]). An example of the implementation of the distributions in a PA-type code is provided in Appendix B of the GoldSim manual [GTG 2007].

Work has been conducted for the Canadian SF disposal programme on identifying key parameters and defining the shapes of PDFs that can be used in probabilistic assessment, and a formal method has been developed for performing sensitivity studies using Iterated Fractional Factorial Design (IFFD) [Melnyk et al. 2006]. This showed that the choice of PDF-shapes can have a significant impact on calculated assessment endpoints; the mean calculated dose rate is a factor of ten higher if the original PDFs are replaced with uniform distributions over the same value ranges.

The importance of finding PDF-shapes that are appropriate to the level of knowledge for parameters is widely appreciated, and has been noted in the responses from several respondents in Appendix A. For example, the response from ONDRAF/NIRAS and SCK/CEN (Belgium) indicates that, owing to a lack of sufficient empirical data, they have described most parameter uncertainties using a log-uniform distribution, for which a best estimate value and an uncertainty factor are estimated.

Example – Determining the sensitivity of PA to different PDF shapes
Under PAMINA WP2.2A, [Destin and Smidts 2009] evaluated the sensitivity of maximum flux and time of maximum flux to PDF-shapes for molecular diffusion and porosity in Boom Clay, considering the clay as a purely diffusive medium (reference scenario) and inclusion of advection (altered scenario). Where simplified assessment models can be applied, the impact of the PDF-shape on the outputs seems limited. In such cases, the emphasis should be placed on thorough justification of each assumption used to simplify the model. However, where more complicated models are needed, the treatment of uncertainty for multiple parameters for which the PDFs are not well known is not straightforward. The sensitivity of the results to the PDF-shape seems higher, and it would be preferable either to rely on more conservative models (integrating the parameter uncertainty into the conservative approach) or to develop a multiple parameter uncertainty assessment with only well-known PDFs. [Destin and Smidts 2009] highlight that demonstrating a conservative assumption for a PDF-shape is not possible in general without a dedicated study and detailed justifications. An arbitrary choice of PDF-shape without any guarantee of conservatism is considered to be unacceptable.

In Sweden, strategies for treating parameter uncertainties are set out in the Data Report for SR-Can [SKB 2006b]. For each of 21 groups of parameters associated with separate parts of the PA, such as ‘Thermal Properties’ or ‘Fracture Data’, a protocol is followed describing:

2. Impact on assessment results.
4. Conditions for which data are supplied.
5. Conceptual uncertainties.
6. Data uncertainties, spatial and temporal variation.
7. Correlations.
8. Quantification.

Where subjective judgements are made, it is stated whether they were made by the SR-Can team or ‘experts’, in which case the names of the experts accompany summaries of their judgments. This systematic approach followed by SKB is useful because it clearly identifies the data available for each parameter and how it has been used in the calculations.

Expert judgement, whether by individuals or panels, plays a role in determining PDFs for parameters in programmes that employ probabilistic assessments (e.g., the Netherlands, Sweden, the UK, and the US). The formal elicitation of expert judgements, particularly in a group setting, can be a labour-intensive effort, and is usually reserved for important parameters whose ranges cannot be determined easily from empirical data. The experience of previous EC-funded research on the use of expert judgement panels is that the methodology employed to process the judgements from individual panel members into joint PDFs is important to the success of the exercise [COSYMA 2000]. In Appendix A, the work in the UK has been based on a group expert judgement methodology that leads to a consensus PDF agreed between the experts present [Nirex 2006], while the DOE-YMP employs a maximum entropy approach to produce joint PDFs.

Example – Use of expert elicitation to derive PDFs

Under PAMINA WP2.2A, a review of the use of expert elicitation to derive PDFs is provided in [Bolado et al. 2009a] and a protocol aimed at determining PDFs for radionuclide solubilities is trialled in [Bolado et al. 2009b]. The protocol involved the following steps:
1. Selection of the project team.
2. Preparation of supporting material and definition of the questions to be studied.
3. Selection of experts.
4. Training sessions.
5. Refinement of the questions to be studied.
6. First individual work period.
7. Presentation of individual approaches adopted by the experts.
8. Second individual work period.
9. Elicitation sessions.
10. Analysis and aggregation of results.
11. Review.
12. Documentation.

Section 7.3 of [Becker et al. 2009b] summarises the key lessons from the trial application of the protocol.
In PAMINA WP2.2A, [Vetešník 2009] distinguished between two treatments of parameter uncertainty, one in which the available information on data uncertainty enables the identification of a PDF, i.e. the frequentist interpretation of probability is applicable, and one in which only a sparse set of empirical data is available, i.e., parameter uncertainty can be expressed only by subjective measures of uncertainty. For the subjective branch, [Vetešník 2009] modelled uncertainty with the use of fuzzy set theory representing an uncertain input parameter mathematically as a fuzzy real number. This approach is discussed further in Section 6.2.

There is a close relationship between model uncertainty (see Section 5.4) and parameter uncertainty. This can sometimes be exploited to treat conceptual model uncertainties through a widening of the ranges for the PDFs of some parameters.

Example – Use of parameter uncertainty ranges to treat model uncertainty
In Appendix A, NRG (the Netherlands), notes:
“...the plastic behaviour of rock salt was modelled by an analytical model that was tuned by measurements and detailed FE calculations. This was necessary because measurements are only limited available and FE calculations are only possible idealised geometries. However, it was possible to cover the model uncertainty by using suitable bandwidths for the model parameters [EVEREST 1996] “.

The limitations of formal probabilistic assessment methods when dealing with some types of uncertainties were explored in the EC-funded MUNVAR project [Robinson and Cooper 1995]. This reviewed the then state-of-the-art with respect to modelling with uncertainty and variability in all areas of technology that might be exploited for PA of radioactive waste disposal programmes. The conclusion was that methods used in advanced repository PA programmes, even at that time, were more highly developed than those in other fields. MUNVAR also identified several alternatives to traditional probabilistic assessment, and advocated further investigation of them. For example, the use of evidence-based systems has been taken up in more recent work, where it has been shown to offer a viable alternative to conventional methods for characterising epistemic uncertainty [Helton 2006]. Although further review work was done on this topic within PAMINA Task 2.1C [Vetešník 2008], the review did not identify situations in which the traditional probabilistic assessment framework in routine use is unworkable, or where alternative subjective methods would definitely be more suitable.

5.3.2 Deterministic approach to treating parameter uncertainties

While a deterministic approach might seem simpler than the probabilistic one, in practice the deterministic approach is often more labour intensive and time consuming. Typically, deterministic calculations are performed running several codes in series, whereas in probabilistic approaches the whole system is implemented in a single model file. As a consequence, deterministic calculations require more effort in performing individual calculations, storing and organising data from sets of calculations, and feeding the output from models from one part of the assessment into
another. These processes are not only labour intensive, they are also more prone to human error.

In programmes that primarily use deterministic models for PA, parameter uncertainties are treated by varying parameter values over a set of calculations performed for each fixed scenario. This can be done in a number of ways:

- By altering the value of a single parameter over its likely or possible range, thereby revealing the range of consequences due to uncertainties in individual parameter values.
- By using a number of different sets of parameter values.
- By employing uniformly conservative parameter values in a model run.

An example of how the use of different sets of parameter values is treated in a deterministic calculation is given by [ANDRA 2005], where the parameter set used in a calculation is drawn from one of the following four types:

- A set of “phenomenological” values is considered to offer the best match between the model’s results and the measured results. This choice must be supported by detailed arguments which may include a representative number of measurements, a physical reasoning that demonstrates that the chosen value is the most representative based on reliable data, or a judgement by recognised experts unambiguously designating it as the most appropriate value for the study context.

- A set of “conservative” values is chosen among those generated by the studies and measurements which give a calculated impact in a range of high values, all other parameters being equal. In the simplest case, where the impact increases (or conversely, decreases) as the value of the parameter increases, a value in the highest (or lowest) range of available values. “Conservative” values cannot be defined if the variations in impact are not monotonic with changes in the parameter.

- A set of “pessimistic” values is one that is not based on a state of phenomenological understanding, but is chosen by convention as definitely yielding an impact greater than the impact that would be calculated using possible values. Such values can represent physical limits. A pessimistic value can also be equal to the conservative value plus (or minus, where applicable) an appropriate safety factor that places it significantly beyond the range of measured values. A value cannot be described as “pessimistic” if the variation in impact in response to a variation in a parameter cannot be characterised.

- In order to explore the possible parameter variation ranges, one or more so-called “alternative” values can be suggested as a means of investigating the effect of contrasting values.
A similar approach to parameter uncertainty is used in Switzerland, albeit with slightly different terminology. In Project Opalinus Clay [NAGRA 2002a; 2002b], a “reference” set of parameter values was established for each combination of scenarios and conceptual models (Figure 3), along with several “alternative” sets. Within each scenario group, sub-groups of cases addressed alternative possibilities arising from conceptual model uncertainties. Individual cases within each subgroup addressed alternative possibilities arising from parameter uncertainties.

Figure 3: An approach to quantifying parameter, conceptual model, and scenario uncertainties for deterministic calculations (Project Opalinus Clay, [NAGRA 2002a]).

One potential problem associated with this approach is the large number of separate deterministic cases that might need to be implemented, evaluated and presented. Making a large number of calculations within a deterministic assessment framework would be potentially time consuming, and post-processing all of the results in order to obtain meaningful conclusions about the relevance of uncertainty may not be a straightforward process.

**Example – Use of deterministic calculations to evaluate parameter uncertainty**

Under PAMINA WP2.2A, [Nordman 2009] performed a deterministic uncertainty analysis exercise based on the KBS-3 disposal concept. The premise was that in the TILA-99 safety assessment there are about 100 calculation cases with different parameter values, but between several cases there are only small differences in the calculated release rates of radionuclides. [Nordman 2009] evaluated the importance of the parameters and the effect of their uncertainty in deterministic calculations. Several parameters were varied without regarding probabilities. Different parameters were found to be important for different radionuclides, showing how valuable information about the functioning of the system can be derived from deterministic parameter variations.
5.3.3 Bounding case approach to treating parameter uncertainties

This approach does not attempt to quantify the most likely state of the whole system, but rather attempts to focus on extreme conditions that would threaten compliance with regulatory standards. There are transparency issues involved with this approach: the consistent use of such models obscures the most likely outcomes and can give the impression that systems are less safe than they really are, resulting in unnecessary over-engineering, or rejection of adequate proposals.

In Finland, parameter uncertainty is primarily analysed by defining bounding analyses and sensitivity cases. In selecting the parameter values from databases (e.g. instant release fractions, solubility), POSIVA uses best estimate and conservative values. However, for certain important parameters in the biosphere assessment, a probabilistic approach is also used if appropriate well-established PDFs can be derived. For radionuclide transport of multiple radionuclides through several connected ecosystems, conservative assumptions are adopted.

5.4 Model Uncertainty

In the context of PA, a model is an analytical representation of a real system and the ways in which phenomena occur within that system [IAEA 2007]. Models are used to assess the behaviour of the real system under specified conditions. Models can be further classified hierarchically as:

- Conceptual - a set of qualitative assumptions used to describe a system or part thereof.

- Mathematical - a set of mathematical equations designed to represent a conceptual model. This can often be further divided into “mathematical models” that are the equations that describe the conceptual model, and “numerical models” that solve these equations.

- Computational - a calculational tool that implements a mathematical model (usually the numerical modelling part of the mathematical model).

Models can be considered at different levels of detail and different degrees of aggregation. For practical purposes, a PA can be considered as typically consisting of one or more linked sequences of models, which together describe the evolution of the repository over time. For example, a simple PA “model” may consist of three component models: estimation of water flow through the geologic media; degradation and mobilisation of radionuclides from the emplaced materials; and transport of mobilised radionuclides through the geologic media and the biosphere.

Sources of model uncertainty can be split broadly into two categories:

1. Incomplete knowledge or lack of understanding of the behaviour of the system, as well as engineered systems, physical processes, or site characteristics.
2. Reduction of knowledge about the real system when developing conceptual models for PA purposes, the representation of conceptual models in mathematical form, and the inexact implementation of mathematical models in numerical form and in computer codes, as discussed in more detail below.

- Conceptual model assumptions are those assumptions made during development of a conceptual model that reflect choices made in reducing the knowledge of the real system to a conceptual model. For example, a conceptual model for radionuclide transport in a fractured geologic media may assume that dissolved radionuclides may advect through the rock matrix (a dual-permeability approach) or may assume such transport is negligible (a dual-porosity approach).

- Mathematical model assumptions are those assumptions made during development of a mathematical model that represents a conceptual model. For example, a mathematical model describing radionuclide transport may be developed for one-dimensional, two-dimensional or three-dimensional geometries.

- Computational model assumptions are those assumptions made during implementation of a mathematical model into a calculational tool. For example, solution of equations describing radionuclide transport may be carried out for numerical grids of differing resolution.

A modelling assumption is a decision or judgment made during development of a model. Model uncertainty is reflected where assumptions, approximations or choices are applied during model development and application for which reasonable alternative assumptions may exist [Hansen 2009]. Not all assumptions contribute to model uncertainty; model uncertainty arises where reasonable alternative assumptions exist. A reasonable alternative assumption is one that has broad acceptance in the technical community and for which the technical basis is as sound as that of the assumption being made. An assumption related to model uncertainty is one that is made with the knowledge that at least one reasonable alternative assumption exists. It is further useful to distinguish assumptions related to model uncertainty into two subsets, namely, assumptions related to model structure and assumptions related to scope or level of detail in the model.

An assumption related to model structure primarily involves a choice in the conceptual or mathematical representation of physical processes or features, for example representing transport of a radionuclide by a simple linear sorption model. By contrast, an assumption related to scope or level of detail primarily involves a choice in the level of detail implemented in the mathematical and computational model, such as the extent of the mathematical model’s domain, the computational grid spacing or the precision of numerical algorithms.

Model uncertainty can be introduced at all levels of the modelling hierarchy, from formation of conceptual models, translation of conceptual models to mathematical models, and during implementation of a mathematical model into a computational model. Conceptual model uncertainties are perhaps the most difficult to quantify and
are least well covered in the programmes reviewed in [Galson and Khursheed 2007] – see Appendix A. The following focuses on conceptual model uncertainty. Treatment of model structure issues in terms of spatial variability and upscaling is discussed in Section 6.3. There are long-standing tools available to treat uncertainty in mathematical models and computer codes (e.g., verification, benchmarking exercises, QA). Verification of computational models involves demonstrating that the models accurately compute the quantities described by the associated mathematical models. Sufficient testing should be conducted to establish a degree of confidence that computational tools are accurate. Model precision and stability is demonstrated by showing that model results are not significantly affected by the numerical methods employed in the computation model. For example, these activities may involve testing for convergence of numerical algorithms such as differential equation solvers, performing spatial or temporal grid refinement studies, or demonstrating stability of results computed with sampling-based methods.

[Hansen 2009] proposes a step-wise method for formally identifying and characterising model uncertainty. Step 1 consists of cataloguing the sources for model uncertainty, which are the assumptions made during development of the PA models. Step 2 involves identifying those assumptions for which reasonable alternatives exist, as well as those model uncertainties which have been mitigated (for practical reasons) by use of conservatisms. In Step 3, the assumptions are characterised to identify those which are key, that is, those assumptions with potential to significantly affect the magnitude of performance metrics, the uncertainty in the metrics, or the judgments about the safety of the repository. Step 3 constitutes a screening process and the assessment of the significance of a model or modelling assumption might be based on previous PA analyses, scoping calculations, or evaluation of more or less conservative approaches.

Example – Identification of modelling assumptions in PA
An illustration of cataloguing modelling assumptions can be found in Appendix MASS of the WIPP Compliance Certification Authorisation [USDOE 1996]. Table 6.8-2 of [NAGRA 2002a] links alternative conceptual models to calculation cases in the PA.

Uncertainty and associated confidence in conceptual models can be handled in a variety of ways, both quantitative and qualitative. Quantitative approaches are considered first below, divided according to deterministic or probabilistic assessment methodologies.

Deterministic approaches to PA offer a simple and transparent approach to treating conceptual model uncertainties, since they consist of a large number of self-contained calculations based on separate models for each part of the PA. In this situation it is relatively easy to change a submodel for a particular part of the PA and to identify the impact on assessment endpoints, in the manner suggested by the scheme for treating uncertainties employed by Nagra in Project Opalinus Clay (Figure 3 – see above example).
Example – Distinguishing between alternative conceptual models

[NAGRA 2002b] considers two alternative models for the dissolution of the fuel matrix. In the reference conceptualisation, the rate of dissolution of the SF matrix is assumed to be controlled by the generation of radiolytic oxidants. In the alternative “solubility limited dissolution” conceptualisation, reducing conditions are assumed to prevail at the surface of the SF matrix, irrespective of the generation of radiolytic oxidants. This alternative conceptualisation results in a fractional fuel dissolution rate that is approximately two orders of magnitude lower over the time interval $10^4$ - $10^6$ years post-closure.

In PAMINA WP2.2B, [Luukkonen and Nordman 2008] compare two conceptual approaches for modelling the retardation of radionuclides during transport: an empirical approach based on distribution coefficients, and a mechanistic approach using a coupled reactive transport model. They investigated transport of uranium through a bentonite backfill, and the two modelling approaches yielded quite different results. The distribution coefficient approach tended to estimate earlier breakthrough times, but the mechanistic approach could result in greater total mass transport over sufficiently long periods.

Alternative deterministic calculations can be used for screening or for deciding how to model a process in the PA. Whether differences between modelling approaches constitute a key model uncertainty depends on the role that the model and its outputs play in the system-level PA.

Example – Distinguishing between representations of a model

In PAMINA WP4.1, [Hart 2009] used several different models to analyse the potential effects on radionuclide transport of buoyancy-driven flow in a hypothetical salt repository. The analysis indicates that buoyancy-driven flow is suppressed when advective flow rate is sufficiently high; however, when these conditions are not met, buoyancy-driven flow may enhance radionuclide transport. These results indicate conditions under which the process of buoyancy-driven flow may need to be part of the conceptual models for flow and transport.

In PAMINA WP2.2B, [Norris 2008] investigated the impact of uncertainties regarding gas migration on repository performance, for both “generic” fractured crystalline rock and for argillaceous rock. The evaluation identifies key aspects of features, events and processes which merit further investigation, in particular during site characterisation, and key aspects to be considered when formulating conceptual models regarding the effects of gas on repository performance.

In a probabilistic PA approach, two independent probabilistic assessments might be needed. Alternatively, a common technique is to include several alternative models in the system-level model, introduce an indicator variable as an uncertain parameter in the system-level analysis that selects among the alternative models, then (by assigning weights to the models) sample among the alternatives in the system-level analysis. This technique efficiently propagates the model uncertainties (represented by the alternative models) to uncertainty in quantitative estimates of system-level metrics, in...
combination with parameter uncertainties. Sensitivity analysis of the system-level metrics can provide insight into the effect of selecting each alternative model, and of the relative effect of model uncertainty (represented by the uncertain indicator variable) as compared to other parameter and model uncertainties.

However, when employing this technique, care should be taken when presenting the results of the PA, because the results mingle outcomes that employ different models. For example, consider two alternative models which result in a system-level metric that is significantly different in magnitude between the models, but which has a similar range of uncertainty for each model. If results from both models are pooled into a single distribution for the system-level metric, a bimodal distribution for the metric is obtained. Although this distribution may represent a fair assessment of the overall uncertainty in the system-level metric (arising from the combined effects of parameter and model uncertainty), the mean (or median) of the distribution is not representative of any typical system state. In this case, the effect of model uncertainty may not be conveyed without presentation and explanation of the full distribution of the system-level metric.

**Example – Including alternative models in a probabilistic assessment**
In the WIPP PA [USDOE 1996] (see Appendix PAR), the probability of microbial gas generation occurring was set at 0.5 (50%). The value of the sampled parameter was used to determine the mechanisms of gas generation included in each simulation.

Comparisons of probabilistic techniques for quantitatively assessing model uncertainty are provided in [Nilsen and Aven 2003] and [Laskey 1996].

Under PAMINA WP2.2E, [Röhlig and Plischke 2009] survey the treatment of model uncertainty in four probabilistic safety assessments from a regulator’s perspective – see Section 6.4.

An alternative quantitative approach to accounting for model uncertainty in PA is to widen parameter PDFs through the use of expert judgment so as to represent a greater range of uncertainty than that accounted for by uncertainty in the parameter values themselves. However, unless there is a process for directly mapping parameter values to specific alternative conceptualisations, this approach begs some difficult questions and could introduce risk dilution. In order to use it there must be some understanding of the effects on assessment endpoints of altering individual parameter values, and a feeling for how much effect conceptual model uncertainties can have on the same assessment endpoints. Deterministic calculations based on the use of alternative models and designed to scope the effect of conceptual model uncertainties can be helpful in this respect.

**Example – Accounting for model uncertainty through parameter PDFs**
The response in Appendix A from DOE-YMP notes that expert panel elicitation methods are widely used to derive shapes and ranges for PDFs that reflect the epistemic uncertainties in the parameters themselves, and to identify any widening that may be required to account for uncertainty arising from the abstraction from detailed process models.
The NRG response in Appendix A provides the example of the PDF of the subrosion rate of a salt dome to demonstrate how a PDF for a parameter can be widened to account for conceptual model uncertainty. Derivation of the subrosion rate for a candidate site for geological disposal would be based on long-term measurements carried out on a large number of similar salt domes. The derived rate has to be regarded as a simplification of several geophysical processes that determine the spatial development of a salt dome but that will not be modelled in the PA. It should be noted that the PDF set for the derived rate will be determined to some extent by the conceptual models used to interpret the measurement data.

In both the UK and the US, conceptual model uncertainties have been considered by conducting a “bias audit”. “Biases” are effects on calculation endpoints that arise from processes and spatial and temporal variations that the implemented model does not address. Biases are identified and estimated by a combination of expert judgement and deterministic scoping models.

**Example – Consideration of biases from model implementation**

In the UK regulator’s Dry Run 3 project, the main aim was to apply an existing probabilistic methodology to address future environmental change. As part of the project, a “bias audit” was conducted [Thorne 1992], which looked at issues that arose from conceptual model uncertainty.

In an inverse approach to considering model uncertainty related to simplification of models, [Nirex 1997] uses simple analytic expressions, termed “insight” models to examine the results of the complex models and provide a simple understanding of which parameter values and processes have a key impact on risk. Confidence can be provided in the results of the complex numerical models by showing that similar results may be obtained on the basis of very simple models.

**Example – Use of simplified models to consider uncertainty and build confidence**

Under PAMINA WP2.2B, [Poole 2009] compared the results from a simple algebraic model and a complex groundwater flow model for time-dependent annual individual risk arising from radionuclides transported to the biosphere by groundwater. Both models produced similar estimates of the magnitude of peak individual risk when sufficient realisations were run. This is because parameter uncertainty, rather than model uncertainty, was the main control on the shape of the mean risk curve in the region of the peak risk.

Qualitative approaches to building confidence in PA models should focus on four aspects:

1. Evidence relevant to the credibility of the chosen PA models for which key model uncertainties are present.
2. The rationale for model selection where reasonable alternatives are present.
3. Influence of key model uncertainties on the decisions under consideration.
4. The use and effects of conservatisms, where conservatisms mitigate potential model uncertainties.

Evidence may be drawn from publically-available technical reports, journal articles, peer reviews, model validation efforts, sensitivity analyses, or other sources.

5.5 Scenario Uncertainty

There are several published definitions for the term “scenario”. According to [NEA 2001], a scenario “specifies one possible set of events and processes, and provides a broad-brush description of their characteristics and sequencing.” [Swift et al. 1999] describe scenarios as “a subset of the set of all possible futures of the disposal system that contains futures resulting from a specific combination of features, events and processes.”

Scenarios can thus be considered as broad descriptions of alternative futures of the waste disposal system, and can be used as the basis for assessments of the phenomena and components of the system, which are usually referred to as features, events and processes (FEPs). Most PAs assess multiple scenarios. The process by which these scenarios are identified, known as “scenario development”, typically contains four basic steps [Galson and Khursheed 2007]:

a) Identify and classify all phenomena (i.e. FEPs) potentially relevant to the performance of the disposal system.

b) Eliminate FEPs according to well-defined screening criteria.

c) Form scenarios from FEPs in the context of regulatory performance criteria.

d) Specify scenarios for consequence analysis.

Scenario development typically involves a structured approach to screening to establish those FEPs included in post-closure system assessment modelling, those FEPs which can be defensibly excluded, and those FEPs for which defensible screening arguments cannot be presented, but which are not included in the PA modelling. The process of scenario development cannot be automated and is heavily dependent on the use of expert judgement, formal or otherwise.

Example – Scenario development methodologies

Recent work on scenario development methodologies has led to increasing use of the concept of safety functions, i.e. those functions that the disposal system should fulfil during different time frames in order to achieve its long-term safety objective (e.g., Figure 4). The aim in a scenario development methodology is to identify deviations from an expected evolution scenario, based on the failure of one or more safety functions. These potential failures can be identified from a functional diagram.
for the expected evolution scenario, based in turn on the implementation of a disposal system design at a particular site and phenomenological studies. In the second stage of the scenario development methodology, altered evolution scenarios are developed by considering the timing of FEPs, their consequences in terms of safety function effectiveness, and the status of other safety functions.

![Figure 4: Safety functions and time frames considered in the Belgian SAFIR safety case (taken from [Bassi and Devictor 2008]).](image)

**Example – Safety function approach to scenario development**


There are essentially three overarching methods for dealing with scenario probability in assessments, depending on the extent of quantification of the FEPs concerned:

- **Quantitative methods**, where all FEPs are represented numerically and event probability is an explicit part of the PA calculation, such as those methods employed in the probabilistic Total System Performance Assessment (TSPA) models used in the US Yucca Mountain and Waste Isolation Pilot Plant (WIPP) Projects.

- **Qualitative methods**, where the likelihood of occurrence of FEPs is described qualitatively or semi-quantitatively, such as used in recent assessments in many European countries.

- **Non-consideration of probability**, especially where few or no relevant data are available and there are large uncertainties associated with describing the
scenario. This is normally the case for inadvertent human intrusion scenarios and, in such cases, plausible descriptions of human activities based on present-day human behaviour may be used in assessments, rather than attempting to develop descriptions of future human behaviour. It is not normally appropriate to assign probabilities, quantitative or otherwise, to these scenarios [ICRP 1998].

Scenarios are often classified based on their probability of occurrence and on the likelihood of the FEPs comprising the scenarios [NEA 2005; Vigfusson et al. 2007]:

- **Reference, main or “base case” scenarios** represent the evolution of the disposal system within the expected range of uncertainty. These scenarios have a nominal probability of one.

- **Altered evolution scenarios** represent less likely, but still plausible, modes of disposal system evolution, such as more rapid barrier degradation than was expected. They also describe how disturbances affect the evolution of the system. The probability of occurrence of a particular scenario may be estimated, or the consequences of the scenario may be qualitatively compared with the reference case, but without a quantitative estimate of probability.

- **Bounding scenarios** portray extreme events that are still within the range of realistic possibilities, such as an extreme ice-age or a major seismic event. Probabilities for this type of scenario are difficult to define and the significance of bounding scenarios must generally be assessed qualitatively.

- **“What if” or residual scenarios** do not aim to be realistic, but are used to explore the robustness of the system, such as complete failure of a confinement barrier for an undefined reason. No quantitative assessment of their significance can be made as they are considered impossible, with a nominal probability of zero.

- **Stylised scenarios** are essentially associated with future human actions (e.g., intrusion) for which few or no relevant data are available and there are very large uncertainties associated with describing the scenarios. Such scenarios can be considered a special type of altered evolution scenario, for which probability estimation is considered meaningless.

Note that the use of stylisation to conceptualise human intrusion scenarios is not to be confused with the use of stylisation to undertake consequence assessment. Human intrusion is an external influence on the disposal system. Once the scenario description has been stylised, there may be extensive data available to model the potential impact of the scenario. However, for some components or characteristics of the disposal system, a stylised assessment approach must be taken. In particular, the evolution of the surface environment (biosphere) – a part of the disposal system in all scenarios – must be assessed using stylised assumptions, because of the large uncertainties involved in predicting how the biosphere will evolve in the far future.

Note that for the specific use of FEP probabilities for scenario development, it is important to distinguish between the probability of a FEP occurring (scenario uncertainty) and the use of probability to characterise uncertainties about a FEP
(parameter value uncertainty, see Section 5.3). Both can be treated using either deterministic approaches or probabilistic approaches. Deterministic approaches to the treatment of parameter value uncertainty are normally paired with deterministic approaches to the treatment of scenario uncertainty. Probabilistic assessment of parameter value uncertainty can be paired with a deterministic approach or a probabilistic approach to the treatment of scenario uncertainty.

In considering scenario uncertainty, we are specifically concerned with the treatment of uncertainty about when and how often particular FEPs (normally, specific events) included in the scenario occur, for which both deterministic and probabilistic approaches can be considered. Deterministic approaches to scenario uncertainty will generally use (best estimate or conservative) single values and ranges for FEP uncertainties. Probabilistic approaches to scenario uncertainty may be supported by a probabilistic representation of FEP uncertainties (e.g., the use of PDFs – the probability that a value occurs within a particular range of values), but also commonly use single values for FEP frequencies or rates.

Whatever method is used to represent uncertainties, the probability of occurrence of most FEPs must be estimated on a site-specific and concept-specific basis. There are a number of theoretical approaches that can be used for determining probabilities (e.g., [Hunter et al. 1992]):

- **Axiomatic.** Axiomatic probabilities can be assigned if a logical analysis of the system shows that different states are equally likely, or have other defined probabilities. An example is the tossing of an unbiased coin, in which it is axiomatic that heads and tails have equal probabilities (ignoring the very unlikely case of the coin landing on its edge). There are very few if any examples of axiomatic probabilities for FEPs associated with disposal systems.

- **Frequentist.** With this approach, probabilities (frequencies) are derived from observations of how often an event has occurred in the past and/or in other locations. A large number of observations, or support from other lines of argument, is required to provide a statistically valid frequency or PDF of system states. Justification is also needed to support projection of data on past events into the future, e.g., no anticipated changes in patterns of volcanism and earthquakes of given magnitudes.

- **Physical Model.** Sampling a model of the physical system using Monte Carlo simulations to generate a PDF of system states. This method can be used if the physical system is well understood and there are sufficient data to support a realistic simulation model.

- **Probability Model.** For events that are considered to occur at random, a probability model (e.g. Poisson) can be used directly in a simulation model or to derive a PDF of system states. For example, for a Poisson model, the probability of an event occurring is conditional on knowing the average occurrence rate and assuming that the times between successive events are independent. If there are insufficient data to support the assumption of randomness, or there are reasons to assume that future events will not occur
randomly, then alternative assumptions regarding FEP probabilities are required.

Although there is a range of approaches for estimating FEP probabilities, there are many examples where there is insufficient information available to quantitatively estimate the probability of rare or non-periodic geological FEPs using these approaches. Where a quantitative estimate of the probability of occurrence for all FEPs identified as potentially significant is required to support fully probabilistic PAs (e.g., US Yucca Mountain and WIPP Projects), the above approaches must be supplemented by additional assumptions based on expert judgement. In deterministic or combined deterministic and probabilistic PAs, it may be possible to use qualitative estimates about FEP probability and to undertake separate, conditional, assessments. Judgement is still required in these cases, not least in comparing results from a range of scenarios, but there is likely to be less reliance on subjective probability estimation methods.

Example – Expert judgement / elicitation in scenario development
A review of expert judgement techniques to assign scenario probability has been undertaken within PAMINA WP2.2C. [Grupa 2009] presents an expert judgement exercise to obtain a credible description of scenario dealing with the abandonment of a disposal facility prior to complete closure. A formal elicitation procedure was tested adopting the following steps: definition of the case structure, identification of target variables, identification of query variables, identification of performance variables, identification of experts, selection of experts, definition of elicitation document, dry run, expert training session, expert elicitation session, combination of expert assessments, discrepancy and robustness analysis, feedback, post-processing analyses, and documentation.

Two main types of approach to include scenario uncertainties in PA calculations may be delineated:

1. A pure probabilistic sampling approach, in which scenario occurrence is sampled from a distribution of possibilities during a Monte Carlo calculation in much the same way that parameter values are sampled from PDFs.

Example – Probabilistic treatment of scenario uncertainty
A probabilistic treatment of scenario uncertainty was developed at SNL about 20 years ago, and is currently the PA methodology prescribed by regulation for the WIPP facility [USDOE 1996]. The PA produces many thousands of ‘futures’ for each set of parameter values, which are then combined in the form of a CCDF of cumulative releases to the accessible environment over 10,000 years.

The treatment of scenario uncertainty using a probabilistic approach has also been investigated in other countries in the past, including Canada [Stephens and Goodwin 1990] and the UK [Sumerling 1992].

Section 2.2.1 of [Galson et al. 2009c] discusses the example of the Yucca Mountain PA.
2. Evaluation of a limited set of deterministically defined scenarios. Although individual scenarios are defined deterministically, scenario consequences may then be assessed probabilistically or deterministically. In this context, probabilistic assessment means a deterministic approach is taken for “irreducible” uncertainties associated with development of the system over time (scenario uncertainties), and a probabilistic approach for “reducible” uncertainties associated with knowledge of the system (many parameter and conceptual model uncertainties). In this approach, although the scenario development process still aims at identifying all relevant scenarios, there is not necessarily the same mathematical constraint that scenario probabilities must sum to one. This means, for example, that both the reference and some altered evolution scenarios can be conservatively assumed to have a probability of one. For less likely scenarios, a qualitative statement or quantitative estimate of scenario probability can be made, depending on the regulatory criteria concerned.

**Example – Deterministic treatment of scenario uncertainty**
Deterministic analysis of scenario uncertainty is currently practiced by most radioactive waste management programmes. For example, see [NAGRA 2002a], [ANDRA 2005].

Section 2.2.2 of [Galson et al. 2009c] discusses the example of the Nagra PA.

An intermediate partial probabilistic approach to evaluation of scenario uncertainty has been adopted in Sweden and Finland.

**Example – Mixed (probabilistic and deterministic) treatment of scenario uncertainty**
Section 3 of [Galson et al. 2009c] discusses the Scandinavian approaches to treatment of scenario uncertainty.

Scenarios including more than a single FEP that is not certain to occur are generally only considered in probabilistic assessments, although there is no reason why deterministic calculations should not include more than one of this type of FEP. There are two situations that can be considered for multiple “scenario-forming” FEPs: a situation in which the FEPs are independent; and a situation in which the FEPs are related or conditional upon each other. In the former case, the scenario probability is the product of the probabilities of the independent FEPs. In the latter case, it is the probability of the initiating FEP (e.g. glaciation) and the conditional probability of each subsidiary FEP (e.g. post-glacial faulting) that must be combined.

Where multiple FEPs are identified for consideration in one or more altered evolution scenarios, several approaches have been used for examining and quantifying combinations. The approach taken largely depends on the methodology used for scenario development, which varies considerably. Several tools have been used, either individually or in combination, to assist in the identification of FEPs for inclusion in scenarios, including:
• Event trees, logic diagrams, and related approaches that analyse alternative combinations of events and/or resulting system status (e.g., Figure 5).

• Fault and/or dependency diagrams that set out in a hierarchical fashion the conditions and/or processes leading or contributing to an end point of interest.

• Interaction matrices that examine the dependency between selected FEPs.

• Safety function failure diagrams/tables that identify scenarios based on the ability of FEPs to lead to partial or total failure or bypassing of particular barriers.

Although all of these scenario development approaches can be used for identifying relevant FEPs to include in scenarios, only the first two support the combining of FEP probabilities and the definition of scenario probabilities for deterministic calculations, or provide a basis for simulating FEP interactions in probabilistic calculations. Audit tables that consider the representation of each FEP within the models or scenarios developed can help to identify omissions and evaluate biases.

Figure 5: Example of a scenario logic diagram from the WIPP Compliance Certification Application [USDOE 1996].
5.6 Conservatism versus Realism

WP2.1C in PAMINA evaluated the issue of adopting conservative versus realistic approaches in PA and the implications for the treatment of uncertainty [Galson et al. 2009b]. Conservatism and realism can be defined as (modified from [IAEA 2006b]):

Conservatism – The conscious decision, made in light of the current state of system knowledge and associated uncertainties, to represent an element or elements of the system in the PA such that the system performance attributable to the element(s) is under-estimated and, thereby, the associated radiological impact (i.e. dose or risk) is over-estimated.

Realism – The representation of an element or elements of the system in the PA, made in light of the current state of system knowledge and associated uncertainties, such that the PA incorporates all that is known about the element(s) under consideration and leads to an estimate of the expected performance of the system attributable to that element. The associated level of knowledge must be able to be justified robustly to stakeholders and be quantifiable in a practicable sense as part of the safety assessment.

Depending on the number of elements of the system represented conservatively or realistically, a whole PA analysis might also be termed conservative or realistic. However, as [IAEA 2006b] points out, models are by their nature only approximations of what is known or surmised about the “real” entity that they intend to approximate. The term “best-estimate” analysis is better used in place of “realistic” to reflect the use of an analysis that attempts to mimic the known behaviour of a system or system element. “Realism” is better applied to convey the conceptual decision to model the system or system element using all that is currently known about that system or system element.

The advantages and disadvantages of conservative and realistic approaches in PA are summarised in Table 3 (see also [IAEA 2006b] and [Galson et al. 2009b]). There are no absolute rules for using one or another approach. Consequently, it is important to be clear in setting out the assessment context which approach has been taken and with what objectives.

- From a regulatory perspective, a conservative approach to PA might be adopted when comparing the results of an analysis to regulatory performance measures for a yes/no decision – supplemented by more realistic approaches to demonstrate system understanding. However, where the decision-making concerns comparison and selection of options, then a more realistic analysis should almost always be considered or, at the very least, a consistent level of conservatism needs to be applied to the analysis of each option.

- Robustness of disposal system safety is generally best demonstrated through the use of conservative PA assumptions and parameter values, to bound uncertainty in the modelling of particular elements or to simplify the PA. However, a degree of knowledge about the uncertainty is needed to demonstrate that the assumptions and parameter values are conservative.
With regard to confidence-building, conservative and best-estimate PA approaches can be used in tandem to communicate different messages: a conservative analysis provides a robust demonstration of safety; a more realistic analysis can be compared to observation and be used to demonstrate understanding, thereby building confidence in the results.

Table 3: Advantages and disadvantages of conservatism and realism in PA (from Table 1 of [IAEA 2006b]).

<table>
<thead>
<tr>
<th>Approach</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
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</table>
| Conservatism | - Often considered easier to perform and defend analyses using conservative assumptions, models and/or parameters than it is to perform and defend realistic analyses.  
- Conservative model and/or data can be used in presence of incomplete data and/or knowledge.  
- Can prove beneficial in supporting confidence building if the estimated system performance conforms to the regulatory criterion.  
- Considered to provide a pessimistic estimate of system performance and, therefore, also provide a margin of safety relative to the “best-estimate” analysis of system performance.  
- Can allow quick decisions early in a project, based on a limited amount of information. | - Requires a sufficient understanding of the disposal system to be able to demonstrate that the analysis is truly conservative.  
- Does not allow demonstration of a scientifically robust understanding of the disposal system.  
- If “best-estimate” analyses are needed to demonstrate compliance when the conservative estimate violates the regulatory criterion, non-technical audiences may lose confidence despite demonstrating sufficient safety for the regulatory authorities unless sufficient emphasis is placed on communication to these audiences.  
- A conservative approach for one exposure pathway (or radionuclide) may not be conservative, but instead could be optimistic, for another exposure pathway (or radionuclide).  
- Inappropriate for the calibration of models.  
- Might result in sub-optimal or erroneous decisions. |
| Realism    | - Allows demonstration of a scientifically robust understanding of the disposal system and so builds confidence.  
- Limits non-physical representations of the disposal system and over-estimation of impacts.  
- Provides the information necessary for making informed decisions. Optimisation of such things as the facility design, waste loading and site characterisation cannot be performed without a “best-estimate” analysis.  
- In concert with sensitivity and uncertainty analyses, provides a means for targeting robust data collection suited for uncertainty reduction and decision making.  
- Provides some scope for calibrating and validating “best-estimate” models. | - Requires a sufficient understanding of the present-day and future disposal system to justify that the analysis is truly a “best estimate”.  
- Demonstration of realism over long periods of time is questionable.  
- It may be impossible or very expensive to collect sufficient data or supporting information for the entire spatial or time domain of interest. |
While the principle of using safety functions in the safety case does not bias the safety case towards conservatism or realism, several mechanisms were identified which have the potential to introduce conservatism into the implementation. Examples from the implementation of safety functions in a number of programmes (see Galson et al. 2009b)) illustrate these mechanisms:

- Selection of conservative values for limits on safety function performance.
- Application of limits on safety function performance without taking into account inter-dependencies between sub-systems and safety functions.
- Regulatory requirements on safety functions/sub-system performance.

The safety functions approach for scenario development discussed in Section 5.5 may concentrate too much on extreme, and unlikely, scenarios (i.e., complete failure of safety functions) and insufficiently on more likely, and still potentially significant, scenarios involving the more gradual degradation of safety functions. When using a safety functions approach in PA, introduction of unintended conservatism, or, in the case of scenario development, an unintended bias towards optimism, can be avoided by:

- Accounting for any inter-dependence of safety functions and safety function indicators.
- Applying performance limits for individual safety functions/barrier/sub-systems within the context of the performance limits for the whole repository system.
- Not placing regulatory limits on individual safety functions indicators/sub-system performance criteria.
- Applying complementary methods for scenario development in order to achieve comprehensiveness.

A graded approach involving conservatism and realism can be adopted for dealing with uncertainties in assessment of complex systems involving many processes and parameters [Galson et al. 2009b]. Assessments are made iteratively, starting with conservative assessments and followed by more realistic assessments when required. For example, if the conservative assessments demonstrate that doses are well below the relevant dose constraints, there may be no need for further detailed assessments to demonstrate compliance with regulatory criteria.
Example – Tiered approach to screening of PA calculations using conservative assumptions

Facilia provides an example of a two-tiered screening approach in [Galson et al. 2009b]. In a hypothetical scenario of radionuclide releases into the biosphere from a geological repository, Tier 1 is a dose assessment using a non-dilution model with a highly conservative set of assumptions, where an individual was exposed over one year to the whole integrated release. Depending on the calculated dose from the Tier 1 assessment, in comparison to a performance measure, a Tier 2 assessment is performed using a generic screening model, with less extreme, but still conservative, assumptions about exposure. Depending on the calculated dose from the Tier 2 assessment, in comparison to a performance measure, further more detailed and less conservative models are identified as potentially being required to demonstrate that the dose is below the regulatory criteria. This approach allows for a reduction in scope of any more realistic assessments that may be required, for example a reduction in the number of radionuclides that need to be considered in detailed site-specific assessments.

5.7 Supporting Arguments and Qualitative Methods Used to Address Uncertainties and Provide Confidence

Three non-numerical or qualitative strategies for managing uncertainties in PA and the safety case are:

1. Robust design.
2. Qualitative assessment methods and use of alternative indicators of system safety and performance.
3. Implementation of specific QA procedures for development of the PA and safety case.

These strategies are discussed in turn below.

5.7.1 Robust design

Uncertainties are managed in many programmes by using conservative engineering design principles. For example, this is expressed in the response from Germany in Appendix A as the adoption of:

“...classical engineering methods, e.g. a safety oriented repository design (safety design), improvement of the natural system, proof of structural reliability of important design elements to reduce variation ranges of their safety related characteristics, and QA.”
In Appendix A, IRSN (France) identifies examples of this type of engineering approach:

- “...limitation of high temperatures to preserve favourable and known physical and chemical environment (the envisaged repository concepts should prevent rises in temperature that could prejudice the containment capabilities of the repository components, adoption of an over-pack is relevant to prevent releases of activity in temperature conditions where transport phenomena are poorly controlled...)

- seals designed with narrow trenches to intercept EDZ

- dead end architecture of disposal tunnels

- location of shaft and repository areas with respect of mapped structures and underground flow patterns”

As another example, the disposal concepts in Finland and Sweden are designed to ensure that the engineered barriers used in the KBS-3 concept are extremely robust, thereby making uncertainties associated with the far field and biosphere easier to discount.

5.7.2 Qualitative assessment methods and alternative indicators

In addition to numerical simulations of repository performance, safety cases also employ qualitative assessment methods to convince a broad range of stakeholders that a geological repository will be acceptably safe. This is particularly true where an assessment considers events far removed in space and time from the original emplacement of waste in the repository, and there are very large uncertainties associated with the quantitative assessments.

Example – Qualitative safety arguments in a safety case

Section 5 of [NEA 2004a] discusses a range of safety arguments (see also Table 2). NEA [2004b] discusses multiple lines of evidence to build confidence in PA models, particularly in regard to representation of the geosphere.

Qualitative arguments can include (e.g., see UK response in Appendix A):

- Comparisons with natural analogues, i.e. occurrences of materials or processes which resemble those expected in a proposed geological waste repository, for example the Maqarin site in Jordan which provides a natural analogue for a cementitious repository.

- Showing consistency with independent site-specific evidence, such as observations in nature or palaeo-hydrogeological information.
Evidence for the intrinsic robustness of the repository system, for example demonstrating that relevant features and processes are well understood, often supported by evidence from underground research laboratories.

- Describing the passive safety features of the repository and demonstrating that the design uses best practice scientific and engineering principles.

The safety case may also include more general arguments related to radioactive waste management, and information on issues such as natural radioactivity levels and radiation doses to put the results of performance and safety assessments into perspective.

In Finland, a wide-ranging, multi-dimensional uncertainty analysis approach has been outlined for the biosphere assessment (see Appendix A). The approach combines traditional uncertainty and sensitivity analysis with methodologies for quantifying non-numerical uncertainties, such as “pedigree analysis” for the evaluation of uncertainties in the knowledge base. The methodology might be extended to other areas of the safety case after more experience on the practical implementation for the biosphere has been gained.

In France, a combined quantitative / qualitative approach was taken in the safety case for the Dossier 2005 [ANDRA 2005]. A qualitative safety analysis methodology was developed for detailed consideration of FEPs. The qualitative safety analysis is a method for verifying that all uncertainties in FEPs and design options have been appropriately handled, thereby justifying the selection of altered evolution scenarios.

Although not qualitative, the assessment of alternative indicators of safety and performance is included here as it presents an option for reducing the uncertainty in the main PA calculations, but not in the manner described in Sections 5.3 to 5.6. Rather, the uncertainty is removed by simply not modelling part of the system. For example, determination of radionuclide flows and concentrations as indicators (perhaps for comparison to natural concentrations or for determination of toxicity) removes most, if not all, uncertainties relating to the biosphere that are included in PA models for the calculation of dose / risk.

5.7.3 QA systems

Implementing appropriate QA systems for conducting repository development programmes (including PA, design, site characterisation, programme management, etc.) plays a part in the process of building a compelling safety case and obtaining approval from regulators and stakeholders. Many programmes discussed in Appendix A have applied custom-designed or internationally accredited QA procedures to their operations.

ANDRA (France) (amongst other waste management organisation) is accredited to ISO 9001 [ISO 9001]. ISO 9001 is a general-purpose QA standard, intended for use in any organisation that designs, develops, manufactures, installs and/or services any product or provides any form of service. It provides a number of requirements that an
organisation needs to fulfil if it is to achieve customer satisfaction through consistent products and services that meet customer expectations. In this case, the “customer” might be considered the regulator and other stakeholders.

NUMO (Japan) has developed its own structured QA approach. This is described in Appendix A:

“In order to maintain flexibility without losing focus and make the work more systematic, NUMO has developed a formalised tailoring procedure, termed the NUMO Structured Approach (NSA) [Kitayama et al. 2007]. The NSA provides a methodology for developing repository concepts in an iterative manner, which couples management of immediate issues with consideration of longer-term developments. The NSA also guides the interaction of the key site characterisation, repository design and Performance Assessment groups and is facilitated by tools to help the decision-making associated with the tailoring process (e.g. a requirement management system, RMS) and with comparison of siting and design options (e.g. multi-attribute analysis). The RMS is being developed to help implement the NSA. This RMS will allow the justifications, supporting arguments and knowledge base used for every decision to be clearly recorded and will highlight when such decisions may need to be revisited, for example due to changing boundary conditions or technical advances. It thus serves as a valuable tool to keep track of the wide range of constraints on designs, while the entire process runs within an overarching Quality Management System (QMS). NUMO has developed its own QMS to ensure high quality of all its technical activities, documents and databases. The QMS will be integrated within the RMS, to ensure the total quality of the repository project, including the safety case development”.

The SNL-WIPP (US) response in Appendix A states that:

“Thus efforts to demonstrate the overall credibility of the approach used in the assessment are likely to be important. These efforts include such things as configuration control for all related computer files, documentation of changes and their impacts, verification and validation of the models, use of formalized methods for assessing uncertainties subjectively, peer review down to the level of the code, etc. Putting these additional activities under QA can help to confirm that the approved methodologies are being used. However, care must also be taken to help ensure that the requirements and delays imposed by QA do not detract from the quality of the assessment.”
6 Calculational Approaches

Having discussed in Section 5 how uncertainties are classified and treated in the specification of calculation cases for the PA, this section reviews calculational approaches for conducting the PA. Some PAs consider uncertainties through a series of deterministic calculations, evaluating the potential implications of each uncertainty in turn. No particular calculational approach is needed for such PAs; this section is concerned with analyses that treat uncertainties using some sort of probability distribution and that assess sensitivities to parameter variability. First, in Section 6.1, the various techniques for conducting uncertainty and sensitivity analysis for models containing parameter ranges or probability distributions are discussed. The particular issues of defining parameters for which limited data are available using subjective probability theory and the treatment of spatial variability are considered in Sections 6.2 and 6.3, respectively. Finally, Section 6.4 discusses fully Probabilistic System Assessment (PSA), where all uncertainties accounted for in the assessment are modelled in a single calculation.

6.1 Sensitivity Analysis and Uncertainty Analysis

The value of sensitivity and uncertainty analyses is widely appreciated in PA and safety case development, and a clear, well-understood distinction is made between the two:

- The purpose of uncertainty analysis is to give an absolute estimate of uncertainty in assessment endpoints such as dose or risk. It is achieved by propagating through the assessment system estimates of uncertainty in the inputs. The analysis produces estimates of uncertainties in key predicted quantities without necessarily explaining which input quantities the uncertainties are derived from.

- The purpose of sensitivity analyses is to understand how the system works and which parameters have a strong influence on assessment endpoints. This leads to the identification of those sources of uncertainty in parameter values or conceptual model implementation where the most benefit would be gained – in terms of reduction in overall uncertainty or greater confidence in PA results – from further investigation or modelling.

If all inputs to an analysis are independent, the individual PDFs assigned to each uncertain parameter are enough to characterise the global uncertainty. The use of a standard sampling analysis, such as the Monte Carlo method, allows the mapping of the input space onto the output variable space and the estimation of the consequences. However, input parameters may interact such that the joint effect is different from the addition of their individual effects (2\textsuperscript{nd} order interactions for two parameters, 3\textsuperscript{rd} order for three parameters and so on) (Figure 6). In general, main effects (individual effects of each input parameter) are more important than 2\textsuperscript{nd} order interactions which are more important than 3\textsuperscript{rd} order interactions, though this is not always true and interactions need to be considered in order to know the true structure of the system.
under study. Not all analysis methods / techniques are suitable for studying interactions and the analysis method must be chosen according to the degree of interactions and the computational demands anticipated based on the complexity of the PA model.

Figure 6: Variation in output $Y$ (vertical axis) related to variation in two input parameters $X_1$ and $X_2$ (horizontal axes). Left-hand figure illustrates the case where there is no interaction between the input parameters and the variation in $Y$ is linear with the variation in $X_1$ and $X_2$. Right-hand figure shows a 2$^{nd}$ order interaction, with the variation in $Y$ becoming larger as both $X_1$ and $X_2$ approach higher values. From [Badea and Bolado 2008].

Another issue can arise in the definition of relevant or important input parameters. An input parameter can be considered important with respect to a given output variable if a strong correlation exists between them (linear relation), but it could also be considered important if the output takes remarkably high values when the input takes values in a given region, or if the input contributes a large fraction of the output variance.

Issues such as interactions and different interpretations of importance and relevance have triggered the development of a variety of sensitivity analysis methods designed to study the model from different points of view. The same methods can be more or less suited to uncertainty analysis, either at the same time or as a separate exercise. WP2.1D of PAMINA focused on methods for probabilistic sensitivity analysis and [Badea and Bolado 2008] provides a review. Sensitivity analysis methods may be divided into three broad types: local methods, screening methods and global methods. Local methods focus on the study of the system model behaviour under very specific system conditions. In a local analysis, the majority of parameters are kept constant while one or a few parameters are varied in order to study the reaction of the model to a specific influence (see Chapter 5 of [Saltelli et al. 2000] and [Cacuci 2003] for more detail). As local methods are concerned with 1$^{st}$ order sensitivities, when they are applied to non-linear problems the results will be valid only for small variations around the specified value of the input. While a local method provides relevant information about the system model, [Badea and Bolado 2008] note that screening methods and global methods fit better within the context of a system PA. Therefore,
these methods are considered further in Sections 6.1.1 and 6.1.2 below. Sections 6.1.3 summarises testing of several sensitivity analysis methods and their utility to the PA of geological disposal facilities in PAMINA. Section 6.1.4 discusses the potential for the use of metamodels for the sensitivity analysis of complex models and the application of this approach to undertake sensitivity analysis of models with non-scalar or functional inputs.

6.1.1 Screening Methods

The objective of screening methods is to identify, at a low computational cost, a subset of inputs that controls most of the variability of the output. This allows model simplification in future iterations of the PA. Screening methods focus on the functional relation between inputs and outputs disregarding input parameter distributions, but paying attention to the ranges of each input.

Example – Screening sensitivity analyses

Chapter 4 of [Badea and Bolado 2008] reviews the screening methods of full factorial design, fractional factorial design, Morris’ One-At-a-Time (OAT) design, and sequential bifurcation.

- The simplest screening method involves fixing one point (typically a middle point) and modifying each input one by one (OAT method). However, this method is inefficient when the number of important factors is small and does not detect interactions. In a full two-level factorial design ($2^k$) or analysis, a model has $k$ parameters and the analysis studies the behaviour at two different levels. Those levels are called the lower level and the upper level, and may be either quantitative or qualitative. For example, for a numeric continuous parameter, the levels could represent the minimum and the maximum values in its range; for a qualitative parameter the levels could be two different competing submodels to simulate a given phenomenon. The analysis considers each possible combination of parameters taking upper and lower levels. Therefore, $2^k$ runs are needed. When the number of parameters increases, this becomes too resource-intensive.

- The theory of fractional factorial two-level designs ($2^{k-p}$) or analysis was developed to cope with larger numbers of parameters. In this case, most of the high order interactions are assumed to be not relevant and the output variables are limited to estimate the effect of single parameters and low order interactions, mainly second order interactions. Fractional factorial design analyses are well suited to develop sequential experiments, where new design points are selected according to the information obtained in previous steps. In an example in Section 4.2 of Badea and Bolado 2008], seven parameters were analysed using only 16 computer runs (rather than $2^7$), identifying three single parameters and two second order interactions as relevant. Again, however, this approach is only adequate when the number of input parameters is moderate, and would become very difficult to implement when the number of parameters is large (several tens or larger).
The Morris Factorial Sampling method [Morris 1991] is a OAT design that aims to classify inputs as having a negligible effect on the output, having a linear effect without interactions, or having non-linear effects and/or interactions. The method assigns a number of levels per input parameter and a number of randomly generated sampling paths. The paths are used to estimate the mean value and the standard deviation of the output associated with each main input. A high estimated mean indicates that the input parameter is important; a high estimated standard deviation indicates important interactions and non-linear effects of that input parameter. This method does not require an excessive number of runs ($[k+1]*r$ where $r$ is a linear function of the number of inputs). However, the main disadvantage that it is not possible to estimate individual interactions among factors. Also, if inputs produce large positive and negative effects, the averaging process of computing a mean can render misleading results.

Sequential bifurcation [Bettonvil and Kleijnen 1996] is a group screening technique that allows screening of a large number of inputs. The number of simulations required is smaller than the number of inputs to be screened. The drawback is that the relationship between each input and the output has to be monotonic and the type of monotony has to be known a priori. Whenever these conditions are fulfilled, the method is very effective.

Full factorial and fractional factorial methods are powerful tools when the number on input parameters is moderate, but their applicability cannot be recommended when the number of input factors is very large; in those cases methods like Morris’ and sequential bifurcation are considered more appropriate.

6.1.2 Global Methods

Global methods pay attention to how the whole input space maps onto the output space, taking into account the input distributions.

**Example – Global sensitivity analyses**

Chapter 5 of [Badea and Bolado 2008] reviews four sets of global methods: graphical methods, Monte Carlo based methods, variance decomposition-based methods, and distribution sensitivity methods. A summary of the statistical methods is provided in Section 2 of [Becker *et al.* 2009a].

- Graphical methods are important tools to support, guide and interpret the results provided by numerical sensitivity analysis techniques. They may also be used as standalone techniques to get further insights about the model under study. Widely used graphical tools to analyse relations between inputs and outputs are scatter-plots, cobweb plots, and Contribution to the Sample Mean (CSM) plots. Scatter plots can only be used to show a limited number of relationships in 2-D or 3-D at any one time, but are visually clear. In some cases, plotting data using logarithmic scales can clarify trends. A cobweb plot shows several inputs (usually 10 or less for clarity) and the output evenly
spread on the x-axis, with a line showing the values on the y-axis of the inputs and outputs for each run in the analysis. Colours can be used to show runs that yield high output values. However, with a large number of runs, cobweb plots become visually difficult to interpret and an alternative is to only plot a subset of runs, such as those yielding high output values (Figure 7). A CSM plot represents indirectly a contribution to the variance of the output. If for a given range in the input parameter, all realisations of the output are very close to the mean, this implies that there is a low contribution to the variance. The main use of CMS plots is to identify important input parameters, but they have limitations (e.g., use of non-bias sampling, positive values), are more difficult to interpret and communicate compared to scatter plots and cobweb plots.

Figure 7: Two examples of cobweb plots for nine input parameters and one output on the right-hand end of each plot. Left-hand figure shows runs colour-coded with yellow showing runs yielding the lowest 25\textsuperscript{th} percentile of outputs, green 25-50\textsuperscript{th}, blue 50-75\textsuperscript{th} and black 75-100\textsuperscript{th}. Right-hand figure shows only those runs yielding the top 10\% of outputs. From [Badea and Bolado 2008].

- The Monte Carlo method consists of sampling at random the vector of input parameters, running the model for each sample of that vector, and during a sample of the vector of output variables. One of the advantages of using the Monte Carlo method is that standard statistical methods can be used to estimate the output variable distributions and to test any hypotheses. This makes it the most straightforward and powerful method available to deal with uncertainty propagation in complex models, as is generally the case for PA models. The method is valid for models that have static and dynamic outputs, and is adequate for working with discrete and continuous inputs and outputs. Monte Carlo samples are extremely convenient since they allow sensitivity analyses and uncertainty analyses to be undertaken using the same sample. Several sampling strategies are available, but the most used are Simple Random Sampling (SRS) and Latin Hypercube Sampling (LHS). The most commonly used analysis is based on the computation of the correlation coefficient. The Pearson correlation coefficient based simply on input and
output values is generally used for linear relationships, while the Spearman correlation coefficient using rank transformations is used for non-linear but monotonic relationships. Standardized regression coefficients (SRCs) and standardized rank regression coefficients (SRRCs) provide measures of the relative importance of a variable and whether its relationship to the output is positive or negative. The calculation of these coefficients is summarised in Section 2.2.2 of [Becker et al. 2009a].

The relationship between an input parameter and the output may not be linear or monotonic. An input parameter might be considered important with respect to a given output variable if there is a clear link only between specific regions of both. Monte Carlo Filtering (MCF) is based on dividing the output sample in two or more subsets according to some criterion (e.g., those that exceed a safety limit) and testing if the inputs associated to those subsets are different or not. If points in each subsets are related to different regions of a given input, then knowing the value of the input parameter would be important in order to be able to predict if the criterion will be exceeded. Among the most popular tools used to provide answers to this type of analysis are the two-sample Smirnov test, the Mann-Whitney (or Wilcoxon) two-sample test, and the two-sample t-test. The two-sample Smirnov test is based on comparing empirical cumulative distribution functions, the Mann-Whitney test is based on ranks, while the two-sample t-test is based on the sampling distribution of the mean of normal variables. The methods are described in more detail in Section 5.2 of [Badea and Bolado 2008], who conclude that the assumptions for the Smirnov test and the Mann-Whitney test are so generic they have a broader applicability in the framework of PA studies compared to the t-test.

Variance-based methods study the contribution of each input parameter, its variance (uncertainty) and its related interactions to the output variance or uncertainty. Variance-based methods are underlain by Sobol’s decomposition [Sobol 1993] of any integratable function \( Y = f(X_1 \ldots X_d) \) into \( 2^k \) orthogonal summands:

\[
Y = f(X_1, \ldots, X_k) = f_0 + \sum_i f_i(X_i) + \sum_{i<j} f_{ij}(X_i, X_j) + \ldots + f_{1\ldots k}(X_1,\ldots, X_k)
\]

The first order function \( f(X_i) \) of the decomposition represents the effect of the input factor \( X_i \) acting independently (and generally in a nonlinear way) upon the output. The second order function \( f(X_i, X_j) \) represents the joint effect of the input factors \( X_i \) and \( X_j \) upon the output \( Y \), and so on. The last term of the decomposition gives the residual influence of all the input factors together.

For independent input factors and using the fact that any two different components of the Sobol decomposition are orthogonal, the variance of the model \( Y = f(X_1 \ldots X_d) \) can be written as:

\[
V = \text{Var}(Y) = \sum_i V_i + \sum_{i<j} V_{ij} + \ldots + V_{1\ldots d}
\]

[Sobol 1993] shows that the individual terms in this expression are the variances of the functions of the corresponding indices in the Sobol
decomposition, such that \( V_i = \text{Var}(f_i(X_i)) \), \( V_{ij} = \text{Var}(f_{ij}(X_i, X_j)) \), etc. Sobol’s decomposition is equivalent to the classical Analysis of Variance (ANOVA) decomposition of variability used in statistics.

*Sobol sensitivity indices* are defined as first order sensitivity indices, \( S_i = V_i/V \), second order sensitivity indices, \( S_{ij} = V_{ij}/V \), and so on until order \( k \). The sum of all the Sobol indices is 1 and as they are all positive: the larger the index (close to 1), the more influential the corresponding input (or group of inputs). However, when the number of input factors is large, there is a correspondingly very large number of indices and their computation and interpretation becomes impossible. This is why [Homma and Saltelli 1996] introduced *total sensitivity indices* which assess the sensitivity of the variance of the output with respect to the standalone and every interaction of the considered input factor. The total sensitivity index can be calculated as \( S_T = 1 - V_{-i}/V \), where \( V_{-i} \) is the variance explained by all the factors except \( X_i \), and this can be calculated as straightforwardly as the first order Sobol indices.

Section 2.2.3.3 of [Becker et al. 2009a] summarises various methods for estimating sensitivity indices. Most methods usually need a specific sampling strategy, with the exception of the simplest method (correlation ratios) and the recently developed methods of Random Balanced Design (RBD) and the Effective Algorithm for computing Sensitivity Indices (EASI – developed under PAMINA). Unlike the Monte Carlo method, the sampling strategy is usually not appropriate to simultaneously undertake uncertainty analysis.

- Distribution sensitivity methods measure the potential impact of changes in the distributions of input parameters on the distributions of the outputs. Two methods to measure the influence of multiple input distribution changes on the means and the distribution functions of the output variables are the weighting method and the rejection method. The weighting method is suitable for measuring the effect of several input distributions on the mean of the output and resembles the variance-reduction technique of importance sampling. The rejection method is suitable for measuring the effect on the distribution function and is based on an acceptance/rejection sampling technique to sample from distributions with no analytical inverse cumulative distribution function.

**Example – Application of global sensitivity analyses**
The regression analysis/classification tree analysis/entropy analysis approach used by the DOE-YMP in the Site Recommendation TSPA [USDOE 2000], the IFFD scheme developed by OPG [Melnyk et al. 2006], and differential sensitivity coefficients [Khursheed and Fell 1997].

### 6.1.3 Testing of Sensitivity Analysis Methods

PAMINA WP2.1D devised a series of tests to evaluate several of the different sensitivity analysis methods described above. A benchmark exercise was set up using a number of simple and well-defined mathematical models amenable to analysis of
their sensitivity to parameter variations. By applying sensitivity analysis methods to such models and comparing the results to the theoretical ones, the accuracy, robustness and reliability of the methods could be assessed. The following models were used for the benchmark exercise:

- **Ishigami function**: a model with three input parameters showing higher order effects. The second and third input parameters have a Pearson Correlation Coefficient of zero. The third input parameter shows no first order effect, but when estimating total effects, the third input is attributed to 24% of the output variance.

- **Discontinuous switch**: a model where a transition or switch in the value of the input parameters drastically changes the output behaviour.

- **A linear model with dependent input data**: The function \( Y = X_1 + X_2 \), but where the input parameters have a joint probability density function.

- **Sobol' function**: A model with eight input parameters as a test case to show if a method is robust enough where many input parameters are considered.

As a more realistic test relevant to use in PA, the sensitivity analysis methods were also tested using a simple standardised repository model, the NEA PSACOIN Level-E system. This model can be used to calculate the radiological dose rate to humans owing to the migration of radionuclides from a hypothetical nuclear waste disposal site through a system of idealised natural and engineered barriers. The model has 33 parameters, 12 of which are taken as independent uncertain parameters.

**Example – Benchmarking sensitivity analysis methods**

The benchmarking of sensitivity analysis methods described above is reported in [Plischke et al. 2009]. These authors identify a category of analysis methods as “cheap” methods where the sensitivity indices can be estimated from a given sample of realisations of the input variables and associated model outputs that may have already been derived, for example, as part of a probabilistic uncertainty analysis. Cheap methods include correlation ratios and polynomial fits. By contrast, “expensive” methods require special sampling schemes. Expensive methods include the RBD and Fourier Amplitude Sensitivity Test (FAST) and Enhanced FAST (EFAST) methods. Nine analysis methods were tested in the PAMINA benchmarking, five cheap methods and four expensive methods.

For the benchmark tests involving the well-defined mathematical models, the different analysis methods seemed to be stable and produced results with only minor differences. Moreover, the results obtained with cheap methods were similar to those obtained with more sophisticated methods. However, there are some pitfalls which are summarised in Section 7 of [Plischke et al. 2009].

Under PAMINA WP2.1D, different analysis methods were also applied to realistic repository models based on the different disposal concepts of the participating organisations. Such models sometimes show specific behavioural patterns that are not
covered by the simple mathematical models and can lead to unexpected results. Specific advantages and disadvantages of the different methods in conjunction with the PA of typical repository systems were identified.

**Example – Testing sensitivity analysis methods using PA models**

The testing of sensitivity analysis methods on realistic PA models under WP2.1D of PAMINA is summarised in Section 4 of [Becker et al. 2009a]. Six systems were analysed: two salt systems (NRG, GRS), two clay systems (NRG, JRC./ANDRA) and two granite systems (ENRESA, Facilia). Each study on each system utilised different approaches to sensitivity analysis and illustrated specific problems that can arise in the sensitivity analysis of such systems.

The NRG salt system was analysed by varying a number of input parameters that determine the closure behaviour of the compacted salt plug and thus the release of contaminants from the near field. At some point in time, the plug reaches a status of practical tightness, and the near field calculation is terminated. Therefore, if the plug permeability is analysed as a time-dependent model output, more and more values are missing with increasing model time. A specific strategy is necessary to handle this problem. Simply ignoring the missing values leads to a decrease of the sample size available for evaluation and to less reliable results. It was found that the best strategy is to replace the missing values by the last available value of each simulation.

For the NRG clay system it was found that the model output, as well as the input parameters, varies over several orders of magnitude so that an evaluation on a linear scale is highly influenced by only a few simulations. Therefore, a logarithmic transformation was applied both to input and output parameters, which lead to a better performance of the analysis. A similar but even harder problem arose in the case of the GRS salt system. About 85% of the possible parameter combinations lead to exact zero output as the near field is closed by convergence before the waste gets in contact with brine. A logarithmic transformation does not work in this case, as it is not applicable to zero values. Therefore, a specific transformation was applied that seemed more adequate and the performance of the sensitivity analysis was considerably increased.

In the ENRESA granite system it was found useful to include “derived parameters” in the sensitivity analysis. These parameters are combinations of the random input parameters of the model that are suspected to have a strong effect on the system behaviour (on the basis of expert experience). Derived parameters should be identified at the beginning of the sensitivity analysis and treated in the same way as the random input variables through the analysis, keeping in mind that they are correlated with some input parameters.

As a general finding, the correlation-based and regression-based sensitivity analysis methods performed well on most of the investigated systems. In most cases, rank-based evaluation performed better than the value-based evaluation since the systems show a monotonic but non-linear behaviour.
Non-parametrical statistics (Smirnov test, Mann-Whitney test and t test) were applied to some of the systems. The parameter rankings obtained by these tests sometimes differ from those calculated with regression or correlation methods, which is due to the principally different mathematical ideas they are based on.

Graphical methods (scatter plots, cobweb plots and Contribution to the Sample Mean plots) were found to provide a good means for analysing and presenting the sensitivity of models to individual input parameters (see also Section 7 of this report).

Different sampling methods (Simple Random Sampling, SRS and Latin Hypercube Sampling) were investigated in the Spanish investigations, but no significant influence of the sampling strategy was identified. SRS is preferred for practical reasons: several samples can be combined to obtain a sample of greater size. Sample sizes up to 25,000 were investigated and it was found that the results of correlation-and regression-based methods became sufficiently robust with samples of about 5000.

6.1.4 Sensitivity Analysis of Complex Models

This section deals with two particular issues that have been evaluated in PAMINA WP2.1D: the potential for the use of metamodels (i.e., a mathematical function fitted to the results of a few full simulations) to perform sensitivity analyses for complex models that take a lot of computer time to run [Iooss and Marrel 2008]; and the use of this approach to undertake sensitivity analysis of models with a functional input (e.g. a geostatistical model that produces a random spatial field) rather than a scalar input [Iooss 2008].

[Iooss and Marrel 2008] derive a Gaussian process metamodel that provides a simple analytical formula for the output of a complex computer code (a 3-D model of $^{90}$Sr transport around a radwaste storage site). The Gaussian process metamodel is developed to fit the results of a limited number of simulations of the complex code, working on a similar principle to geostatistical kriging techniques that interpolate the value of a random field at an unobserved location from observations of its value at nearby locations. The Gaussian process metamodel can then be used to derive analytical expressions of the Sobol indices for the complex code, thereby allowing sensitivity analyses to be undertaken for the complex code without running a large number of simulations.

[Iooss 2008] proposes a joint modelling approach whereby the mean and the dispersion of the complex code outputs are meta-modelled using two interlinked Generalised Linear Models (GLM) or Generalized Additive Models (GAM). The meta-model of the mean allows the sensitivity indices of scalar input variables to be estimated, while the meta-model of the dispersion allows the sensitivity indices of functional input variables to be estimated.
6.2 Subjective Formalisation of Uncertainty in Calculations

As discussed in Section 5, PAs include a wide variety of uncertainty types. Alternative approaches may be required when selecting a proper mathematical model for an individual uncertainty. [Vetešník 2008] reviewed interval analysis, [stochastic] probability theory, and subjective probability theory approaches to the treatment of uncertainty.

Interval analysis is intended to estimate the bounds of conditional model solutions (the best and worst case scenarios) and is designed for cases where the distribution of the probability structure of a variable is not known. Where the structure is known, standard probability theory can be used, representing the uncertainties using probability distributions. The model solutions also form a set of probability measures, and the probability of the model solution is usually approximated by means of Monte Carlo simulations.

PA often requires investigation of the consequences of rare events for which limited data are available. The lack of information may adversely affect the application of the probability model of uncertainty. Where only limited data are available to define probability distributions, subjective probability theory may be used instead of probability distributions to formalise uncertainty. Such approaches use a measure of subjective confidence – the degree to which it is believed that the statement is supported by the available evidence:

- The random set approach uses the idea of obtaining degrees of belief for one question from subjective probabilities for a related question and a rule describing how such degrees of belief can be combined when they are based on independent evidence.

- By introducing a possibility measure, i.e., the degree of possibility that a parameter takes a certain value, fuzzy sets can be determined from a limited sample of data.

- The transferable belief model (TBM) includes a rule specifying that, where several belief functions are compatible with the available knowledge, the function that gives the minimum support to each proposition should be selected. This approach ensures that no more support is given to a proposition than is justified. Data are given a weighting based on the reliability of the source, such that less reliable data are discounted by a specified factor.

Example – Application of random sets, fuzzy sets and the TBM to defining uncertainty

[Vetešník 2008] presents examples of the subjective probability theory techniques discussed above. More details of each technique can be found in [Oberguggenberger 2005].
Subjective approaches, such as random sets, fuzzy sets and the transferable belief model, allow the uncertainties of rare events to be treated formally within a mathematical structure.

**Example – Use of fuzzy set theory to treat parameter uncertainty where data are sparse**

[Vetešník 2009] presented a model of radionuclide transport in the near-field region of a high level nuclear waste repository in which the uncertainties in retardation of caesium and uranium in bentonite were described, respectively, by a triangular fuzzy number and a log-normal fuzzy number.

### 6.3 Treatment of Spatial Variability

In contrast to engineered systems, the geosphere shows a strong spatial variability of facies, materials and material properties. Although this phenomenon can be interpreted as a specific type of (statistical) variability, it also results in (often considerable) uncertainties when describing and modelling a site and its hydrogeological setting. While the presence / absence of facies and their properties is often known at specific locations (outcrops, exploration boreholes), the remaining larger part of the domain of interest remains unknown. Moreover, reducing uncertainties by means of drilling might result in adverse impacts on the safety functions to be performed by the geosphere and should therefore be planned with caution.

Model assumptions can be made on the basis of borehole and outcrop interpretation, on geophysical measurements, and on “soft” information, e.g., about site genesis. Such assumptions are either made “manually” based on expertise or by using mathematical models describing the evolution of a site. In both cases, however, the remaining uncertainties are not quantifiable. Geostatistical methods provide means for uncertainty quantification but are rather weak with regard to the incorporation of “soft knowledge”. Although it is recognised that the utilisation of geostatistical methods in hydrogeology might contribute to a consistent treatment of uncertainties in probabilistic safety assessments, most existing PAs are still based on manually-derived hydrogeological models.

**Example – Geostatistical treatment of spatial variability in PA**

Some attempts to utilise geostatistical methods in PA models have been undertaken (e.g., [LaVenue et al. 1992]; [Zimmerman et al. 1998]; [Jaquet et al. 1998], [Jaquet and Siegel 2006]; [Röhlig et al. 2005]; [Srivastava 2007]). These and other examples are compiled and compared in [Plischke and Röhlig 2008]. The problem of including a geostatistical model (that produces an input to the PA based on a random function rather than a simple value) in a sensitivity analysis is evaluated by [Iooss 2008] and discussed in Section 6.1.4.

Hydraulic conductivity upscaling is a process that transforms a grid of hydraulic conductivity defined at the scale of the measurements, into a coarser grid of block
conductivity tensors amenable for input to a numerical flow simulator. The need for upscaling stems from the disparity between the scales at which measurements are taken and the scale at which aquifers are discretised for the numerical solution of flow and transport. The techniques for upscaling range from the simple averaging of the heterogeneous values within the block to sophisticated inversions.

Example – Upscaling of flow parameters
[Rodrigo-Ilarri and Gómez-Hernández 2007] reviewed the following methods for upscaling of hydraulic conductivities: local techniques; non-local techniques; block geometry; and direct block-conductivity generation. Examples of each method are provided in the review.

The classic advection-dispersion equation (ADE) for solute transport in a porous medium assumes the dispersive solute flux follows a Fickian or diffusion-like law. Dispersion is linearly related to the advective velocity. However, although this relationship is supported by several theoretical models and verified under well-controlled laboratory conditions, dispersion is known to display a scale sensitivity. Variations in fluid velocity take place at the pore scale, and at larger scales. For example, at the field scale, geological structures can influence contaminant transport drastically, leading to velocity variations over several orders of magnitude. Because dispersivity is related to the variability of the velocity, neglecting or ignoring the true velocity distribution (i.e., by replacing the heterogeneous medium by an equivalent homogeneous one) must be compensated for by a corresponding higher apparent (or effective) dispersivity. Whereas typical values of dispersivity from column experiments range between 0.01 and 0.1 m, values of macroscopic dispersivity (or macrodispersivity) are in general three to four orders of magnitude larger. It has also been widely observed that field-scale dispersion coefficients increase with distance and with time [Rodrigo-Ilarri and Gómez-Hernández 2007].

Example – Upscaling of transport parameters under the Fickian approach
[Rodrigo-Ilarri and Gómez-Hernández 2007] reviewed how transport parameters and in particular, longitudinal dispersivity, can be upscaled based on different characterisation methods for heterogeneous permeability fields. The major assumption that has to be drawn in this framework is that the classical Fickian transport model remains valid at every scale of interest. The approach is equivalent to considering a macroscale volume of rock/soil and deriving equivalent macroscale flow and transport parameters. Three approaches are reviewed: stochastic theory; fractal geometry; and inclusion models. The stochastic method is relatively popular but is limited to low permeability variability. It also needs a statistical characterisation of the permeability field requiring large amounts of data, that are generally not available in field-scale problems. The fractal method does not require an assumption of low variability, but it basically requires a similar level of characterisation as the stochastic approach. The inclusion approach allows the derivation of apparent dispersivity values for highly heterogeneous media. However, the main limitation of this approach is that diffusive and local-scale dispersive transport are not considered, which might induce a serious bias when considering media with low permeabilities.
The scale dependency of dispersivity is typical of “non-Fickian” transport. Deviations from the classical ADE behaviour are commonly observed, particularly in natural systems. While the ADE can treat “homogeneous” porous media under some conditions, such homogeneity rarely, if ever, exists. The heterogeneity of natural geological formations at a wide range of scales can necessitate consideration of more sophisticated transport theories. The high degree of variability in these heterogeneities rules out, a priori, the possibility of obtaining complete knowledge of the pore space in which fluids and contaminants are transported. Further, contaminant migration is sensitive to heterogeneities at all scales - small-scale heterogeneities can significantly affect large-scale behaviour. The issue of “homogenisation” arises – at what scale does the effect of heterogeneities simply average out and become insignificant? Transport can be considered to be anomalous, or non-Fickian, when the contaminant encounters, at each scale, a sufficiently broad spectrum of velocities and stagnant areas resulting from the heterogeneities.

Example – Upscaling of transport parameters under the non-Fickian approach
[Rodrigo-Ilarri and Gómez-Hernández 2007] show measurements of tracers in "homogeneous", meter-length flow cells that display “anomalous” early time arrivals (i.e., later than Fickian) and late time tails. Detailed analysis shows that the motion and spreading of the chemical plumes are characterised by distinct temporal scaling; that is, the time dependence of the spatial moments does not correspond to a normal (or Gaussian) distribution. In Section 2 of [Rodrigo-Ilarri and Gómez-Hernández 2007], a Continuous Time Random Walk (CTRW) approach to representing such transport phenomena is discussed. Other approaches of volume averaging, stochastic and alternative effective transport formulations (multirate mass transfer, fractional derivative equations) are discussed in Sections 3 and 4 of [Rodrigo-Ilarri and Gómez-Hernández 2007]. The authors consider that the CTRW framework represents a powerful and effective means to quantify transport in a wide range of porous and fractured media.

6.4 Fully Probabilistic System Assessment

Amongst PAs using probabilistic approaches, there is wide variation with regard to the nature and range of uncertainties being addressed by probabilities or probability density functions. In fact, it is rarely the case that “all” uncertainties are addressed probabilistically (“all” meaning not all uncertainties which exist but all uncertainties accounted for in the assessment). PAs where more than one scenario and/or more than one modelling alternative is assessed without assigning probabilities to these scenarios or models can be considered an assessment using a “combined” (deterministic-probabilistic) approach.

The idea of performing “fully” probabilistic assessments for radioactive waste disposal programmes was promoted as early as the 1980s. Since then, a number of assessments has been carried out in different regulatory environments and by different organisations under the labels “Total System Simulation”, “Environmental system simulation”, “System Simulation Approach”, or “Probabilistic System(s) Assessment
(PSA)”, in which the idea of accounting for all uncertainties by means of probabilistic approaches has been implemented to a varying extent. For example:

- The “Dry Run 3” exercise [Sumerling 1992] carried out by the UK HMIP in the early 1990s represented an early attempt to perform a fully probabilistic assessment.

- Assessments carried out by the US Department of Energy (USDOE) in support of the applications for certification [USDOE 1996] and re-certification [USDOE 2004] of the Waste Isolation Pilot Plant (WIPP) and of the license application for the Yucca Mountain Repository [USDOE 2008] adopted a particular approach to deal with aleatory and epistemic uncertainty in probabilistic assessment.

- The Swedish SR-Can assessment published by SKB in 2006 [SKB 2006a] considered a risk criterion using an assessment approach in which deterministic and probabilistic methods were combined and is, compared to other recent European assessments, one rather heavily relying on probabilistic techniques.

**Example - Fully probabilistic system assessment**

Under WP2.2E of PAMINA, an integrated approach to a fully probabilistic safety assessment has been developed and tested by [NAGRA 2010]. The approach considered the Swiss disposal concept for spent fuel and higher activity wastes in clay. Parameter, model, and scenario uncertainties were addressed using probabilities or PDFs in the case of co-existing phenomena, but alternative conceptualisations were addressed using weighted branches of a logic tree.

[ENRESA 2009] performed a simplified PSA using the GoldSim code for the same disposal concept, to provide a set of results complementary to the more detailed calculations done by [NAGRA 2010]. A 2D GoldSim model was developed for each of the five different waste types, by representing the length of disposal tunnel and the fraction of host formation that correspond to a single waste package. In addition, simplified 1D models were created. Probabilistic calculations of 1000 runs were undertaken, and mean doses over time and by radionuclide were presented. The results from the 1D and 2D models were similar, with the less realistic 1D models being more “conservative” in that the doses arose earlier and peak doses were slightly higher.
7 Communication of Uncertainty

7.1 Introduction

The methods used for the communication of uncertainty depend to a large degree on the audience and its associated needs and level of knowledge. There are significant risks with poorly-focused communication in that the messages will not be understood and/or that the PA results will be mis-interpreted or mis-used. Despite this, it is apparent from the responses to the WP1.2 questionnaires (Appendix A) that only a few waste management programmes have gone as far as commissioning research into different approaches to communicating uncertainty.

Key audiences for PA results and associated uncertainties include:

- Internal project staff, who might use the PA in design and to focus future work.
- Programme managers, who might use PA results and uncertainties in decision-making on options and programme direction.
- Regulators, who will compare results and associated uncertainties against regulatory requirements.
- Other stakeholders, including the public, who may be interested in particular issues or who may not have a technical understanding but are interested in top-level messages.

Each audience wants information for particular purposes and, consequently, would prefer it communicated in a particular manner. The regulatory audience is considered in Section 8. Below, the work in PAMINA is considered in terms of a technical audience, which might include project staff, managers and regulators, and a non-technical or lay audience.

7.2 Communication to a Technical Audience

According to SKB’s response to the WP1.2 questionnaire, a variety of methods has been used to communicate assessment outcomes in Sweden, although no best method has been identified. The following examples of good practice from [SKB 2006a] (SKB TR-06-09) are quoted:

- Data uncertainty as simple box and whisker plots or cumulative distribution functions, see e.g. Figures 9-25 and 9-30 of SKB TR-06-09.

Figure 8 shows a simple box and whisker plot from [SKB 2006a] showing the median and distribution (in terms of percentiles) of a range of values.
Figure 8: Example of a “box-and-whisker” plot showing the travel time of particles released at 2,020 AD, 3,000 AD and 9,000 AD [SKB 2006a]. The statistical measures are the median (red), 25th and 75th percentile (blue bar) and the 5th and 95th percentile (black “whiskers”).

Figure 9: Box and whisker plot construction proposed by [Bolado and Badea 2009]. Box shows the range between the lower quartile (Q₁), the median, and the upper quartile (Q₃). The length of the “box” is the interquartile range (IQR = Q₃-Q₁). Outliers are also shown, being any data that lies outside the interval \([Q₁ - 1.5 \times IQR, Q₃ + 1.5 \times IQR]\).
Use of box and whisker plots is also advocated by [Bolado and Badea 2009] (Section 4.3) and [Iooss and Devictor 2008] (Section 4), as they communicate the range of uncertainty easily and can be used to compare alternatives or different sets of calculations readily. However, [Bolado and Badea 2009] and [Iooss and Devictor 2008] propose a slightly different construction of the plot to that shown in Figure 8 to show extreme outlier values that fall outside the percentile ranges (Figure 9).

In constructing plots such as Figure 8 and Figure 9, therefore, it is important to be clear about what is presented and to consider what the audience wants. Section 9.3 of [Morgan and Henrion 1990] presents a study of ways to communicate uncertainty in a single variable and finds, perhaps unsurprisingly, that the presentation styles that explicitly contain the information that people need perform best. For example, in making a judgement about the location of the “best estimate” in a display of probability density, people show a tendency to select the mode rather than the mean unless the mean is explicitly marked.

- Output data uncertainty for a particular calculation case as percentiles of dose as a function of time, see e.g. Figures 10-16 and 10-17 of SKB TR-06-09.

Figure 10: Result of the probabilistic base case calculation of the pinhole failure model for Forsmark [SKB 2006a], as an example to illustrate the presentation of a variable over time in terms of the mean, median and percentiles. The 1st and 5th percentiles are both zero on this plot and are therefore not shown.
- **Impact of conceptual uncertainty as comparisons of mean values as a function of time of probabilistic calculation results using different assumptions, see e.g. several Figures in section 10.5.7 of SKB TR-06-09.**

![Figure 11: Example of a plot comparing alternative hydrogeological interpretations of the Forsmark site [SKB 2006a]. Lines represent the means from probabilistic simulations using each model.](image)

- **A clear verbal description/interpretation of the results is often more important than the particular technique used when presenting the numerical results.**

A template for consistent presentation of the main characteristics of PA results and/or performance indicators to the technical community is reported as part of WP2.1B by [Bolado and Badea 2009] (Section 7). Sets of statistical indicators (as defined and explained in [Bolado and Badea 2009]) are proposed for presenting the uncertainty and sensitivity analyses for time-dependent and non-time-dependent variables, dividing each sets into suggested and optional indicators. Suggested indicators are considered to provide essential information, while optional indicators are those that are considered to provide complementary information. In some cases, the reason for considering some indicators as optional is to avoid providing too much either overlapped or redundant information, in order to keep a moderate report size. In the opinion of [Bolado and Badea 2009], suggested statistics should always be provided, while analysts have to decide what optional statistics have to be included in order to provide additional relevant pieces of information about the output variables and the system under study.

For non-time-dependent output variables, the suggested quantitative indicators (presented in tables) for uncertainty analysis are the mean and standard deviation, a selection of quantiles (at least 1% and/or 5%, median, 95% and/or 99%), the skewness
coefficient and the kurtosis. For a graphical indicator, [Bolado and Badea 2009] propose the use of the Empirical Cumulative Distribution Function (ECDF), with optional consideration of PDFs and box and whisker plots.

For the sensitivity analysis of non-time-dependent output variables, suggested quantitative indicators are Standardised Regression Coefficients (SRCs) and Standardised Rank Regression Coefficients (SRRCs) and their respective coefficients of determination ($R^2$), first-order sensitivity indices calculated via correlation ratios, and Smirnov and/or Mann-Whitney statistics based on any meaningful rule to divide the output sample (null/non-null observations, 10%/90%). For graphic indicators, the use of cobweb plots and contribution to the sample mean plots (CSM plots) is proposed while scatterplots should only be used to highlight or support specific findings.

For time-dependent output variables, similar sets of indicators are advocated, but reported as plots of the uncertainty or sensitivity indicator versus time. Plots are always preferred because they summarise information in an optimal way. Nevertheless, when the natural scale of the ordinate axis (y axis) is logarithmic, providing the information in tables for specific times may also be considered, owing to the difficulty of estimating a value given in such kind of scale. This is the case, for example, of means, standard deviations and quantiles evolving over time.

**Example – Presentation of sensitivity / uncertainty analyses**

Section 8 of [Bolado and Badea 2009] applies the proposed template for the presentation of uncertainty and sensitivity analyses to the dose rates from $^{129}$I for the Spanish reference disposal concept for spent fuel in granite.

### 7.3 Communication to a Non-Technical Audience

In the UK, research has been commissioned by Nirex (now the NDA) and other government agencies on the question of how best to communicate risk and uncertainty associated with radiation exposure and repository PA. The overall conclusion from research carried out for the UK Food Standards Agency [FSA 2003; FSA 2004] was that the appetite of the public for information on individual dose/risk exposures is small, and that a non-technical audience poorly understands the concept of dose.

With respect to how best to communicate uncertainties in assessments, Nirex states that:

“…the regulatory guidance in the UK leads the developer to a probabilistic approach, so such an approach is of most value in communicating the uncertainties to the regulators.

*Scientific uncertainty can undermine public confidence in environmental and technological projects. However, one of the ways that scientists can undermine confidence in their work is by maintaining an exaggerated sense of certainty. Therefore, it is important to be open and honest about uncertainty, and to*
explain how it is managed and why it is still possible to have confidence in the assessments and the proposed facility.

Explicitly stating the uncertainties associated with assessments will enable stakeholders to develop more informed responses to the situation. It will also help them to engage in the debate and feed back important information about their issues of concern. This could influence the scenarios that are assessed or enable measures to be put in place to lessen the socio-economic impacts of any uncertainties or risks.”

As part of PAMINA WP2.1B, a stakeholder panel consultation concerning the communication of uncertainty was undertaken in the UK [Hooker and Greulich-Smith 2008]. The workshop was attended by fourteen participants drawn from local authorities and stakeholder groups with interests in radioactive waste management issues. The workshop focused on presentation of safety issues in general, rather than PA results. However, several styles of presentation were tested using posters and videos. The conclusions reinforce the points made above that the lay audience is not generally interested in technical detail, but it is important to be clear that uncertainties exist.

Example – Presentation of PA and safety arguments to a non-technical audience
Section 2.2 of [Hooker and Greulich-Smith 2008] presents five posters containing different types and styles of messages on the safety of geological disposal. Sections 2.2 and 2.3 and Appendices D and E of [Hooker and Greulich-Smith 2008] summarise the critique of the posters by the workshop participants.

Poster 1 – Multiple Barrier Systems for ILW and HLW.
Poster 2 – Repository Systems in Practice.
Poster 3 – Transport and Repository Operations.
Poster 4 – Learning from Nature.
Poster 5 – Post-closure Safety.

[Hooker et al. 2009] describes the results of an exercise to use a series of brochures to communicate about safety to lay audiences in the UK and Slovenia.

With regard to the communication of uncertainty in particular, the following points came out of the workshop:

- The posters tended to contain too much text and technical detail. Communication via a poster should focus on one key issue, stating what is known and being clear about the uncertainties. One lesson learnt from the workshop is that graphs (presented in posters) can cause people problems, as they can be difficult to understand. Different graphical types (logarithmic and linear axis scales, bar charts, pie charts) were tested and none fared well. Therefore, graphs should only be used with care.

- While communication of basic technical information (describing radioactive wastes, where it comes from, the nature of radioactivity, and the need for
geological repository) was considered necessary, key safety issues, uncertainties and knowledge gaps that become apparent when having to consider repository performance over hundreds of thousands of years should also be presented.

- Communication methods should be aimed at today’s young people and should be modern and forward-looking, using the latest technology.

- Making predictions of how UK climate and society are likely to evolve over the next million years was recognised by participants as being difficult. Participants felt that members of the public would be mainly concerned with the next hundred years or so. However, it was considered important to address a vision of the future in a safety case, and to describe how a geological repository would evolve in the far future. In this respect, participants tended to feel that examples from nature (natural analogues) were potentially useful to illustrate the processes and explain long-term issues.

- Particular attention may need to be given to how uncertainties that are in the news, such as human-induced carbon dioxide emissions and climate change impacts, are addressed.

ARGONA (Arenas for Risk GOverNAnce) is an EC project that aims to demonstrate how transparency and public participation can be achieved in radioactive waste management programmes as part of a process of effective risk governance. Approaches to risk communication have been evaluated through interviews and focus group discussions. CIP (Cowam In Practice) assists participating countries to make progress in the national governance of radioactive waste management, and aims to increase societal awareness of, and accountability for, radioactive waste management. A ‘Methodological Task Force’ (MTF) prepares research briefs on issues identified by National Stakeholder Groups (NSG) in France, Romania, Slovenia, Spain and the UK. The research briefs are then presented to the relevant NSGs for discussion and iterative learning. While both ARGONA and CIP tend to consider overall safety, rather than the specific issue of uncertainty, several lessons for presentation of uncertainty in the context of the safety case can be drawn [Richardson and Galson 2009]:

- In the public mind, safety is often about what WILL affect me, my family, my neighbours (e.g., transport, construction, operational impacts) and less about what MIGHT impact society in the far future.

- “Soft” messages can be used to build confidence, for example, concern-driven risk management (versus “risk-informed”), a listening culture, community involvement in defining research programmes, stepwise programme development, and a strong and independent regulator acting on behalf of the public and deciding based on application of well-justified regulatory criteria.

- Messages may be received more strongly through small group one-on-one discussions, as opposed to larger, more impersonal public meetings or written material.
• If the messenger (an individual) is trusted, the message is more likely to be accepted, even if the institution is not fully trusted.

• Joint fact-finding or information-gathering panels involving developer and community personnel can be influential in building trust and confidence in waste management organisations.
8 Regulatory Decision-Making and Uncertainty

The uncertainties present in PAs and safety cases for geological repositories present problems for any system of regulation that may be used to license such facilities. Lack of consideration or mismanagement of uncertainties by repository developers can seriously impact regulatory compliance. The regulatory regimes operating in some of the participating countries therefore contain specific requirements for the treatment of uncertainties in PA and in safety cases.

We summarise here the status of regulation specific to geological repositories and the treatment of uncertainty (Section 8.1) and – based on the review and a workshop conducted under PAMINA [Hooker and Wilmot 2008] – conclude with general observations on the approaches that can be taken in regulatory guidance and legislation (Section 8.2) and how the treatment of uncertainty in PA can be considered in regulatory review and decision-making (Section 8.3).

8.1 Status of regulation specific to geological disposal

8.1.1 International Context

A European Pilot Study on the Regulatory Review of the Safety Case for Geological Disposal of Radioactive Waste has been established on the basis of agreement between several European regulators. The Pilot Study seeks to consider jointly how issues raised in implementing geological disposal facilities can be addressed in regulation. A case study considering the treatment of uncertainties in safety cases for geological repositories has recently been published, based on co-operative work between regulators in Belgium, France, Germany, Switzerland, and the UK [Vigfusson et al. 2007].

In addition, the International Atomic Energy Agency (IAEA) is taking an increasing interest in the establishment of safety requirements and guidance directed towards the disposal of radioactive wastes. For example, the IAEA has recently published Safety Requirements on geological disposal of radioactive waste [IAEA 2006a].

Finally, regulatory development is also being assisted by the NEA, which, among other things, sponsored a workshop in Stockholm in 2004 [NEA 2005] that considered issues of uncertainty and risk in regulation. The Regulators’ Forum of the NEA Radioactive Waste Management Committee has been conducting an initiative on long-term safety criteria and recently issued a report titled “Regulating the Long-Term Safety of Geological Disposal: Towards a Common Understanding of the Main Objectives and the Bases of Safety Criteria” [NEA 2007b].

8.1.2 National Developments

There is wide variation in the development of regulation covering the treatment of uncertainty for geological disposal of radioactive wastes, with the more advanced
countries having developed regulations and some countries that are still at the concept development/feasibility stage having no specific regulation yet. We provide below several examples, first of more detailed regulation, followed by several examples of programmes that are at a more variable level of regulatory development.

In the UK, where the programme is at the first stage of site selection, the regulators have set out guidance on the principles and requirements against which any application for authorisation of a radioactive waste repository will be assessed (the Guidance on Requirements for Authorisation, the GRA) [EA and NIEA 2009]. The GRA includes four principles and eleven requirements covering all aspects of the design, construction, operation and closure of a radioactive waste repository. In particular, for the period after authorisation (i.e., at the withdrawal of institutional controls), the GRA states that: “…the assessed radiological risk from a disposal facility to a person representative of those at greatest risk should be consistent with the risk guidance level of $10^{-6}$ per year …” The term “assessed radiological risk” corresponds to the product of the estimated effective dose that could be received, the estimated probability that the dose will be received, and the estimated probability that detriment would occur as a consequence to the person exposed. The GRA also makes a distinction between quantifiable and unquantifiable uncertainties, noting that some scenarios will involve future events (such as intrusive human actions) so uncertain that it is not appropriate to undertake risk assessments for comparison with the risk guidance level. The GRA proposes that deterministic what-if-type calculations can be undertaken for such scenarios and that such calculations should be given separate consideration in the safety case.

In Finland, where the programme has advanced to the repository construction stage, specific regulatory guidance was given as part of the government decision in favour of the POSIVA programme in 1999. This guidance establishes that a safety assessment shall include uncertainty and sensitivity analyses and complementary discussions of such phenomena and events that cannot be assessed quantitatively. The regulatory approach in Finland also endorses the idea of using conservative modelling assumptions so as to provide a high level of confidence that potential future radiological exposures are over-estimated.

In Switzerland, HSK-G03 requires the implementer to reduce uncertainties as far as necessary, to outline systematically the influence of the remaining uncertainties on the modelling results, to use conservative assumptions and comprehensive scenarios, and to show by means of sensitivity analyses how uncertainties influence the conclusions concerning repository safety.

In the US, specific and comprehensive regulation has been implemented for the licensing of the WIPP [USEPA 1993; 1996a; 1996b]. These regulations provide the developer a detailed, prescriptive path for the conduct of supporting assessments, and include the assessment period to be covered (10,000 years), limits on the cumulative release of radionuclides to the accessible environment, assumptions to be used in assessing particular Features, Events and Processes (FEPs), and requirements on the treatment of uncertainties. In addition to complying with radionuclide release limits, the WIPP must comply with individual and groundwater protection standards.
The EPA and the NRC have developed the standards that would have applied to the disposal of HLW and SF in the potential repository at Yucca Mountain (40 CFR Part 197 and 10 CFR Part 63). These standards differ from those that apply to the WIPP in that the main assessment endpoint is ‘critical group’ dose to an individual member of the public, rather than cumulative release of radionuclides. In the Supplementary Information published with the rule, the NRC has stipulated the application of a probabilistic framework for total system performance assessment (TSPA):

“The strategy used to demonstrate long term safety may include a number of approaches, including, without being limited to:
1. Scoping assessments to illustrate the factors that are important to long term safety;
2. Bounding assessments to show the limits of potential impact;
3. Calculations that give a realistic best estimate of the performance of the waste management system, or conservative calculations that intentionally over-estimate potential impact; and
4. Deterministic or probabilistic calculations, appropriate for the purpose of the assessment, to reflect data uncertainty. (Section 5.2 of G-320)

Probabilistic models can explicitly account for uncertainty arising from variability in the data used in assessment predictions. Such models may also be structured to take account of different scenarios (as long as they are not mutually exclusive) or uncertainty within scenarios. (Section 5.2.3 of G-320)

The need to evaluate the uncertainty in the assessment model through deterministic sensitivity analyses or through probabilistic calculations is determined by the level of confidence needed in the model results. The acceptable level of confidence is governed by the purpose of the assessment, the safety factor built into the acceptance criteria for safety indicators, and the importance of the assessment model results to the safety case... (Section 7.6.3 of G-320)

...Model evaluation should include sensitivity analyses to show whether the model output responds as expected to variations in the model input parameter values. Model evaluation should also include uncertainty and importance analyses to show which parameters control the variability in model output. These analyses should demonstrate how well the model replicates what is known and understood about the processes and mechanisms being simulated... (Section 7.6.3 of G-320)

...Neither sensitivity studies nor uncertainty analyses of deterministic or probabilistic models can inherently account for uncertainties in the underlying conceptual model, or uncertainties resulting from limitations of the mathematical model used to describe the processes. Investigation of such uncertainties would require the use of different mathematical and computer models based on alternate conceptual models. Confidence in the assessment model can be enhanced through a number of activities, including (without being limited to):

1. Performing independent predictions using entirely different assessment strategies and computing tools;
2. Demonstrating consistency between the results of the long term assessment model and complementary scoping and bounding assessments;
3. Applying the assessment model to an analog of the waste management system;
4. Performing model comparison studies of benchmark problems;
5. Scientific peer review by publication in open literature; and
6. Widespread use by the scientific and technical community. (Section 7.6.3 of G-320)”

In France, the regulatory framework for geological disposal is based on guidance published by the Nuclear Safety Authority (ASN), among which the revised Basic Safety Rule n°III.2.f [ASN 2008]. This guidance document includes the major regulatory expectations with respect to the characteristics of the host rock, the choice of the site, the design, and the safety assessment. The philosophy that informs the regulatory regime has its source in engineering disciplines where there are highly
developed techniques for dealing with ‘risk’. In the ‘Dossier 2005’ [ANDRA 2005], a scheme was used by ANDRA for treating uncertainties through the safety case by referring to the notions of risk analysis, known as ‘qualitative safety analysis’ (AQS).

In Belgium, the regulator (FANC) has recently issued guidance on the management of license applications, which contains safety principles that apply to any disposal facility for radioactive waste in Belgium [FANC 2007]. FANC is currently developing more detailed guidance for near-surface disposal facilities that will be issued in the next two years. The development of more detailed regulatory guidance for geological disposal facilities for high-level waste is also planned, and will be based in large part on the guidance developed for near-surface disposal facilities.

In July 2009, BMU (Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit) in Germany published safety requirements governing the disposal of heat-generating waste in geological disposal facilities [BMU 2009]. At the request of the Federal States (Länder), BMU will discuss these requirements with the Federal States before setting them into force.

The programme in Spain is at the stage of general feasibility studies, and so far there has been only limited regulatory development for geological disposal. Currently the only regulatory criteria established are that the individual equivalent effective dose does not exceed $10^{-4}$ Sv/y, or that the individual annual risk does not exceed $10^{-6}$. There are no specific requirements on the treatment of uncertainty.

8.2 Regulatory approach to the treatment of uncertainties in PA

As summarised above, regulatory requirements on the treatment of uncertainties in PAs vary from detailed mandatory requirements in the case of, say, the WIPP project, with the use of a prescribed methodology, to none at all in some programmes still at the concept development stage. In all cases where programmes have developed past the initial stages, regulators accept the need to address uncertainties inherent in PA for geological disposal.

Examination of regulatory approaches towards the treatment of uncertainties in PA delineates the following, potentially overlapping options:


2. Detailed regulatory guidance or “expectations” on treatment of uncertainty; objectives defined only.

3. No particular national guidance yet defined for geological disposal; direct use of international (i.e., IAEA, ICRP) guidance on disposal or reliance on pre-existing regulatory framework.

To a greater or lesser extent, in adopting one or more of these approaches, regulators share the burden of making the safety case for geologic disposal and deciding on PA assumptions and requirements, with approach (1) placing the greatest burden on the
regulator for pre-licensing consideration of uncertainty treatment and the safety case. The advantages of approach (1) are consistency in the standard of assessments, at least in presentational terms, and the clearer framework for planning and dialogue by developers and regulators. The main drawback to adopting prescriptive regulation is that it could narrow the range of likely results and the way in which they are presented, and may bias the outcome of assessments through not considering local factors and excluding the use of better methods.

**Example – Mandatory regulatory guidance**
The regulatory approach adopted for the WIPP project [USEPA 1996a; 1996b] can broadly be placed in category (1). 40 CFR Part 194 prescribes, among other things, the scope of the assessment, how to treat certain phenomena such as mining and drilling, and the presentational format of the results (the timescale of the assessment is specified in 40 CFR Part 191). The WIPP approach is of interest because it represents a highly developed example of its kind, and practical experience has been gathered of its use.

The regulatory approach to treatment of uncertainties that many countries are taking is (2), through the publication of non-binding guidance or “expectations” with respect to scope and methods for performing the assessments, coupled with licensing procedures at local and national levels.

**Example – Regulatory guidance on treatment of uncertainty**
For examples of regulatory guidance in the style of category (2), this approach has been adopted in Canada [CNSC 2006] and the UK [EA and NIEA 2009], and has been discussed in the European Pilot Project [Vigfusson et al. 2007].

Approach (3) is not foreseen anywhere for licensing of deep repositories but, where the implementation of disposal projects is still some way off, specific national regulations may not yet have been developed. The lack of disposal regulation does not stop projects in these countries from undertaking feasibility studies, PA, safety case, and even siting work. This is so for two reasons. First, an increasing number of international requirements and guidance documents specific to geological disposal has become available in the last 10 or so years. In addition, there is a highly evolved system of regulation and guidance for radioactive discharges at international and national level that takes into account the uncertainties present in radiological assessments; applying these regulations in a non-prescriptive way provides a framework for considering releases from a geological disposal facility as well at the feasibility stage.

Approach (3) may also be useful for countries that produce little of their own radioactive waste, where there may be limited expertise and infrastructure for radioactive waste management, but where there is still a need to provide a national site for a geological repository.
Example – International guidance on treatment of uncertainty
The IAEA safety guide on safety requirements for geological disposal of radioactive waste [IAEA 2006a] provides an example of generic guidance for best practice that could be adopted in lieu of specific national guidance.

8.3 Regulatory review of the treatment of uncertainties in PA

Having discussed the regulatory requirements on the treatment of uncertainty, there remains the issue of how regulators review safety cases and PAs and decide on whether uncertainty has been addressed adequately to feed into decision-making. This was covered in a workshop organised under PAMINA WP2.1A [Hooker and Wilmot 2008]. Overall, less emphasis than before is being placed on the traditional comparison between safety assessment calculation results and dose/risk criteria. Best available techniques (BAT), optimisation and safety functions are increasingly being used as alternative safety indicators or additional arguments in a safety case in support of compliance with the regulatory dose/risk criteria and to build confidence in the long-term safety.

Although international harmonisation of dose and risk constraints would be ideal for communication with the public, the practicalities of national contexts mitigate against this being achieved. [NEA 2007b] concludes that the diversity of safety criteria is essentially grounded in societal differences, but that quantitative differences have no significant consequences in terms of radiological impact.

Most regulators at the PAMINA workshop had a desire to match the level of scientific understanding and knowledge of the developer/implementer in order to be capable of performing meaningful reviews of research, development and demonstration (RD&D) programmes, safety cases and license applications. Further, many regulators have taken steps to have modelling capabilities independent of the developers’ capabilities in order to be able to verify the results of the developers’ assessment calculations and to investigate alternative conceptual or physical models.

Example – Regulatory capability for review and assessment of safety cases
See the presentations by Stromberg of SKI and Wanner of HSK in Appendix A of [Hooker and Wilmot 2008] for illustrations of how regulators maintain independent technical and modelling capabilities.

Participants agreed that close dialogue between a regulator and a developer is beneficial to the development of a safety case and a license application, but the dialogue must be controlled and documented and not lead to a compromise of a regulator’s freedom to make decisions.
9 Uncertainty and Needs-Driven Programme Development

There is widespread awareness that identification and management of uncertainties is an iterative process that can lead to a stepwise reduction of uncertainties in PA. However, there are variations in the degree to which this awareness has been translated into concrete elements of programmes.

A powerful tool in the iterative process for evaluating knowledge-based (epistemic) uncertainties in PA is sensitivity analysis. An example of a structured use of sensitivity analyses taking place within a probabilistic assessment framework is provided by the WIPP project (US) (see Appendix A15):

“During late site characterization and early Performance Assessment development, the project performed a systems prioritization where Performance Assessment tools were used to determine the sensitivity of parameters under investigation to Performance Assessment outputs. This information was used to prioritize experimental and other site characterization work that was ongoing with the intent of developing or justifying Performance Assessment parameters. Highly sensitive elements were given priority while less sensitive elements were reduced or eliminated. This prioritization resulted in better management of resources and expedited the final Performance Assessment and compliance certification application.

After the site was operational, sensitivity assessments, operational efficiency changes and other drivers led the project to investigate many Performance Assessment related elements such as ground water level anomalies in the WIPP vicinity and refinements in models and computer codes to increase efficiencies and assess changes to the repository designs. This type of information is necessary for periodic compliance recertifications and change requests."

The emphasis here is on reducing knowledge-based (epistemic) uncertainties through further investigations, model refinement, and consideration of repository design modifications. Other programmes, such as that from Germany, place a greater emphasis on reducing uncertainties through engineering design. In choosing a strategy, factors to weigh will include “how reducible” the uncertainties are, the likely effectiveness of engineered solutions, and costs associated with both strategies. In addition, for an operational repository such as the WIPP facility, some aspects of the design will be frozen, and there is less scope for design modifications.
Example – RD&D programme in Sweden
The Swedish waste management company, SKB, is required to submit a programme for research, development and demonstration (RD&D) to the regulators every three years. The programme is reviewed and circulated widely for comment. The focus of the programme varies depending on the emphasis in SKB’s activities at the time. The 2007 programme [SKB 2007] was focused on technological development to support applications for a geological disposal repository. Tables 19-1 and 19-2 of [SKB 2007] illustrate how R&D in the area of safety assessment is focussed on the initial states and processes of importance to long-term safety. Prioritisation of issues is based on whether the results should make a crucial difference in the assessment of safety (either positive or negative) and when the issues have to be resolved to the point that agreement to proceed with the next stage of the project can be made.

Example – R&D programme in the UK
In the UK, the Nuclear Decommissioning Authority (NDA) identifies information needs and prioritises R&D to fulfil these needs through measurements of impact on safety and/or delivery and the “readiness gap”, which is the gap between current knowledge and that which needs to be acquired [NDA 2009]. The figure below illustrates the scope of work required to meet R&D needs for these two measures.

As a relative measure of the readiness gap, the NDA is working to assign Technical Readiness Levels (TRLs) to the topics in the R&D programme. The TRL is a management tool originally developed by NASA and used extensively in US and UK government organisations.

In the responses to the WP1.2 questionnaire in Appendix A, there is a wide variation in what are considered key uncertainties in different programmes. Uncertainties on a broad range of performance measures are cited as having the potential to impact the
progress of projects. Much of this variety arises out of the different stages that programmes are in their development and the diverse range of repository concepts and host rock formations in the programmes. However, almost no organisations identified uncertainties that may challenge programmes, suggesting a high level of confidence in respondents’ ability to site and design geological disposal facilities so as to manage uncertainties effectively. Respondents variously identified the engineered barrier system, the geosphere, the biosphere, and future drilling activities as key sources of uncertainty that require further investigation. This range may also point to the need for objective methods for determining where dominating uncertainties arise in the PA.
10 References


[ONDRAF/NIRAS 2007] ONDRAF/NIRAS, *Selection and Description of Scenarios for Long-term Radiological Safety Assessment – NIRAS-MP4-02 Version 1, NIRONDT-TR 2007-09 E*, February 2008. [Note that this report is currently undergoing revision; the revised version will be available in 2011.]


Appendix A – Completed Questionnaire Responses

This appendix presents the responses by organisations to the questionnaire circulated under WP1.2 [Galson and Khursheed 2007]. The responses are structured around 15 questions set out in the questionnaire concerning the treatment of uncertainty in the radioactive waste management programme of each organisation. Note that the responses were produced in 2006/2007 and there may have been significant changes in programmes (e.g., in administrative issues, organisational responsibilities or legislation) since then. Such changes are not reported here.

A1 Belgium – AVN (from April 2008: Bel V)

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1. What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?

After the publication of its SAFIR 2 report in 2002, ONDRAF/NIRAS decided to change the nature of its milestone reports for the high-level and long-lived radioactive waste management programme from a state-of-the-art report (SAFIR, 1989 and SAFIR 2, 2001) to a safety case type of report. The publication of the safety and feasibility case report 1 (SFC1) is planned for 2013. At that moment ONDRAF/NIRAS will officially submit its SFC1 to the institutional stakeholders (supervising minister and possibly the safety authorities). A national and/or international review of SFC1 after its submission to the authorities is possible.

The objective of the SFC 1 is to substantiate that, for a defined zone in the Boom Clay and for all currently foreseeable B&C waste streams considered in the Belgian program, the proposed disposal system:

1. has the capacity to ensure operational safety and passive long-term safety,

2. is judged to be feasible.

It should also substantiate that the proposed disposal system can be taken forward for further development and optimisation.

Our answers to the present questionnaire are based on the preliminary discussions between Belgian regulators and implementers about the development of the Safety and Feasibility Case 1 by ONDRAF/NIRAS. Due to the preliminary stage of development of the radioactive waste disposal programme, only some of the
2. What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?

Our approach is based on international guidance. Harmonization of basic requirements is directly or indirectly promoted by the working groups and the publications of international organizations such as the IAEA, OECD/NEA or ICRP. The recommendations laid down in the IAEA Safety Series documents play an important role in defining good practice and the IAEA “Joint Convention” (Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management) adds a binding commitment of the Convention Parties to certain basic safety requirements. The publications of the ICRP are influential in establishing common radiation protection standards. The various publications of OECD/NEA in the field of radioactive waste safety offer a good description of the state of the art, the different approaches currently followed and the degree of consensus nevertheless achieved in many fields.

Moreover, a draft document (untitled “A minima requirements on argillaceous sedimentary formations”, ref. [4]) providing a guidance about sitting in argillaceous sedimentary formations for the geological disposal of radioactive waste has been developed. The document states fundamental requirements to be fulfilled by the host formation as well as a guidance on the role to be fulfilled by the environment of the disposal system.

These outcomes are derived from:

(1) the general regulatory framework applicable in Belgium;

(2) the safety approach and related principles of a geologic disposal of radioactive waste;

(3) the specific implementation constraints of repositories in argillaceous formations.

In the document emphasis has been put on three aspects: the fundamental principles (no quantitative “criteria”); the disposal system considered as a whole system; and the safety and feasibility aspects.

The document is foreseen as a living document to be updated by the regulators along the different steps of the siting process. Present potential applications of this guidance are the identification of (a) favourable zone(s) in argillaceous formations in Belgium.

Apart from the preceding considerations, as no specific regulations exist in Belgium...
for the disposal of radioactive waste, there are at the present time no official positions from the regulatory authorities concerning the handling of uncertainties or perturbing phenomena.

3. How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.

In Belgium, the three following types of uncertainties are considered:

1. Uncertainties concerning potential future evolutions of the repository system (i.e. uncertainties about scenario) are addressed by requiring a well-structured procedure for the development of scenarios in order to ensure that a comprehensive set of reasonable scenarios will be considered. A scenario is not always meant to represent a plausible situation, but is designed to encompass various situations that are sufficiently similar. It is also possible to develop “What-if?” scenarios which might allow demonstrating robustness of certain repository components.

2. Uncertainties about models include simplification in the numerical models and numeric solutions. The conceptual, mathematical and numerical models (including codes) to be used in assessments should be developed according to established quality assurance procedures.

3. Uncertainties concerning parameters include both uncertainties concerning the exact value of a parameter at a fixed time and a certain place as well as uncertainties about extrapolation of this value for other times and places.

4. How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.

It is the opinion of FANC/AVN (from April 2008: Bel V) experts that dividing overall periods into different time frames may be very valuable in carrying out safety assessments and in providing safety cases (although it should not be considered as a necessity). Furthermore, it permits to take account of the evolution of uncertainties through time.

When defining the different time frames to be considered, one has to cover all stages of the life of the repository and, in particular, the overall period(s) after closure, at least up to (and even beyond) the peak risk for each of the considered radionuclides. The reasons seen by FANC/AVN (from April 2008: Bel V) experts for dividing overall periods into time frames are to put in evidence, in the presentation of a safety case, that:
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- Appropriate specific arguments (e.g. quantitative, qualitative) and safety indicators (e.g. dose, risk, radionuclides fluxes from the geosphere, …) are used in relation with the uncertainties for the time period considered;
- Overall performance of the disposal system is not unduly dependent on a single safety function and/or safety barrier especially when the potential hazard due to the repository is still high;
- The efforts of investigation envisaged for each time frame are proportional to the potential hazard of the repository. The investigations are relying on a reasonably well-established available knowledge.

The time frames could be defined, among others, on the following basis:
- The validity of prediction of the models;
- The states of the safety functions of the different components of the disposal system;
- The complexity and the possible coupling of physical and chemical processes. The existence of several consecutive processes (for instance in the early times after repository closure) may indeed be in favour of defining a finer division in time frames.

### 5. How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.

According to FANC/AVN (from April 2008: Bel V) experts it is possible, for some scenarios, to compensate the lack of knowledge by considering highly stylised and pessimistic hypotheses in the impact evaluations. In the view of the timescales it is the case for instance of the modelling of the biosphere for any types of scenarios. This aspect is being discussed at the present time between regulators and implementers in Belgium. A stylised approach is also used in the case of human intrusion scenarios.

Thus, examples of stylized approaches comprise the use of reference biospheres for future timescales and use of hypotheses about the constancy of human characteristics. It appears difficult to justify any other choices due to our lack of knowledge about the future.

As concerns integration of uncertainties within models, the way it is to be carried out highly depends on the level of uncertainties: the models and parameters that best reflect the physical reality as can be understood must be distinguished from those.
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intended to provide a pessimistic representation (referred to as 'conservative' or 'penalizing or pessimistic', depending on the degree of pessimism). The model selection strategy is based on the following selection principles:

- in case of low uncertainty, the most scientifically supported model ('phenomenological' model or best estimate model) is selected;
- in case of high uncertainty, a conservative or pessimistic model or value is selected;
- the most simple and robust models are privileged, as long as this choice does not lead to underestimating the impact.

The notion of 'low' or 'high' uncertainty inevitably entails a degree of subjectivity, even though in certain cases it may involve statistical considerations (dispersion of experimental values, level of confidence, etc.). The experts in charge of proposing the models and values discuss decisions regarding uncertainty on a case-by-case basis.

Finally, concerning uncertainties attached to models, it is generally preferred to use simpler, less-sophisticated models than more sophisticated ones that would imply higher uncertainties. This is drastically linked to the demonstrability of long-term safety in order to build the confidence through the different stages of the development programme.

6. What approach to system PA is preferred / appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of “fuzzy mathematics”; others)?

Treatment of uncertainties is generally accomplished by using a combination of scenario variants, conceptual model variants, and parameter variations. It can be undertaken, among other ways, by the use of conventional deterministic or probabilistic uncertainty evaluation tools.

For uncertain parameters, either conservative choices are to be made or reasonable probability density distributions are to be derived. Probability distribution functions are based on collected data, on formal expert elicitations, or on a combination of these two approaches. Where there is no sound distribution for the creation of a probability distribution function, a bounding or conservative single value may be used. Sensitivity studies are performed to help understand the effects of uncertainty.

If the probability of a particular situation can be defined, if not always calculated, it can be much more difficult for a whole scenario. This is especially the case for “What if” scenarios which are not meant to represent a realistic situation but to test
the robustness of the design.

Deterministic approach is the approach mainly considered up to now by ONDRAF/NIRAS in the development of its safety case. This approach is recognized as providing simplicity of interpretation and judgement of the results in the analysis of scenarios or assessment cases.

It is the opinion of FANC/AVN (from April 2008: Bel V) experts that both approaches (deterministic and probabilistic) are however valuable and should be considered when possible as complementary contributions to the safety case. Comparisons show the coherence between a deterministic and a probabilistic approach as long as they rely on the same underlying assumptions. However, the results of a probabilistic calculation, such as a distribution of expected dose, are difficult to use in a context where it is expected that the results of the calculation should be compared to a pre-defined threshold.

Therefore the regulator does not impose a probabilistic or a deterministic approach. Both approaches can be combined. However the regulator often has a preference for deterministic evaluations.

Five types of scenarios could be considered in the safety case (see document [1]):

1. the reference evolution scenario(s) for the foreseeable evolution of the repository with respect to the most likely effects of certain or very probable events or phenomena;

2. The altered evolution scenarios taking into account the least likely effects of these events or phenomena and the consequences of events or phenomena that are not integrated into the reference scenario, as the likelihood of occurrence is lower;

3. The “beyond design limit” scenarios, result of very unlikely events, for which it appears that it is not reasonably possible to thwart the occurrence or the consequences. The consequences are closely linked to the strategy “concentration and containment” selected;

4. The imposed or conventional scenarios that are also known as “what if” scenarios, for which the occurrence of an event or random phenomenon is postulated although it seems possible to exclude it through design or the level of knowledge available;

5. And finally the scenarios relating to human intrusion.
Parameter uncertainty can be dealt with by using sensitivity and uncertainty analysis. In sensitivity analysis, the model input parameters are varied over sensible ranges to determine the effect of these variations on the model result. This increases our understanding of which parameters have to be determined with the greatest accuracy, and thus helps prioritise data collection requirements.

Sensitivity analysis provides a logical and verifiable method of optimizing the distribution of resources used to determine the most important parameters. It also indicates which parameters have to be included in the uncertainty analysis.

Uncertainty analysis gives a numerical estimate of how the uncertainty in the input parameters results in uncertainty in the model results (fluxes, doses, etc).

Considering the different phases throughout a disposal lifetime, uncertainties increase progressively with time, especially those associated to scenarios. For very long-term periods, when uncertainties become tremendously high, the importance set to the numerical results of the performance evaluations is reduced, and expert judgement is more commonly used in the safety assessments. While proceeding this way, it remains possible to cope with high levels of uncertainties.

Concerning the probability of occurrence of scenarios, simplified assumptions can also be made when uncertainties can not be easily estimated: for instance, in Belgium, a drastic assumption has been taken into account for “near-surface disposal”, as it is not possible to determine precisely the probability of occurrence of the “human intrusion scenario” in the very-long term, it has been decided to consider that this scenario has a probability of occurrence equal to the unity, which avoids further useless discussions about how likely such an event is or not. In case of geological disposal, this topic has not yet been formally discussed between operator and regulator.

Concerning uncertainties attached to parameters, a number of very useful information for evaluating them can be obtained from literature reviews, as many...
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Research programmes have been and still are commonly carried out throughout the world on high-level and long-lasting radioactive waste geological disposal. For less-studied subjects, R&D projects should also be initiated to increase knowledge when necessary.

10. **What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?**

11. **How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.**

The Belgian programme is still at a preliminary stage of development. Hence, there is currently no particular example of how the management of uncertainties may influence the R&D programme.

However, there have already been exchanges of points of view between operator and regulator about the necessity of enhancing the study of the different types of uncertainties (uncertainties attached to parameters, models and scenarios) in the R&D programme. A particular highlight has been set on the necessity of developing an integrated approach when assessing uncertainties, which implies studying interdependences between the different components of the system.

12. **What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.**

One important advantage of a stepwise implementation process for a radioactive waste repository is that safety assessments are iteratively done and discussed with the regulator and the public at the different stages of development. The outcome of the assessment of uncertainties and especially the sensitivity analysis in an early stage is thus available to guide the preparation for the following stage of the process.
PAMINA RTDC-1 Work Package 1.2: Questionnaire for RTDC-1 Participants

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<tr>
<td>Responsible Person(s):</td>
<td>Vincent Nys</td>
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<td>Date:</td>
<td>January 2007</td>
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13. With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.

14. Any other comments?

15. What are the key references that support your response?

Our responses are based on preliminary discussions about Safety & Feasibility Case 1 (SFC1, to be published in 2013, see question 1 above) as well as on the following documents:

1. “Geological Disposal of Radioactive Waste: Elements of a Safety Approach” (document developed within the general framework of the Franco-Belgian collaboration)

2. Draft documents of a working group of European regulators (“European Pilot Group”) about geological disposal of radioactive waste

3. Answers to the “IGSC Timescales Questionnaire” (2005)


Numerous international documents (IAEA, NEA, etc.)
1. What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?

With the publication of its SAFIR 2 (Safety Assessment and Feasibility Interim Report) in 2001 ONDRAF/NIRAS ended the second phase of methodological R&D regarding the deep disposal programme for high-level and long-lived waste. Since 2004 the programme entered the third methodological R&D phase. The prime aim of these methodological phases is to progressively establish if it is feasible, technically and financially, to design, build, operate and close a safe deep repository for this waste on the Belgian territory, without prejudging the actual disposal site. The R&D programme is mainly focussed on a reference argillaceous host formation (i.e. Boom Clay) and based on in situ data acquired in an underground research laboratory located in Mol/Dessel (NE Belgium) which is the reference site.

With the decision to install a moratorium on reprocessing of spent fuel in 1993 (confirmed in 1998) ONDRAF/NIRAS was asked to study both the options of disposal of reprocessing waste and of direct disposal of spent fuel.

It should be noted that neither deep disposal nor argillaceous formation(s) have yet been formally agreed upon or designated by the Belgian Government as the long term management solution for high-level and long-lived waste. Decision-in-principle to go for disposal in argillaceous settings will be requested on the basis of a national waste management plan supported by a strategic environmental assessment to be elaborated by ONDRAF/NIRAS in the next few years (2007-2010).

The next technical and scientific milestone of the deep disposal programme will be the publication and submission to the supervising Minister and the safety authorities of the Safety and Feasibility Case 1 (SFC 1) by 2013 which should lead to a “go for siting decision”.

2. What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?

No disposal specific regulatory standards exist at the moment in Belgium, and the regulatory body (the Federal Agency for Nuclear Control) is currently defining protection criteria for disposal and is developing regulatory guidance.
3. **How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.**

Uncertainties are classified in the categories “scenario uncertainty”, “model uncertainty”, “parameter uncertainty”. We also make a distinction between poor knowledge (lack of data) and variability in space and time, but this distinction is not yet systematically introduced in the programme.

**Examples**

- **Scenarios:**
  1) altered evolution scenarios themselves can already be considered as an uncertainty in the evolution;
  2) variants of a scenario: in expected evolution scenario: evolution of climate: Milankovitch or greenhouse;

- **Models:** transport of actinides in clay: complexation by organics (fulvic acids) vs. low solubility and sorption on clay minerals;

- **Parameters:** for essential parameters (e.g. solubilities and transport in clay) parameter distributions have been estimated.

4. **How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.**

- **Scenarios:** separate simulations of the variants of a scenario are carried out;

- **Models:** simulations are done for both models and results are compared to estimate the potential impact on the output variable;

- **Parameters:** both stochastic (Monte Carlo simulations) and deterministic, depending on the problem.

5. **How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.**

For most issues there is not enough knowledge to quantify in a rigorous way the uncertainties.

E.g. transport parameter values (sorption coefficients, solubility limits, …) : it is not possible to identify pdfs by applying statistical techniques; therefore, most
uncertainties are described by a log-uniform distribution for which a best estimate value and an uncertainty factor were estimated.

Conservative parameter values are often used to avoid the problem in quantifying uncertainty (see also answer to question 6).

6. What approach to system PA is preferred / appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of “fuzzy mathematics”; others)?

A distinction is being made between “process modelling” and more detailed scopings on the one hand and compliance assessments on the other hand. The former assessments are part of the assessment basis and aim at an adequate system understanding, based on a more realistic modelling approach where possible and appropriate. The latter are the more simplified conservative assessments, which are dealt with in the quantitative safety and performance assessment part of the safety case.

Deterministic and probabilistic calculations are seen as complementary and both approaches are adopted. The deterministic approach presents advantages when interpreting the results in terms of compliance and when presenting the results to various stakeholders. Probabilistic calculations are a tool for evaluating some type of uncertainties (combined parameter value uncertainty) and sensitivities.

7. How does the PA conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.

With sensitivity analyses we are trying to determine which elements (e.g. input variables) have the largest contribution to the uncertainty in the output variable (e.g. dose).

With uncertainty analysis we try to quantify the uncertainty in the considered output variable.

In mathematical terms: sensitivity analyses look at the relation between Y (output variable) and X (input variables), whereas uncertainty analysis considers only Y.

8. What supporting arguments are available / relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.

The systematic identification of uncertainties as a central element of a safety case is a first and most important way to provide confidence.

In compliance assessments conservative assumptions are made to take into account
The identified uncertainties and a safety case should make these conservatisms “visible”. For the most important contributors to safety (e.g. the geological barrier ensuring very low radionuclide migration once the radionuclides are released from the EBS) it is argued that an adequate understanding is available. The remaining uncertainties for these major contributors to safety (e.g. from a critical radionuclide like Se the radionuclide speciation and the effects on the migration parameters) are treated by making conservative assumptions or by making assessments for the possible cases.

The effects of these remaining uncertainties are assessed in order to evaluate if they can jeopardize the safety of the system.

### 9. What measures other than numerical analysis can be utilised to manage the uncertainties (e.g., methodological, QA, etc.)? Please provide examples.

**Design options, introduction of conservatism.**

- **Design option:** the use of a long-lived (a few thousand years) container avoids that the uncertainties associated with temperature evolution and parameter values applicable at elevated temperatures (radionuclide releases from the waste form and radionuclide migration) have to be taken into account in the analysis of the expected evolution scenario.

- **Conservatism:** conservatism is already applied during the data collection; for parameters for which there is little information available, conservative parameter values are used.

- Another conservative approach is the introduction of the robust concept: components that might, even significantly, contribute to the performance of the repository system are not considered in the evaluations, e.g. sorption of radionuclides on the iron(hydr)oxides that were formed in the near field during corrosion of the container.

### 10. What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?

For the vitrified HLW and spent fuel Se-79 is the most critical radionuclide. Uncertainties on its speciation in the waste form and during migration in the Boom Clay, and, consequently on its migration behaviour are remaining and important for assessing the safety. Biosphere conversion factors for Se-79 are another important remaining uncertainty.

Critical radionuclide inventories (Se-79, I-129, Sn-126, …) for HLW and spent fuel (for different burn-ups, UOx and MOX) are also an important source of uncertainties.
The EBS behaviour and performance (engineered containment, radionuclide release rates for vitrified HLW and spent fuel in the supercontainer design) are also a source of uncertainties requiring further work.

11. **How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.**

The uncertainty analyses in formal SA calculations or in scoping assessments aim to identify the most important uncertainties for safety. In a second step one evaluates the need and possibility(y)(ies) to reduce the important uncertainties. This is to a large extent expert judgment and is done in an integrated manner, i.e. by involving “design”, “system understanding” and “safety” people.

ONDRAF/NIRAS is developing a comprehensive methodology of safety and feasibility statements to systematically evaluate the need for further R&D&D work on specific issues in view of preparing the next safety case (2013). This process is fed with scoping PA and SA calculations. Formal SA calculations are planned in the final phase of safety case development.

12. **What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.**

In discussions with stakeholders other than the regulator the question of uncertainties is often related to the question “have you considered or taken into account this or that?” (e.g. early failure mechanisms, seismic events perturbing the host rock, …).

The time scales are definitely an issue in discussions with these stakeholders and a multiple lines of reasoning approach is required to deal with these time frames (different safety arguments for the different time frames).

In view of the preparation of a licence application for the surface disposal of short-lived waste, the interaction with the regulator is ongoing, and the way to deal with uncertainties is one of the issues.
13. With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.

Main gaps:

Classified: +/- OK; (1) scenarios, models, parameters; (2) poor knowledge, variability in space and time.

Managed: most uncertainties can be managed individually (pdfs, geo-statistics, alternative models, scenario variants, conservatism, etc.); more difficult issues are how to describe the increase of uncertainty with time.

Analysed: the individual uncertainties can be analysed; however, the main remaining problem is how to combine all of them in a coherent and consistent way; the traceability of the treatment of uncertainty remains a difficult issue.

Conclusions for future work: determination of research priorities by combining identified open questions and results of sensitivity analyses: +/-OK

Communication: remains difficult.

14. Any other comments?

15. What are the key references that support your response?

- SAFIR 2
- Ongoing work in view of the safety case 2013 (safety and feasibility case 1)
A3  Canada - OPG

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<td>Theo Kempe and Paul Gierszewski</td>
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1. What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?

See INTESC response I.2, with the following update (ref. attached paper submitted to NEA Symposium):

- The Canadian Nuclear Safety Commission (CNSC) has issued a draft scoping document for the Environmental Assessment (EA) required prior to licensing, and an associated CNSC public hearing took place on October 23, 2006 in Kincardine;
- CNSC are expected to make a recommendation on EA ‘track’ (Comprehensive Study or Panel) to the Minister of the Environment, followed by the Minister’s decision.
- The first phase of detailed site characterization is under way. A 2-D seismic survey was carried out in October 2006, and drilling of the first two deep boreholes started at the end of 2006. OPG will consult with CNSC staff with regards to the adequacy of the subsurface characterization data to support EA preparation in 2009.

2. What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?

Requirements are given in the Nuclear Safety and Control Act and regulations. Specific regulatory expectations are given in a CNSC Policy (P-290) and Regulatory Guide (G-320; draft issued for public comment April 2005; expected to be published by the end of 2006). The guide gives CNSC’s expectations and compliance is not mandatory. However, similar expectations are given in the EA scoping document, which must be followed in the EA review.

The NSCA and regulations, also P-290 and G-320 can be found on the CNSC’s web site, at

http://www.nuclearsafety.gc.ca/eng/regulatory_information/documents/index.cfm

Material relevant to uncertainty is in draft G-320, Sections 7.2, 7.5, 7.8, 8.0, and 9.0 (these sections may change in the final).
3. **How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.**

Following guidance given in IAEA documents, uncertainty in assessments is recognised as:

- uncertainty in the evolution of the disposal system over the timescales of interest (scenario uncertainty);

- uncertainty in the conceptual, mathematical and computer models used to simulate the behaviour and evolution of the disposal system (e.g. owing to the inability of models to represent the system completely, approximations used in solving the model equations, and coding errors); and

- uncertainty in the data and parameters used as inputs in the modelling.

In addition, IAEA suggests that a further type of uncertainty, subjective uncertainty (uncertainty due to reliance on expert judgement), is also linked with the above sources of uncertainty.

See also INTESC response II.12.

4. **How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.**

See INTESC responses II.12, II.19, II.20, II.22 and III.3.

5. **How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.**

The Safety Case emphasises the geosphere and the studies carried out to date indicate that favourable geological and hydrogeological conditions exist at the Bruce site, as summarised in Section 8 of the attached paper to the NEA Safety Case Symposium. The validity or otherwise of these assumed favourable characteristics will be tested in ongoing site characterization work and work aimed at developing a geosynthesis, or integrated geoscientific understanding of the past, present and future evolution of the Bruce site.

The main uncertainties relate to characteristics of the geosphere, and are expected to be resolved to a level acceptable to the regulator by this ongoing work. Current safety assessment work takes account of these uncertainties by analyzing several scenarios, e.g. a what-if case which assumes unfavourable features such as advective flow in certain strata. The safety assessment will incorporate the results of ongoing
site characterization and engineering work in an iterative manner.

See also INTESC response IV.7.

6. What approach to system PA is preferred / appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of "fuzzy mathematics"; others)?

Analyses are primarily planned to use realistic assumptions however certain conservative assumptions are inevitable for deterministic calculations where there is uncertainty. It is planned that interpretation of results and application of criteria will take account of the features of the analysis. Overall, our approach could be described as deterministic complemented by probabilistic, and a balance of simplified and complex modelling.

See also INTESC responses II.16 and II.22.

7. How does the PA conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.

See INTESC responses II.12, II.17 and II.18.

8. What supporting arguments are available / relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.

See INTEST responses II.9, IV.10 and IV.11. These arguments are also summarized in Section 4 and 8 of the attached paper submitted to the NEA Safety Case Symposium.

9. What measures other than numerical analysis can be utilised to manage the uncertainties (e.g., methodological, QA, etc.)? Please provide examples.

See previous responses.

The uncertainty in the future evolution of the site is to be addressed using a transparent and comprehensive scenario development and justification methodology, which will ensure that an appropriate range of potential futures is considered. Physical variability and individual parameter uncertainty will be treated using sensitivity and uncertainty analyses, whilst conceptual model uncertainties will be treated using alternative conceptual representations of the system. The uncertainties related to computer codes will be reduced through the use of appropriately verified and validated computer codes (selected considering the available data and the calculation end points). Subjective uncertainties will be managed by using a systematic and transparent approach, consistent with the ISAM methodology, which
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allows subjective judgements to be documented, justified and quantified (as far as possible).

### 10. What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?

In accordance with G-320 and the EA scoping document (see response to Q. 2), acceptance criteria are to be proposed and discussed with the regulator, CNSC.

It is expected that uncertainties can be managed, primarily through the stepwise and iterative approach adopted. Presentation of the overall Safety Case will be an important factor.

### 11. How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.

See INTESC response II.2.

### 12. What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.

Key elements in presentation of the Safety Case for the DGR include emphasis on simple robust arguments supported by multiple lines of reasoning including more detailed calculations, and consistency with international practice.

See also INTESC responses VI.2.

### 13. With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.

At this stage of the DGR project gaps in understanding have not been identified other than those identified to be addressed in planned work. This will be explored in ongoing interaction with the regulator, CNSC.
14. **Any other comments?**

Technical note: For parameter sensitivity analyses, we are using a numerical technique based on Iterated Fractional Factorial Design (IFFD) and implemented in a pair of codes SABERS/SAMPLE. A description of the approach is given in a paper by T. Melnyk et al. (Identification of important parameters in large safety assessment system models, IHLRWM conference, Las Vegas, 2006; copy attached).

15. **What are the key references that support your response?**

See the references given in INTESC response I.4. These references are available on the OPG DGR website, at [http://opg.com/power/nuclear/waste/dgr.asp](http://opg.com/power/nuclear/waste/dgr.asp) (Please advise if paper copies are needed.)

- Golder 2003 is under the “additional reports” link
- Golder 2004 is under “Independent Assessment Study”
- INTERA 2006 is under “Site Characterization Plan”
- Parsons 2004 is under “Conceptual Design”, and
- Quintessa 2003 is under the “additional reports” link


The paper referred to in the responses, submitted to the NEA January 2007 Symposium on the Safety Case, is attached.

The OPG response to the NEA INTESC questionnaire is attached.
NEA/RWM/IGSC(2006/2)

CNSC to enable them to proceed with the Environmental Assessment process required under the Canadian Environmental Assessment Act. Draft EA guidelines setting out the scope and process for the EA have been issued by CNSC for public comment (comment period closed July 17, 2006).

A Safety Case will be required as part of the EA review in order to provide confidence in the prediction of environmental impacts. The Safety Case will be updated for the Construction Licence application following further detailed site characterization and additional iterations of the design and safety assessment.

OPG is consulting with CNSC on an ongoing basis with respect to site characterization activities. Consultation is continuing with stakeholders in local communities.

There is a separate national program for spent fuel, under the Nuclear Fuel Waste Act (NFWA). This Act required the nuclear utilities to establish a waste management organization to study and recommend an approach to long term management. The legislation authorizes the government to decide on the approach. The approach will then be implemented by the waste management organization. The management of L&ILW is not addressed by the NFWA.

I.3 What decisions within your programme will be based on or affected by the conclusions of the current safety case?

The safety case currently under development will be submitted as part of the studies required for EA approval under the Canadian Environmental Assessment Act. EA approval is required before the regulator, the Canadian Nuclear Safety Commission (CNSC), can grant a Construction Licence for the DGR under the Nuclear Safety and Control Act. The safety case to be submitted for EA approval is preliminary, and further site characterization and safety case development will take place before the application for a Construction Licence.

I.4 Please provide a primary reference (e.g. a safety report, guidelines, regulations, standards...) and, if necessary, a small number of additional references that support your responses to this questionnaire.

The safety case is currently under development. A number of supporting reports to the safety case will be prepared prior to submission of the EA Study Report. A paper on the Safety Case is being prepared for submission to the NEA Symposium on “Safety Cases for the Deep Geologic Disposal of Radioactive Waste: Where Do We Stand?”, to be held 23-25 January 2007 in Paris. Primary references for the present response are:


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<td>Responsible Person(s):</td>
<td>Ales Laciok and Jiri Landa</td>
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<td>March 2007</td>
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1. **What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?**

Initial stage (deep geological repository) – preliminary analyses focused mainly on constructability aspects and general environmental impacts has been performed so far. Comprehensive safety assessment has not been carried out so far (only particular analyses has been performed – near-field processes, biosphere processes,..). Six selected sites were evaluated in desk top study complemented by airborne geophysical reconnaissance in previous years (assessment of available geological information, clash of interests, comparison with exclusion and limiting criteria,..), geological survey was interrupted after protests of local inhabitants 3 years ago.

2. **What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?**

Regulatory requirements are specified in the Decree of SONS no. 307/2002 Coll., on radiation protection. The relevant part is Par. 52:

“The fulfilment of the requirements for radiation protection in radioactive waste disposal shall be demonstrated by safety analyses of potential hazards of radioactive waste disposal. Based on the knowledge of the site where the repository shall be built, safety analyses shall demonstrably and plausibly assess the potential risks during the operating period as well as during the period after the repository is closed. Based on the safety analyses, acceptance criteria for radioactive waste disposal shall be determined.”

SONS = State Office for Nuclear Safety (regulatory body in the area of nuclear safety and radiation protection).

3. **How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.**

No specific rules for classification of uncertainties in repository safety evaluations have been established in SONS decrees or other binding documents so far.

4. **How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.**

Quantitative PA – appropriate tools used in other branches.
### Wider safety case – referencing to quantitative PA results, rather qualitative and semi-quantitative approaches would be used, comparisons, reasoning by analogy...

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<th>5.</th>
<th>How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.</th>
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<tr>
<td><strong>It is probably subjective perception/view of scientists reflecting their professionalism, level of knowledge and experience. In reality it is a matter of compromise – peer reviews, clarification of views of professionals from different fields, evaluators, other stakeholders, etc.</strong></td>
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<th>6.</th>
<th>What approach to system PA is preferred/appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of “fuzzy mathematics”; others)?</th>
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<tr>
<td><strong>Such questions are correlated with the stage of development of repository. Due to the initial stage of deep disposal programme in the Czech Republic, the total performance assessment would be based on simplified, but reliable models (rather deterministic than probabilistic). Reliability (enveloping of impacts, safety margins) could be based on more complex models of main processes (and their coupling), incorporating evaluation of uncertainties at this level of modelling.</strong></td>
<td></td>
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<td><strong>In consequent stages, role and use of probabilistic approaches will be considered.</strong></td>
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<th>7.</th>
<th>How does the PA conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.</th>
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<td><strong>It is recommendable to follow standard scientific literature and relevant references.</strong></td>
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<th>8.</th>
<th>What supporting arguments are available/relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.</th>
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<td><strong>In the Czech disposal programme, natural analogues are used for qualitative argumentation concerning confidence in character and intensity of events and processes.</strong></td>
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<th>9.</th>
<th>What measures other than numerical analysis can be utilised to manage the uncertainties (e.g., methodological, QA, etc.)? Please provide examples.</th>
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<td><strong>QA is integral part of deep disposal programme, but QA procedures alone cannot substitute evaluation of uncertainties.</strong></td>
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10. **What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?**

Unclear context and not properly defined limits of safety analysis, undefined purpose of use of probabilistic approaches and non-coherent and biased argumentation could jeopardise expected results.

11. **How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.**

Rather intuitive actions and following of international activities are main drivers of research priorities. Uncertainties are used only in qualitative ways if any.

12. **What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.**

Possibility to comprehend the presented results and ways of derivation of results (appropriate level of simplification, graphical forms rather than only numerics) and argumentation by reasonable similarities/anlogs. Different approaches for different forums are needed!!

13. **With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.**

Role of uncertainty and sensitivity analysis has to be clearly defined before starting complex calculations and their interpretation as a part of the safety case.

14. **Any other comments?**

15. **What are the key references that support your response?**

- RAWRA (Czech Radioactive Waste Repository Authority)
  

- SONS (State Office for Nuclear Safety)
  
5 Finland - POSIVA

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<td>Responsible Person(s):</td>
<td>Marjut Vähänen</td>
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1. **What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?**

   Status of the national programme:

   - **1983-1985:** Site identification surveys to select sites for preliminary investigations.
   - **1993-2000:** Detailed site investigations and safety assessment TILA-99.
   - **In 1999:** POSIVA proposed Olkiluoto in the municipality of Eurajoki as the site for the final disposal facility.
   - **In 2000:** The Government made a policy decision in favour of the project in December 2000.
   - **In 2001:** The Parliament ratified the Government’s policy decision in May 2001 by 159 votes to 3. After that the Municipal Council of Eurajoki approved siting the final disposal facility at Olkiluoto by 20 votes to 7.
   - **2001-2003:** Posiva focused further investigations on Olkiluoto and began preparations for the construction of an underground characterisation facility, ONKALO, which will form part of the final disposal facility.
   - **In 2003:** The municipality of Eurajoki granted a building permit for the ONKALO in August 2003.
   - **In 2004:** The construction of the ONKALO started in June 2004 and excavations of the access tunnel started at the end of September 2004. The construction of and installations in the ONKALO are to be carried out between 2004 and 2011 together with characterisation and investigations to support the application of construction licence.

2. **What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?**

   Generally, management of uncertainty shall be an integrated element in all parts of the Safety Case. The management of uncertainty shall correspond to the stage of the repository programme.
In accordance with the Government Decision on the safety of the disposal of spent nuclear fuel (Government of Finland 1999), a safety assessment shall include uncertainty and sensitivity analyses and complementary discussions of such phenomena and events which cannot be assessed quantitatively. The computational methods shall be selected on the basis that the results of the safety analysis, with high degree of certainty, overestimate the radiation exposure or radioactive release likely to occur. Simplification of the models as well as the determination of input data for them shall be based on the principle that the performance of any barrier will not be overestimated but neither overly underestimated. Employing of relatively simple deterministic models facilitates comprehensive uncertainty analyses based on systematic combinations of the best-estimate and conservative parameter values. In addition, uncertainties are covered and the significance of barrier functions are illustrated by means of bounding and “what if” analyses.

3. **How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.**

Concerning the release from spent fuel assemblies, near-field transport and geosphere transport, the uncertainties are more related to limited knowledge than to random spatial or temporal variability. Therefore, their modelling in the near future may be based on deterministic parameter values.

In report Posiva 97-11 the classification of FEPs in Finnish safety assessments have been presented. In principal the approach has been the same in TILA-99 two years later. Examples:

- Post glacial faulting: Treatment by separate scenario.
- Uncertainties in solubility limits: Treatment by separate calculation case with more conservative data parameters.

Gas expels water from canister: Treatment by separate scenario or model. What’s the difference between model and scenario? The conceptual model differs from base case but the same computer model REPCOMM has been used.

4. **How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.**

Parameter uncertainty is primarily analysed by defining bounding analyses and sensitivity cases. In selecting the parameter values from databases (e.g. instant release fractions, solubility), the recommendation is to use the best estimate and conservative values; for certain important parameters in the biosphere assessment, a stochastic approach might be used if appropriate well-established probability density
functions can be derived.

The applied parameter values, the data the values are based on and the reasoning behind the selection of a given value should be reported. In cases when just one parameter value is used in modelling reporting should include discussion on the effect of the parameter uncertainty on the results. Furthermore assessing the consistency of modelling results against other relevant models and any experimental or field observations can be done.

Structural approach, including iterative analyses, are being developed to handle parameter sensitivities and uncertainties.

5. How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.

Considering site description, preliminary measures to discuss sufficiency of data have been established so that there exists common understanding adequacy of site description (i.e. processes and relevant data) and the further work needed. Currently, the site description is not unambiguous.

Uncertainties with respect to evolution related scenarios can’t currently be circumvented by other means than combination of deterministic analysis and complementary (somewhat) realistic bounding analyses.

Estimates of unexpected events when radionuclides are released and their consecutive concentrations in various media together with their radiological effects bear more comprehensive uncertainties. It seems that radionuclide transport related uncertainties are due to the current perception of site hydrogeology and how it is parameterised. Therefore, the only means to master these uncertainties is to use quasi-stochastic estimates i.e. to assess the robustness using several sets of assumptions and parameters.

6. What approach to system PA is preferred / appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of “fuzzy mathematics”; others)?

See answer to question number 3 concerning the release from spent fuel assemblies, near-field transport and geosphere transport.

Regarding the biosphere, a realistic approach is taken for the description of the site, and the description of the evolution of the site will be based on realism-oriented modelling. For the radionuclide transport of multiple nuclides through several
7. **How does the PA conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.**

This is a philosophical question. E.g. changes in solubility limits, source term or canister failure time may be considered as sensitivity analyses in TILA-99. Gas expels water or post glacial faulting scenarios may be considered as uncertainty analyses.

8. **What supporting arguments are available / relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.**

Properly sealed copper canister in KBS-3 concept is inherently chemically resistant and with cast-iron insert mechanically resistant and therefore canister is inherently integrated thus providing long-term isolation.

Canister integrity is supported by buffer material enclosing it. Buffer eliminates or attenuates the influences of near-field conditions to canister i.e. decouples these effects either totally or with sufficiently long reaction times so that the effect of disturbance in conditions faced by buffer remains sufficiently small.

In case canister is groundwater flows into canister e.g. through a defect in sealing, solubility of fuel matrix is negligible and even when being leached, the pressure inside the canister remains considerably small when compared to the pressure at buffer or the pressure at depth of the repository. Also the retardation parameters of majority of critical nuclides is well known and proven.

9. **What measures other than numerical analysis can be utilised to manage the uncertainties (e.g., methodological, QA, etc.)? Please provide examples.**

For the biosphere assessment, a multi-dimensional uncertainty analysis approach has been outlined to be taken into use in largest extent practically achievable. The approach combines traditional uncertainty and sensitivity analysis with methodologies for quantifying non-numerical uncertainties, such as pedigree analysis for the evaluation of uncertainties in the knowledge base. The methodology might be extended also to other areas of the safety case after more experience on the practical implementation has been gained.
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10. **What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?**

Interaction of the intended buffer and backfill material with the groundwater composition prevailing at specific times. An additional uncertainty relates to the interaction effects of stray materials used in constructing the repository and engineering barrier materials (e.g. cement used in groundwater inflow control into excavated volumes and its interaction with clays intended for buffer and backfill.

11. **How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.**

The results can be used to identify processes and parameters that have a combination of high impact on the safety assessment end-results (such as doses to man and other biota) and epistemic uncertainties that could be further reduced. This can provide valuable input for where the focus of future work should be, especially monitoring programs and R&D activities. In analogy, uncertainty analysis results are valuable to identify processes and parameters less significant for the safety assessment end-results, which is also important when optimising the resources.

Construction methods and materials are being optimised with respect to their potential implications on the long-term performance of the repository. The greater the uncertainties are, the more conservative (= time and labour consuming) design and construction methods are used.

12. **What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.**

Transparent and continuous discussion.

13. **With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.**

How to classify the relative importance of new uncertainties appearing once in a while.
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A6 France - ANDRA

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1. **What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?**

   **INTESC I.2** Describe briefly the status of your national programme (the programme may, for example, be at the stage of generic feasibility studies, or be in the process of selecting a site or sites for characterisation from the surface or from underground), including your programme constraints (see table A.3 for examples).

   The French Waste Act dated 30th December 1991 initiated a research programme to define methods for the long-term management of HLLL waste [2]. It has entrusted Andra, the French National Radioactive Waste Management Agency, with the task of assessing the feasibility of deep geological disposal of this waste, and of producing a report after 15 years of investigations, including (i) a feasibility-assessment report on clay formations namely the dossier 2005 Argile based notably on the work conducted on the site of the Meuse/Haute-Marne Underground Laboratory and in foreign laboratories; and (ii) a report concerning the advantages of granite rocks based on the available bibliography on French granites and on the investigations carried out by Andra under research partnerships with foreign laboratories.

2. **What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?**

3. **How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.**

   **INTESC II.16** If conservative model assumptions and pessimistic parameter values are used for the treatment of some uncertainties, what rationale is used for the selection of uncertainties to be treated in this manner?

   Depending on the knowledge acquired for each phenomenon or material, four different types of models might be available at a given stage of the project development:

   - A so called "modèle phénoménologique", or "best estimate model", is either, the model that is based on the most comprehensive understanding of
the phenomenon to be modelled, and whose ability to account for direct or indirect measurements has been confirmed, or in comparison with the other available models it might be the one offering the best match between the reality that it is supposed to represent and the numerical results that it generates in the impact calculation. Examples of the former include basic physical models (Coulomb's law, etc.) and mechanistic models representing Fick's law or Darcy's law for example. Examples of the latter include all models subject to a broad-reaching experimental validation and/or a solid international consensus among experts in the field.

- A so called "modèle conservatif", or "conservative model", addresses a case in which it is possible to demonstrate that its use, all things being equal otherwise, tends to overestimate the repository's impact, compared with the results that would be obtained by taking into consideration all the relevant phenomena in the chosen parameter variation range. For example, selecting a transport model that ignores chemical retention could, in situations where retention has a potentially significant effect, be deemed "conservative".

- A so called "modèle pénalisant", or "pessimistic model", designates a model that is not based on phenomenological understanding, however empirical, but that definitely overestimates the repository's impact. For example, making an assumption that waste packages immediately release radionuclides is, except in special cases, a pessimistic choice.

- Finally, an "alternative" model stands for a model that can't be classified according to this three items list but offers a different perspective. Examples might include models that don't have an unequivocal effect on the impact, or models that appear more comprehensive than the selected reference model but have been less thoroughly validated.

A parallel classification is defined as regards parameter values:

- A "phenomenological" value is considered to offer the best match between the model's results and the measured results. This choice must be supported by detailed arguments which may include a representative number of measurements, a physical reasoning that demonstrates that the chosen value is the most representative based on reliable data, or a judgement by recognised experts unambiguously designating it as the most appropriate value for the study context.

- The "conservative" value is chosen among those generated by the studies and measurements which give a calculated impact in a range of high values, all other parameters being equal. In the simplest case, where the impact
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increases (or conversely, decreases) as the value of the parameter increases, a value in the highest (or lowest) range of available values. "Conservative" values cannot be defined if the variations in impact are not monotonic with changes in the parameter.

- A "pessimistic" value is one that is not based on a state of phenomenological understanding, but is chosen by convention as definitely yielding an impact greater than the impact that would be calculated using possible values. Such values can represent physical limits. A pessimistic value can also be equal to the conservative value plus (or minus, where applicable) an appropriate safety factor that places it significantly beyond the range of measured values. A value cannot be described as "pessimistic" if the variation in impact in response to a variation in a parameter cannot be characterised.

- In order to explore the possible parameter variation ranges, one or more so-called "alternative" values can be suggested as a means of investigating the effect of contrasting values.

4. How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.

INTESC II.12 Give a brief description of your strategy for the management and treatment of uncertainty in your assessments, including any scheme that is adopted for different timescales or for the categorisation of uncertainties (e.g. as scenario, model and data uncertainties). (Note: your response may overlap with that for the following questions; please use forward and backward referencing where appropriate)

The assessment of a repository feasibility assumes that a sufficient knowledge of the behaviour of the repository components has been acquired, in particular, thanks to the composition of a large corpus of scientific knowledge and development of a repository architecture down to a sufficient level of detail, and taking into account unavoidable uncertainties when considering evolution over hundred of thousand of years. Over such timescales, no feedback is available other than by means of natural and archaeological analogues. This does not mean, however, that these residual uncertainties related to the long durations, specific to the dossier, cannot be managed with a sufficient degree of confidence:

- Provisions are taken with regards to the repository conditions which would allow overcoming uncertainty consequences: choice of a very stable geological medium hardly affected since its deposition (155 million years ago), compartmentalisation of the repository into zones to prevent...
interactions between various kinds of waste, use of simple materials whose behaviour is well-known.

- In addition, to ensure the control of uncertainties, safety is integrated upstream the design phase in order to orient the choices toward the most robust solutions with respect to a possible lack of knowledge.

Finally, uncertainties are systematically investigated, and taken into account in the safety assessment. Their potential effects are examined, particularly in qualitative safety analyses.

To conduct that investigation, Andra implemented three complementary approaches to synthesise the knowledge, describe the repository evolution and manage the uncertainties:

- Knowledge reference documents were made up in order to provide a complete view of the scientific understanding on the following studied components: geological medium, engineered materials, packages, etc. They describe indeed the state of knowledge, correlatively identify the lack of knowledge and thus contribute in determining the sources of uncertainty and orienting the actions to reduce them.

- Once a good level of knowledge is reached on each component and the global architecture is defined, the evolution of the repository over space and time is described as finely as possible: this is the purpose of PARS, which describes the phenomena (thermal, mechanical, hydraulic, chemical, radiological) and their coupling throughout the repository evolution and specifies the phases of this evolution from its construction up to 1 million years. The systematic work accomplished with APSS/PARS led to a list of uncertainties (on phenomenology, models, data, component characteristics...).

The uncertainties are not of the same kind depending on the time periods, components or parts of the repository and its environment. The various timescales considered are integrated in the safety analysis within the scope of the safety functions; the performance assessment and the analysis of the uncertainties (see details in questions II.21).
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5. How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.

**INTESC II.14 What are the criteria or procedures whereby some FEPs or parameter combinations are excluded from detailed consideration and others are included (including e.g. the use of expert elicitation and peer review)?**

A qualitative safety analysis (QSA) methodology was developed for detailed consideration of FEPs in the Dossier 2005 Argile [3]:

The qualitative safety analysis is a method for verifying that all uncertainties in particular in FEPs and design options have been appropriately handled in previous steps of the analysis, thereby justifying post hoc, e.g., the selection of altered evolution scenarios. It also led to the identification of a few additional calculation cases and has, in principle, the potential to inform design decisions and the derivation of additional scenarios. Some uncertainties can have a direct influence on the confidence that can be had in a given safety function. For example, if the uncertainty about the permeability of the host formation is too great, this could call into question the performance of the function « prevent water circulation ». Uncertainty is the subject of a systematic study that identifies:

- which component is concerned by this uncertainty, with if relevant the effects caused by one component on another by means of a perturbation;
- which performance aspects of which safety function can become altered. A qualitative, but argued assessment, including the use of special calculations if relevant, is conducted on the risk of a significant reduction in the expected performances;
- if applicable, and if such information is useful, the time period involved.

The first objective is to identify whether the uncertainties are correctly covered by the SEN, either in its reference version, or in the sensitivity studies considered. If some of the uncertainties are not, it must be confirmed that they would have little impact on the repository, or that they refer to very unlikely situations.

As a second stage, if the uncertainty is not covered by the SEN, the function(s) and component(s) that could be affected must be identified. A systematic component-by-component analysis is used in particular to identify the shared causes of the loss of several functions: for example, an incorrect assessment of the long-term behaviour of a material can affect all the components that contain it, even though these could have
different functions. The qualitative safety analysis provides an assessment of the degree of independence of safety functions, by identifying the possible uncertainties affecting several functions.

The effect of taking each uncertainty into account is described (i.e. the behaviour of the repository if the worst-case value of the parameter in question was the actual value, or if the risk envisaged actually occurred), in terms of the repository's evolution. This is done on the basis of the functions that are likely to be lost. For example, if a series of uncertainties can call into question the function « regulate the pH in the vitrified wastes cells », the corresponding situation is described, i.e. the effects of an uncontrolled increase in pH. If the design can cancel this effect, or if this is taken into account in the SEN or in its sensitivity calculations, the analysis stops at this stage. If a safety function can be affected and the evolution of the repository could start to diverge from normal, with a possible impact on other components, this effect is then specifically identified.

The qualitative safety analysis was conducted by Andra engineers who were not involved in writing the scientific documents. In this way, the safety analysis is given a certain degree of independence, since the people in charge of analysing the uncertainties and the possible altered situations (the safety engineers) are not the same as those who established the phenomenological plan for normal evolution. Four altered evolution scenarios have been adopted by Andra: the seals failure scenario, the package failure scenario, the bore-hole scenario and a severely degraded scenario which radically lower performances of safety functions. Specific qualitative analyses of external events were also conducted.

6. **What approach to system PA is preferred / appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of “fuzzy mathematics”; others)?**

**INTESC II.13 Do you adopt a probabilistic and/or deterministic approach for the analysis of scenarios or assessment cases and what is the rationale behind your choice?**

In accordance with the French Safety Rule RFS.III.2.f, the kind of approach, which has been adopted for the safety analysis, is mainly deterministic. This is implemented at two different stages; first for the definition of the SEN (normal evolution scenario) and SEA (altered evolution scenario), and then during the scenarios modelling computation and analysis itself.

The normal evolution scenario is defined as a set of evolutions that appear probable enough to be treated as normal, rather than as a single linear scenario. Therefore, in
In addition to the deterministic elements, it also comprises some events defined with a high occurrence probability. For instance, the welding of the caps of the canisters is a very accurately monitored process, but it has been considered that a certain percentage of faulty quality checks would be unavoidable. Then, considering the present nuclear industry standards, a deterministic assumption of one canister’s default per each waste type was considered within the SEN.

As regards the modelling and computation of the scenarios, the approach is also mainly deterministic. Usually, computation cases are carried out with a given set of fixed parameters. Comparisons are made by changing only one parameter at a time, or in any case a limited number. (See answers in III.5 for more details about the models and parameters selection and use.)

7. How does the PA conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.

INTESC II.17 What kinds of analyses are carried out to explore parameter sensitivity and the impact of uncertainties in parameter values?

The SEN and SEA and their sensitivity studies form a non-dissociable whole.

The scenario is made up of a series of calculation cases. As an example in the case of the Normal Evolution Scenario is a « reference calculation » that sets out Andra's current knowledge of the repository's foreseeable evolution, in an approach that considers both the fruits of scientific research and the safety strategy. The purpose of this calculation is to assess factors that would increase the impact of creating a repository. To this end, it includes a series of parameters and models, chosen on the best available scientific knowledge. It incorporates a degree of conservatism that varies according to the uncertainties, being less conservative where the parameters or models have been validated in detail, and being more conservative where substantial questions remain outstanding. In addition, a series of single- or multi-parameter sensitivity analyses that set out of rank the parameters and models by determining the ones that, if they were to vary, would have the greatest consequences for the overall assessment.

8. What supporting arguments are available / relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.
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#### 9. What measures other than numerical analysis can be utilised to manage the uncertainties (e.g., methodological, QA, etc.)? Please provide examples.

See question 5 for QSA Methodology.

Also note QA:

**INTESC II.6 How does the quality assurance (QA) plan cover the different elements of the safety case? Which components of a safety case are covered by a QA?**

According to the principles defined in the ISO 9001 standard, Andra has defined processes regrouping activities, which contribute to the same finality and are oriented toward a customer’s satisfaction. The definition of a process allows transversally looking at the units’ activities and defining the actions of improvement related to the relevance, effectiveness and efficiency of the process with respect to its objectives. The performance of the processes is reported through indicators. The processes are assessed in one or two annual reviews during which the results obtained are examined. They are linked to the notion of « continuous progress », which is essential in the quality field. A progress action does not necessarily indicate an insufficiency in the process, but rather an opportunity to improve its operation. This organisation allowed inciting engineers in charge of the studies to identify possible ways of improvement. They involved especially the management of the project’s configuration and the control of the scientific data. A general document management procedure is related to project management (on the establishment of management plans, controlling reviews, etc.). Additionally, according to adequate procedures, at each key step of the establishing of the safety case (design options, scenarios, quantification of scenarios and related data sets), internal reviews are implemented and recorded in order to get experts’ views and make decisions.

#### 10. What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?
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11. How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.

The management of uncertainties and open issues in future project stages

**INTESC IV.7 Have uncertainties, and assessment methodology, open siting and design issues been identified that must be addressed in future project stages? If yes, which ones? How are they identified and prioritized?**

The dossier 2005 Argile, presents a few lines of progress from the conclusions of the safety analysis with a view to possible future work for instance in its last chapter of the safety tome, without pre-empting the decisions which will be taken in 2006 regarding research work on the deep geological repository. These focus on several areas: consolidation of the data acquired within the Meuse/Haute-Marne laboratory, full-scale technological tests to support more detailed engineering studies, work to explore the transposition zone on a larger scale and a more precise evaluation of the safety through more thorough knowledge of the phenomenology. On this final point, Andra stressed that the representation of the processes and their inclusion in the safety assessment of Dossier 2005 involves simplified, conservative models in certain cases and that it would be important in a later phase to represent them in a more precise manner in order to increase the confidence that can be placed in the assessments. In chapter related to lessons learnt, it was mentioned that the construction of a working programme for the years post-2005 depends on decisions from the public authority; on the other, it depends in part on the result of the assessment of the dossier and the recommendations arising from it.

Dossier 2005 also marks progress compared with the previous dossiers produced by Andra in that, for the first time, it explicitly envisages the influence of climate changes on the hydrogeological model and on the biosphere. A finer appreciation of climate sequencing could result in greater detail being provided for these assessments. It must however be emphasised that any effort in this area must be set against the uncertainties weighing on the evolution of the surface environment, encouraging the adoption of very robust and partly stylised approaches.

Characterisation of the transport properties of the excavation damaged zone, immediately after sinking, then their evolution under effect of mechanical or even thermo-mechanical constraints in the concerned disposal cells, is an important subject for which the underground laboratory has already started and will continue to contribute important information. Today the EDZ assessment is conducted by modelling; the data obtained during experiments will enable specifying the mechanical behaviour of the rock with the aim of optimising the concepts.
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Modelling of transient phases also requires pursuing the works for representation of the coupled phenomena. The Dossier 2005 has already built on the transport-chemistry coupled calculations that allowed specifying the phenomena extension. Detailed understanding of the earliest phases of life takes place through the pursuit of modelling work on couplings, including those induced by heat (thermo-mechanical behaviour of EDZ, pursuit of studies on the heat-transport coupling). Representation of coupling due to hydraulic transients –particularly models in an unsaturated medium - will also enable refining the control and understanding of the initial centuries of the repository's evolution with particular attention paid to controlling the conditions in which the materials evolve over time in the repository.

The continuation of studies into the conditions under which corrosion develops within the repository should enable the conceivable speed ranges to be reduced by approaches which are both theoretical (for example, coupling with modelling in an unsaturated medium) and experimental (with possible experiments in situ on metallic materials). It is possible that we could therefore revise the corrosion gas pressure build-up assessments downwards and, through this, the influence of the gases on the hydraulic transient. Furthermore, by studying the various hydrogen migration pathways, it will be possible to provide further detail for the overall evolution diagram, based here too on modelling and a more experimental approach.

Finally, as a result of the qualitative safety analysis, it has been possible to draw up an initial list of processes, the implementation of which during the operating phase could restrict the duration of this phase from the point of view of long-term safety. Reversibility appears possible over a few centuries (typically two or three hundred years) or potentially longer periods. The design approach adopted by Andra, privileging joint, homogeneous treatment of the questions of safety and reversibility, leads to architectures in which these two notions do not appear to compete with each other. The same approach will be continued in the future.

12. **What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.**
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13. With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.

14. Any other comments?

15. What are the key references that support your response?

**INTESC I.4 Please provide a primary reference (e.g. a safety report, guidelines, regulations, standards…) and, if necessary, a small number of additional references that support your responses to this questionnaire.**

INTERNATIONAL EXPERIENCE IN DEVELOPING SAFETY CASES- INTESC

Andra’s answers to the questionnaire.

Primary references include the French Act and the series of reports submitted accordingly:

- The French Safety rules namely RFS.III.2.f, guidelines [4].
- Synthesis Report, Evaluation of the Feasibility of a Geological Repository, Meuse/Haute-Marne Site (in English and French) [5].
- Architecture and Management of a Geological Disposal System Report (TAG; C.RP.ADP.04.0001) (in English and French) [6].
- Phenomenological Evolution of the Geological Repository Report (TEP; C.RP.ADS.04.0025), (in English and French) [7].
- Assessment of Geological Repository Safety Report (TES; C.RP.ADSQ.04.0022) (in English and French) [8].

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<td>Responsible Person(s):</td>
<td>Contact persons for PAMINA WP1.1 group: Lise GRIFFAULT and Sylvie VOINIS</td>
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5) Andra 2005, Dossier argile 2005, synthèse (English version will be available soon).


### A7 France - IRSN

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<td>Responsible Person(s):</td>
<td>Christophe Serres</td>
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1. **What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?**

   See Andra contribution

2. **What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?**

   Basic safety Rule III.2.f related to deep geological repository of LL-HLW.

3. **How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.**

4. **How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.**

   See Andra contribution

Uncertainties may be encompassed through special design provisions or by adopting hypotheses increasing their effects and studying the consequences on global installation safety of a partial or total loss of function of the various repository components. IRSN considers that uncertainties over the evolution of containment performances of engineered repository components (packages, over-packs, seals) may be taken into account by postulating failures of these components with varying degrees of severity.

Complement from IRSN:

Use of modelling approaches aiming at testing the robustness of the repository for possible components failures or postulated states and environmental conditions.

Concerning the French case in Callovo-Oxfordian formation, IRSN considers that the possible effects of a hypothetical fracture crossing the geological barrier must be assessed. IRSN considers in fact that although the properties of the Callovo-Oxfordian formation seem overall favourable to containing radioactivity, the current state of knowledge is insufficient to conclude that the tectonic damage (fractures) of the clay formation is as slight as observed in the laboratory over all the zones in the...
sector likely to host a potential repository, or to disregard the possible effects of an earthquake on the host formation, right below the structures potentially detected under this formation. IRSN studies have nevertheless shown that the consequences of this type of short-circuiting are in principle minor as soon as sufficient clearance distance is maintained between the fracture and the engineered repository structures.

5. How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.

6. What approach to system PA is preferred / appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of “fuzzy mathematics”; others)?

IRSN intends to conduct a preliminary study aiming at identifying assets of the probabilistic calculation types for the long-term evolution of the total-repository-system assessment. The integrated analyses carried out so far by IRSN are exclusively of deterministic type. The international community has been using widely probabilistic calculations; ANDRA is developing such probabilistic computational capacity. Consequently, it is useful that IRSN acquires a capacity of analysis for this type of computational method.

Because of the large amount of memory and computer time required for running 3D radionuclide transport models, it is unrealistic to couple this model with probabilistic subroutines. It is the reason why IRSN prefer study a process of simplification of the model to allow a statistical treatment of uncertainties linked to variation of parameters as well as to the different conceptual assumption. Simplification process combined with probabilistic approach is judged by IRSN as complementary to the deterministic 3D one aiming at integrating as realistic as possible features and possible alteration and dysfunction of the system governing RN transport and radiological impact. This methodology for PA/SA is consistent with safety approach preferred by IRSN and Nuclear Safety Authority which is based on a stepwise collection of arguments conceived upon defence in depth principle but not risk-based principle.
7. How does the PA conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.

8. What supporting arguments are available / relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.

9. What measures other than numerical analysis can be utilised to manage the uncertainties (e.g., methodological, QA, etc.)? Please provide examples.

Design adaptation:
- limitation of high temperatures to preserve favourable and known physical and chemical environment (the envisaged repository concepts should prevent rises in temperature that could prejudice the containment capabilities of the repository components, adoption of an over-pack is relevant to prevent releases of activity in temperature conditions where transport phenomena are poorly controlled…)
- seals designed with narrow trenches to intercept EDZ
- dead end architecture of disposal tunnels
- location of shaft and repository areas with respect of mapped structures and underground flow patterns

Seeking for national/international consensus: for example, hypotheses describing biosphere can not be based on strict technical expertise but must rely as much as on possible consensus of various stakeholders concerned

10. What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?

Base data:
- wastes: inventory (amount and volume) of waste generated depend on operating hypotheses which may vary in time, degradation kinetic
- geological/hydrogeological data: presence and role of fractures in the clayey
host rock formation and surrounding limestone layers

- response spectrum for earthquake and possible effect on host rock

Changes in repository components

- margins for thermal dimensioning

- characterisation of gas release (corrosion) and transfer in poorly desaturated media and complex components (seals or plugs)

- mechanical behaviour of rock and extension of EDZ around excavations

- transient state of cement, steel and clay components under repository conditions

Construction and Operational phase, Long term behaviour of repository and dosimetric impact (long term performances will depend on the initial and real state of the components during construction and operational phase

- How to practically measure the level of quality which will be actually reached in situ for the various components of the repository: methods, process, quality control to detect defects (e.g. of canisters…) and account for effects of natural heterogeneities and defects due to in situ manufacturing,

- How to derive from this measurement the in situ performance of component? what will be the criteria, function indicators upon which (below which) the long term performance of the component should lead to an altered evolution of the repository?

- influence of the repository chemical environment conditions occurring during transient phase on confinement properties of components and long term behaviour of repository

- extrapolation of canisters and seals performance over period of time not available to experiments and in situ monitoring (in connection notably with interactions during short or longer transient phase)

- derivation and classification of evolution scenarios according to the level of confidence in the specified characteristics of the components, the tolerance, deviations from specifications…

- biosphere and model transfer for radionuclides likely to cause the major dose (I129, Cl36…)
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11. **How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.**

Needs for demonstration tests in situ.

12. **What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.**

13. **With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.**

14. **Any other comments?**

15. **What are the key references that support your response?**
### A8 Germany - BGR, DBE, GRS

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1. **What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?**

Radioactive waste with negligible heat generation: The Konrad repository is licensed, but a lawsuit pertaining the license has been filed and is pending.

Low- and intermediate-level waste: The Morsleben repository ERAM was licensed in the former German Democratic Republic and was operated until 1998. The approval procedure for backfilling and sealing is in progress.

HAW: The Gorleben Salt Dome was investigated as a potential repository site for all types of radioactive waste. The detailed site characterisation was interrupted in 2000 for political reasons.

The performance of a new site selection procedure is presently discussed.

2. **What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?**

In 1983 the then responsible Federal Ministry of the Interior published safety criteria for the final disposal of radioactive waste. These criteria specify the maximum acceptable individual dose limit. The criteria do not include requirements pertaining to treatment of uncertainty. An amendment of the safety criteria is under way.

3. **How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.**

Uncertainties are classified in the following categories:

*Scenario uncertainties:* Means, that a scenario has a probability of occurrence, which is very uncertain and can only roughly be estimated.

*Model uncertainties:* In some situations, it is unclear, which model has to be applied for describing a specific effect or part of the repository. It may, e.g., be unknown whether the radionuclides take one or another way through the host rock, and these two possibilities may require different models.

*Parameter uncertainties:* Nearly all parameters of an integrated PA study are more
or less uncertain. This can be due to poor knowledge about the system or its future development, an insufficient experimental basis, or principal reasons. In the latter case, the parameter uncertainties have to be accepted as a physical fact, and are called aleatoric. Uncertainties, however, that can, in principle, be reduced by additional measurements or improved system investigation are called epistemic.

### 4. How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.

**Scenario uncertainties:** If its probability of occurrence seems very low, a scenario is excluded from further investigation. Normally, an undisturbed evolution scenario is considered, and, additionally, a low number of disturbed evolution scenarios. Since the probabilities of occurrence are very uncertain, the scenarios are chosen such that they represent, as far as possible, the worst cases. The selected scenarios are considered independently.

**Model uncertainties:** In the case of a known model uncertainty, the probabilities of alternatives are estimated and a parameter is defined that switches between the respective models, depending on its value, in a probabilistic analysis. This technique was used, e.g., to consider different possible transport paths within the ERAM repository.

**Parameter uncertainties:** Uncertain parameters are analysed and an adequate distribution function is defined for each of them. If, e.g., only an interval of possible values is known, a uniform distribution is chosen, if a preferred value is known within the interval, a triangular or normal distribution is chosen. For deterministic calculations, parameters are preferably taken from the conservative end of their interval, but sometimes, this is not unique. Parameter uncertainties are best treated with a probabilistic approach. Aleatoric and epistemic uncertainties require, in principle, their own techniques of analysis, but in reality, most uncertainties can be considered to be epistemic.

A detailed probabilistic uncertainty analysis for a generic HLW repository was done in the SAM study [1].

The methodology was also applied for the long term safety assessments of the ERAM LAW repository and the ASSE mine.

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5. How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.

Presently, an important uncertainty is the behavior of the EDZ during saturation. As the EDZ is coupled to the access shafts and drifts it must be regarded as a potential pathway. In PA the flow resistance of the EDZ is included into the flow resistance of a geotechnical barrier. Practical experience shows that the hydraulic behavior of the EDZ depends significantly on mechanical stress state during saturation. This aspect is not always included in PA.

Another important issue is the compaction of crushed salt. Uncertainties exist about the development of the compaction process at very low porosities and require conservative assumptions.

6. What approach to system PA is preferred / appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of “fuzzy mathematics”; others)?

Integrated PA is done with essentially simplified 1-D models in order to allow for computing long time frames within a reasonable real time. If a lot of uncertainties exist, a simplified approach seems acceptable. The results, however, must not be misinterpreted as an exact prognosis of future effects but as a safety indicator. Deterministic reference case calculations and local parameter variations are performed to increase the general understanding of the system. As far as possible, parameters are chosen conservatively, but in many cases conservativity can not be proven. Therefore, it is always necessary to complement the deterministic calculations by a probabilistic uncertainty and sensitivity analysis.

7. How does the PA conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.

A statement about the safety of a repository is only possible if the level of confidence in the calculated results is known. Therefore, uncertainty analysis is a necessary part of all comprehensive safety assessment studies. The uncertainty is analysed probabilistically by performing a number of runs with randomly chosen parameters. There are different requirements to the uncertainty analysis. Proposed regulations require that, with a confidence level of 90%, the 90%-quantile of the calculated results be below the limit, which is a rather weak criterion and can be proven with a low number of runs. A more detailed uncertainty analysis, yielding information about the distribution of results, requires several hundreds of runs.
The sensitivity analysis is first performed as a local sensitivity analysis with deterministic parameter variations, and then as a probabilistic global sensitivity analysis, ranking the parameters after their global influence on the result. Generally, it requires a larger number of runs than the uncertainty analysis. Different linear and non-linear methods for sensitivity analysis are known. The task is independent of the uncertainty analysis, but often done within one step and using the same set of calculations.

8. What supporting arguments are available / relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.

A proper uncertainty analysis can yield information about the existing uncertainties, but not reduce them. To prove the safety of a repository, it is sensible not only to rely on one line of argument. Additional safety indicators, such as radionuclide flows and concentrations, can improve the safety statement by excluding a complete field of uncertainty, e.g. all uncertainties relating to the biosphere, and using completely different safety measures. This has been tested in the SPIN project [2].

The uncertainty of the safety statement can also be reduced by means of additional, over-conservative investigations that only use data of low uncertainty. For example, the radiotoxic inventory of the repository can be compared with the natural radiotoxicity of the surrounding rock, and by showing that it falls under this reference after some time by decay, one can establish a limited timeframe, during which a proper functioning of isolation measures is necessary. Such an investigation has been done for the ERAM repository.

9. What measures other than numerical analysis can be utilised to manage the uncertainties (e.g., methodological, QA, etc.)? Please provide examples.

Classical engineering methods, e.g. a safety oriented repository design (safety design), improvement of the natural system, proof of structural reliability of important design elements to reduce variation ranges of their safety related characteristics, and QA.

10. What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?

The HM coupling of the EDZ acting in parallel to geotechnical barriers and the long-term evolution of the geotechnical barriers. In case of salt rock the behaviour of the EDZ and the geotechnical barriers of a well designed repository are decisive for the classification of brine intrusion scenarios (undisturbed or disturbed).
From the scientific point of view the likelihood is small, in public communication, however, this uncertainty can not be neglected.

11. How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.

If uncertainties affect safety, engineering measures are used to reduce uncertainty, e.g. by an optimized design.

12. What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.

German RTDC-1 participants have no experience in communicating uncertainty in different ways.

13. With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.

There are no unique rules for establishing the distributions of uncertain parameters. Distributions and intervals are often chosen more or less arbitrarily, which leads to results of the uncertainty analysis that themselves are uncertain. A similar problem exists with parameter correlations; sometimes there is a vague feeling that two parameters are statistically correlated, but there is no unique rule to quantify the degree of correlation. Internationally accepted rules for analysing the knowledge about uncertain parameters and their correlations should be established.

Moreover, there are no unique rules for performing a probabilistic uncertainty analysis and assessing its results. It is unclear, how many runs should be made, which criteria should be fulfilled, and how the results should be communicated to the public. In Germany, there are no regulatory rules so far. An international consensus would be desirable.
**PAMINA RTDC-1 Work Package 1.2: Questionnaire for RTDC-1 Participants**

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14. **Any other comments?**

15. **What are the key references that support your response?**

A9  Japan - NUMO

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<td><strong>Organisation(s):</strong> Nuclear Waste Management Organization of Japan (NUMO)</td>
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<td><strong>Responsible Person(s):</strong> K. Ishiguro and K. Wakasugi</td>
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1. **What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?**

Taking into account the technical achievement of generic feasibility study over last twenty years, which was integrated in JNC’s H12 [1], the Japanese programme for geological disposal of HLW stepped into an implementing phase with the promulgation of the “Specified Radioactive Waste Final Disposal Act” (hereinafter referred to as “the Act”) in June 2000. Following the Act, NUMO was established in October 2000.

The Act specifies that the siting process shall consist of three steps. Firstly, Preliminary Investigation Areas (PIAs) for potential candidate sites are nominated based on site-specific literature surveys (LS) focusing on long-term stability of the geological environment. Secondly, Detailed Investigation Areas (DIAs) for candidate sites are then selected from PIAs following surface-based investigations, including boreholes, carried out to evaluate the characteristics of the geological environment. Thirdly, detailed site characterisation, including investigations using underground research facilities, leads to selection of the site for repository construction. According to the present schedule, repository operation may start as early as the mid-2030s.

NUMO announced the start of open solicitation of volunteer municipalities for PIAs with publication of an information package on December 19, 2002 and has been at the first stage of the siting process. NUMO just received an application from Toyo town in Kochi prefecture, effective as of January 25, 2007. NUMO initiated an internal procedure that includes confirming the geological conditions in Toyo town. The LS will be started off in the near future. NUMO is continuing to call for other municipalities to apply as volunteer areas for exploration.

In accordance with the new framework specified by the Atomic Energy Commission of Japan, JAEA (successor of JNC) continues to be responsible for R&D activities aimed at enhancing the reliability of disposal technologies and establishing safety assessment methodologies and associated databases. JAEA has thus been actively promoting R&D aimed at contributing to the implementation of disposal by NUMO and to the safety regulations to be formulated by the Nuclear Safety Commission of Japan (NSC) and the Nuclear and Industrial Safety Agency (NISA).
2. **What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?**

Although regulatory compliance requirements have not been defined yet, NSC[2] and NISA[3] have been discussing the framework of the regulation of HLW repository. More recent NSC report on common key issues for radioactive waste disposal suggests the need to consider scenario-based criteria by classification of assessment scenarios based on the possibility of occurrence, with specifying corresponding dose constraints.

3. **How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.**

The long-term safety of a given geological disposal system cannot be assessed conclusively due to the incompleteness of our knowledge about the system and its future behaviour. These uncertainties can be classified into the following types in the H12 report [1]:

- **Scenario uncertainty:** Scenario uncertainty arises from limited knowledge of the evolution of processes such as chemical interactions, the timing and frequency of events on geological environment and future human activities.

- **Model uncertainty:** In some cases, two or more alternative conceptual models are able to explain the observed behaviour of phenomena equally well, but lead to significantly different predictions when they are used to extrapolate the observations over time and/or space. This is one source of model uncertainty. Model uncertainty can also arise from possible errors in formulating and simplifying mathematical equations and in programming software.

- **Data uncertainty:** Data uncertainty arises from measurement errors, interpolation of spatially heterogeneous geological properties and extrapolation of results of experiments and natural analogue studies over times and conditions relevant to the assessment.

It’s noted that there is another types of uncertainties, stochastic variability and lack of knowledge, referred to as Type A and Type B, respectively. It can be thought they express the difference of sources about uncertainties. On the other hand, the former classification expresses the treatment of uncertainties in the PA.

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4. **How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.**

The treatment of the uncertainties has not been determined yet in NUMO. But the same manner as that dealt with in the H12 report [1] will be used at the early stage of site investigation. The general treatments of the different uncertainties are as follows. See also Table 1 for another categorization and its treatment in the H12.

- **Scenario uncertainty:** The scenarios are classified into base case scenario, altered scenario and destructive event scenario. The altered scenario and the destructive event scenario are evaluated as a what-if like scenario.

- **Model uncertainty:** A deterministic analyse are performed using an altered model from the model which is used at the reference case. (e.g. colloid transport model)

- **Data uncertainty:** A deterministic analyses are conducted using varied parameters from those used at the reference case analysis.

The treatment of uncertainty will be affected by the requirements of the regulatory body.

5. **How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.**

Major uncertainties have not been identified because site characterization has not been commenced yet. General perspective is described as follows [4].

Generally, available literature and site-specific database could be quite limited at the early stage of site investigation, in particular, the LS stage and the largest uncertainties may be associated with the geological environment. Little weight should then be placed on barrier performance of the geosphere at this stage, but EBS or near-field processes may be able to provide a robust safety case with minimal performance from the geosphere (predominantly isolation and protection of the EBS). Qualitative arguments in the safety case may be more meaningful than quantitative PA calculations at this stage, to scope uncertainties and identify data requirements for the preliminary investigation (PI) programme and to provide strategy and guidance for the development of the repository concept and safety case at later stages.

At the PI stage, in which field investigations are initiated, more detailed technical evaluation is required within the safety case in order to justify the important (and politically sensitive) selection of DIAs. At this stage, the safety case will include
more quantitative evaluations based on surface geological investigations and modelling, although availability of geological information will still be limited and significant uncertainties may remain. Site-specific data, based on several boreholes and geophysical investigations, will be available for the repository concept and safety case development, although again the importance of remaining uncertainties needs to be borne in mind. An emphasis may still be placed on EBS performance in cases with limited geological information or complex and heterogeneous geology [5]. The safety case at this stage also provides guidance for subsequent, more detailed investigations (including that in underground characterization facilities at the DIAs) to reduce any identified uncertainties in the geological database.

Since there are many approaches for PA, they should be used appropriately depending on the purpose of PA. The fig.1 shows modelling strategy in NUMO [5]. Process models express the behaviour of sub-system or system components in detail. System models integrate all process models conservatively and describe the behaviour of total system and safety relevant view.

At the LS stage, the available literature and site-specific database may be quite limited, so PA will be conducted by using a simple system model and generic data set. Since the largest uncertainties at this stage will be associated with the geological environment, uncertainty analysis is mainly focused on the site descriptive model for the geological environment such as groundwater flow (note qualitative arguments about uncertainties may be more meaningful than quantitative PA calculations at this stage). The deterministic approach may be used in order to provide a transparent assessment of sensitivity of the system to variations in the geological condition. The results will be reflected the selection of the PIAs.

At the PI stages, the surface-based investigations, including borehole survey and geophysical prospecting will be conducted. The uncertainty analysis based on the site-specific data will be performed to select the DIAs. Since available geological information will still be limited and significant uncertainties may remain, probabilistic approach, stochastic approach or use of fuzzy mathematics using the system model may be appropriate to give feedback information to site characterization works and R&D (e.g. priorities of the further investigation and key issues). ((i), (ii) in the fig.1)

At the DI stage, NUMO will be required to provide all safety relevant evidence including information to be associated with uncertainties to make a decision by stakeholders whether NUMO can go into the construction phase or not. In this
situation, it is important that NUMO understands the system behaviour by using process model (often complex models) as realistic as possible and quantifies the safety margin by comparing the results from system model ((iii), (iv) in the fig.1). The system model at this stage should be simple and easy to understand to promote an understanding of stakeholders, while considering the results of process models ((v) in the fig.1). In any case, what types of approach and model (deterministic or probabilistic, realistic or conservative, etc.) we use is strongly dependent on requirement from the regulator.

**Fig.1 Modelling strategy of NUMO**

7. **How does the PA conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.**

NUMO hasn’t decided detail methodology for PA yet, since the site characterization has not been commenced. But the same manner as that dealt with in the H12 report [1] will be used as a fundamental PA methodology. In the H12 report the assessment consists of the following steps (see the fig.2):

- Reference Case based on the reference system and reference design is defined in order to provide a central case for comparison of numerous calculation cases.

- Sensitivity analyses are performed to understand the response of system performance to uncertainties in scenario, model and data, and alternative geological environment cases and alternative design cases to address various geological disposal systems.
The key phenomena and uncertainties are identified based on the results of sensitivity analyses.

To evaluate the system safety, the combinations of uncertainties and variations are considered in the total system performance analysis. The rational combinations are considered to reduce to a number that is manageable using a deterministic approach.

The results are compared with some safety standards. Sensitivity analyses provide that which deviations from the likely characteristics and evolution the system affect overall performance and the performance of individual system components. These analyses should be performed prior to the total system performance analysis to make a number of analysis cases more reasonable and manageable. Uncertainty analysis wasn’t defined explicitly in the H12 report.

Evaluation of Confidence

- Results of foreign safety assessments
- Supplementary safety indicators
- Natural analogues

8. What supporting arguments are available / relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.


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9. **What measures other than numerical analysis can be utilised to manage the uncertainties (e.g., methodological, QA, etc.)? Please provide examples.**

- Peer review by independent experts
- Appropriate management methodology or tools (e.g. QMS, NSA, RMS)

In order to maintain flexibility without losing focus and make the work more systematic, NUMO has developed a formalised tailoring procedure, termed the NUMO Structured Approach (NSA)[4]. The NSA provides a methodology for developing repository concepts in an iterative manner, which couples management of immediate issues with consideration of longer-term developments. The NSA also guides the interaction of the key site characterisation, repository design and PA groups and is facilitated by tools to help the decision-making associated with the tailoring process (e.g. a requirement management system, RMS) and with comparison of siting and design options (e.g. multi-attribute analysis). The RMS is being developed to help implement the NSA. This RMS will allow the justifications, supporting arguments and knowledge base used for every decision to be clearly recorded and will highlight when such decisions may need to be revisited, for example due to changing boundary conditions or technical advances. It thus serves as a valuable tool to keep track of the wide range of constraints on designs, while the entire process runs within an overarching Quality Management System (QMS). NUMO has developed its own QMS to ensure high quality of all its technical activities, documents and databases. The QMS will be integrated within the RMS, to ensure the total quality of the repository project, including the safety case development [4].

10. **What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?**

The main uncertainties at the generic PA are listed in Table 1 based on the H12 analysis [1]. However the largest uncertainties may be associated with the geological environment as available literatures and site-specific database could be quite limited at the early stage of site investigation. See also the answer for the question 5.

11. **How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.**

Since NUMO’s strategy for safety case development is constrained by a staged siting approach, uncertainty analysis will be used depending on the objectives of PA in each stage.
The aim of PA at the LS stage is to illustrate fundamental safety of the repository concept at the volunteer site, utilising evidence from the literature information for the site, complemented by generic and international experiences. Generally, available literature and site-specific database may be quite limited. At this stage the uncertainty analysis will be used to identify key uncertainties that will be associated with geological environment. Another objective of uncertainty analysis at this stage is to provide information to the selection of PIAs, and the strategy and guidance for the site investigation in the PI stage.

At the PI stage more detailed technical evaluation is required in order to justify the selection of DIAs. At this stage, site-specific data, based on several boreholes and geophysical investigations, will be available for the repository concept (RC). So the uncertainty analysis in this stage will be used to compare between the potential areas for DIA and their system design options.

The PA at the DI stage will be required to be more convincing and complete to justify the construction of a repository at a selected DIA and to demonstrate compliance with regulations. Site-specific data from the underground experimental facility will be a significant input for the development of the RC. The uncertainty analysis using process model which can deal with detail process/barrier geometry may be useful to understand system behaviour and optimize the repository design. The uncertainty analysis using system model may be useful to identify key issues (see fig.1). In the safety case, NUMO will submit all safety relevant evidence including results of uncertainty analysis to make a decision by stakeholders as the licence application. The uncertainty analysis in the safety case may complement the robustness with respect to satisfying the safety criteria.

12. **What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.**

13. **With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.**

14. **Any other comments?**
15. What are the key references that support your response?

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<thead>
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<td>• Boundary conditions (e.g. dilution volume)</td>
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<td>• natural phenomena</td>
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<td></td>
<td>• initial defects</td>
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<td>• future human intrusion (e.g. probability drilling at the site, drilling a well, etc)</td>
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A10  Netherlands - NRG

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<td>J. Grupa and J. Hart</td>
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1. What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?

Concept assessment.

2. What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?

The Dutch legislative and regulatory framework governing the safety of spent fuel and radioactive waste management is contained in:

- the Nuclear Energy Act (1963, as amended 2004);
- the Environmental Protection Act (1979, as amended 2002);
- General Administrative Law Act (1992, as amended 2003);

In The Netherlands there are presently no specific requirements for the long term safety of a radioactive waste disposal system, since there is no intention to dispose radioactive waste in a geological disposal system in the near future.

Still, the general radiation protection requirements apply (very similar to the ICRP radiation protection principles), and also prescriptions following from the standard format of the Environmental Impact Statement apply.

Moreover, based on the existing safety studies for the generic disposal concept, specific requirements are expected to address the following issues:

1. Probabilistic analyses to obtain estimates of uncertainty bandwidths.

2. Monitoring of the system to detect unexpected behaviour, i.e. behaviour ‘outside’ the uncertainty bandwidth.

3. If the system develops to a situation outside the foreseen uncertainty bandwidth, if necessary mitigative actions can be undertaken up to the extent of retrieval of the waste.
A generic probabilistic safety analysis (PROSA, [1]) of the Dutch generic reference disposal concept has been performed. In this study:

A systematic approach to scenario selection has been used that ultimately leads to a set of selected scenarios that covers all aspects relevant for the long term safety.

Within each scenario, uncertainties are treated by determining suitable probability density functions for the values of the model parameters (or probabilities of specific values if the parameter is discrete), followed by a large computational effort including statistical pre- and postprocessing to determine probability density functions for the individual effective dose.

This approach implies two main types of uncertainty:

a. It is uncertain which of the selected scenarios will cover the actual future development of the disposal system.

b. It is uncertain what the precise model representations are of the actual development even if it would be known which scenario is applicable. This type of uncertainty includes conceptual model uncertainty (i.e. how a system is subdivided into “nodes”), modelling uncertainty (how accurate are descriptions of the various phenomena), and uncertainty in the model data.

In PROSA, the second type of uncertainty is simulated by applying suitable bandwidth in the model parameter values (‘parameter uncertainty’). This also covers model uncertainty: if a mathematical model has only limited applicability, this is ‘stretched’ to the applicability needed by increasing the bandwidth of the values of the model parameters.

Parameter uncertainty is covered by determination of an adequate probability density function for the value of the model parameter. In practise, however, for most of the more complex processes, the bandwidth of the value of a model parameter is dominated by model uncertainty.

*Example: the probability density function of the subrosion rate of a salt dome is based on measurements of many similar salt domes, and determination of the long term history of the subrosion rate. This has to be regarded as a simplification of more complex geophysical models that describe the spatial development of a salt dome.*

In some cases model uncertainty is linked to scenario uncertainty, since the selection of a specific scenario implies the application of dedicated models to address the role
A special ‘Reliability Assessment’ was included in PROSA which implies motivated and explicit decisions on how to deal with model uncertainties (e.g. treatment by scenario definition or by additional parameter-uncertainty).

The so-called ‘conceptual model uncertainty’ has not been dealt with explicitly in PROSA. Conceptual models are built on the basis of features like legal requirements, availability of and experience with computer codes, and availability of time/resources. In addition, knowledge, experience and expert judgement are important prerequisites for building a conceptual model. As such, the influence of the modeller on the final results might be significant. This might imply that conceptual model uncertainty can be a dominant type of uncertainty.

‘Conceptual model uncertainty’ can be addressed by external reviews and comparisons with other studies (benchmarking).

4. How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.

Scenario uncertainty:

In PROSA very unlikely scenarios have been screened out and were not analysed. Unlikely scenarios and probable scenarios were treated on an equal basis. i.e. in the overall assessment it was assumed that the probability of each selected scenario is almost 1. This assumption is equivalent to use a deterministic ‘worst case’ analysis for a safety assessment rather then a probabilistic analysis.

Example: the calculated doses in the PROSA study [1] from the brine intrusion scenario are presented and evaluated as if the scenario would occur, although the scenario is actually unlikely. The reason is that the calculated maximum doses are almost six orders of magnitude below the natural background, so for the purpose of that study there is no further benefit in considering the probability of this scenario.

Model- and parameter uncertainty:

For each selected scenario a separate probabilistic analysis has been performed, where model uncertainty and parameter uncertainty are all translated into parameter uncertainty.
Example: the plastic behaviour of rock salt was modelled by an analytical model that was tuned by measurements and detailed FE calculations. This was necessary because measurements are only limited available and FE calculations are only possible idealised geometries. However, it was possible to cover the model uncertainty by using suitable bandwidths for the model parameters (EVEREST [2]).

A safety case (that is wider than the probabilistic safety analysis in PROSA and EVEREST) has not been prepared. Conceptual model uncertainty is not addressed explicitly, but a safety case could provide a useful framework for this issue.

5. How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.

There are a thousand or more model parameters that have to be addresses in a full Performance Analysis. In a full probabilistic analysis for each of these parameters probability density functions have to be determined, and also cross-correlation functions. Without an initial screening procedure, the total number of probability density functions and cross-correlations is unmanageable.

In practise, the uncertainty in most of the model parameters does not contribute significantly to the uncertainty in the endpoints of the calculations, and does not correlate with the uncertainty in most other model parameters. This allows a screening procedure that reduces the number of parameters to be addressed in a probabilistic analysis to manageable proportion.

The initial screening is essentially an expert judgement activity. Since the model parameters are inseparable from the associated model, and the model is connected to a process, (feature or event), in PROSA [1] the initial screening can be combined with the scenario identification procedure. This allows a systematic documentation of the expert judgement rationales for all models and associated model parameters.

Example: In PROSA, radiolysis (FEP 3.4.5) is judged to be of minor importance. This implies that also the model parameters related to radiolysis do not have to be addressed in the probabilistic analysis.

The determination of the probability density functions and correlations for the selected model parameters is often difficult and often also based on expert judgement.
6. What approach to system PA is preferred / appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of “fuzzy mathematics”; others)?

A system PA consists of deterministic as well as probabilistic analysis. Deterministic analysis are used to get a good understanding of the performance of the system in various conditions.

In deterministic analyses the best available values of parameters have to be used. In addition, for parameters that are less well characterized conservative assumptions are implemented. Undue conservatism must however be avoided. To remove undue conservatism complex modelling is often required. For those parameters that will be addressed in probabilistic assessments realistic assumptions can be made, since the conservative assumptions will be part of the probabilistic assessment. In a broad sense, undue conservatism can be avoided amongst others by probabilistic analyses.

Probabilistic analyses usually require simplified models due to practical limitations to computational resources. Deterministic results with obtained with complexer models are used as ‘benchmarks’ for the probabilistic results.

Statistical tools for the probabilistic analyses can be complex, but are well defined in mathematics. until now the standard approaches (where we regard ‘fuzzy mathematics’ as non-standard) have been adequate.

7. How does the PA conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.

There is a mathematically well defined difference between sensitivity and uncertainty.

If the endpoints of the calculation consists of n values (e.g. doses at various times, nuclide concentrations in given locations, etc.) these can be mathematically represented in a n-dimensional vector \( \mathbf{r} \). The input parameter values can be represented in an m-dimensional vector \( \mathbf{s} \).

The sensitivity for a single input parameter \( s_i \) is defined as: \( \frac{\partial \mathbf{r}}{\partial s_i} \) (this includes correlations in \( \mathbf{s} \)).

To obtain sensitivities, a deterministic case has to be selected (represented by a specific \( \mathbf{s} \)), and no probability density functions for \( s_i \) are required. But sensitivity already includes cross correlations.

Commonly the mathematical sensitivity is normalised with respect to the bandwidth in \( s_i \). This gives the opportunity to rank the various model parameters with respect to
their sensitivity-impact on the endpoints of the calculations.

Alternatively, a number of deterministic calculations where one parameter (say $s_p$) is varied gives information about the behaviour of $[\frac{dr}{ds_p}]_s$ and can therefore be called a sensitivity analysis.

*Example:* in PROSA calculations have been performed for disposal facilities at various depth (from 200 to 500 m depths). The results showed that the maximum dose is relatively insensitive for the depth of the facility.

To obtain uncertainty bandwidths of the endpoints of the calculations, usually a probabilistic analysis is performed. The statistical techniques needed are more complex than in the above described sensitivity analyses. There are various techniques to rank the model parameters with respect to their impact on uncertainty in the endpoints.

*Example:* For the subrosion scenario the following statement is found in PROSA: “In case of the deep diapir (being the host rock), the probability for the dose rate to be greater or equal to 53 μSv/year is 1%.”

8. **What supporting arguments are available / relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.**

Uncertainty analysis is a sound scientific ingredient of a safety assessment. A probabilistic analysis gives additional endpoints such as total risk (rather than dose).

Confidence, or trust, or acceptance, are primarily not provided by uncertainty analyses.

Example taken from on a special issue of ‘radiation protection dosimetry’ on ‘Expert Judgement And Accident Consequence Uncertainty Analysis’ Special Issue, Vol. 90 No.3 2000):

“The approach typically applied consisted of a scenario analysis comprising a great variety of exposure situations at the different stages of scrap processing, steel production and product use. It turned out that it was difficult to define the right degree of conservatism in defining the scenarios. (...) It was therefore decided to develop a stochastic simulation model to assess the distribution of individual doses to the general public committed by recycling of contaminated scrap. (...) This marked a breakthrough and paved the way for an overall concept of clearance which has been supported by probabilistic considerations in different areas. In the justification, however, a higher profile is given to a properly selected set of deterministic exposure scenarios.”
9. **What measures other than numerical analysis can be utilised to manage the uncertainties (e.g., methodological, QA, etc.)? Please provide examples.**

Uncertainties as dealt with within PA may cause logistic problems because of the large amounts of expert judgement decisions to be taken. This can be dealt with by coupling the issue to a systematic approach of scenario identification.

*See also Question 5.*

A clear distinction must be made between uncertainties that are dealt with in the PA, and uncertainties that are out of scope.

*Example: in most studies operational issues of the disposal facility were seen as out of scope of the generic safety study. However, the issue of retrievability opened up scenarios like the pre-closure abandonment scenario 3)], which was originally out-of-scope. However, the treatment of this type of scenarios is actually independent of the issue of retrievability, i.e. the uncertainty with regards to the proper decommissioning of a facility must be addressed in a safety case, irrespective of the retrievability issue.*

This stresses the importance of a safety case, as this will put the embedded PA in perspective.

10. **What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?**

The PROSA probabilistic study has shown that large uncertainties arise from the hydrology in the overburden and in the amount of dilution in the exposure pathways in the biosphere. It is inherent in the disposal concept that engineered barriers and the near host rock must behave very reliable, which explains why these important parts of the disposal system do not dominate the uncertainty.

*Example: The hydrology in the overburden, as well as the dilution in the biosphere are depending on far future climatic conditions. Within the next 100 000 years one or more ice ages are likely to occur. However, climatic models are unable to predict when. This causes a very broad bandwidth in possible local climatic and hydrological conditions.*

It should be noted that the strength of the disposal concept is found in the reliable behaviour of the engineered barriers and the near host rock, as these systems are not affected by e.g. an ice age.
11. How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.

Results of uncertainty analysis are reported, in general with the purpose to substantiate conclusions that were already drawn from deterministic analyses.

*See Question 8.*

More and more the dose limits used for license submissions are expanded to cover also probabilistic results.

*Example: a limit like ‘the dose should not exceed xx mSv’ is adapted to probabilistic results as ‘the probability to exceed a dose of xx mSv should be less then yy%’.*

Work programmes and priorities have to take into account that uncertainty analysis require a lot of effort.

12. What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.

A performance analysis is complex. The contribution of the uncertainty analysis to this complexity is relatively small. The information should be presented in a wording that fits the audience. The complexity therefore requires that much effort is given to the presentation. In practice, uncertainty can be communicated by using products as maps, graphs, tables, charts, flip books, images, and written or oral presentations. Selecting an appropriate product type and carefully crafting the contents can substantially reduce the likelihood of misunderstandings.

13. With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.

There is a link between uncertainty analysis and scenario identification methodology that can be useful. The way this link can be utilised is however specific to the various analysis strategies.

A demonstration of this link is planned in RTDC 2 in the form of a formal scenario definition exercise and a combined uncertainty analysis of this scenario. The demonstration is focussed on the abandonment scenario that has deterministically
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addressed in the Dutch CORA [3] study. The two related activities are:

1. scenario definition by applying a formal expert elicitation procedure
2. an uncertainty screening followed by a probabilistic analysis of this scenario.

14. **Any other comments?**

- 

15. **What are the key references that support your response?**


CORA Study:

A11 Spain - ENRESA

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<td>Responsible Person(s):</td>
<td>Jesús Alonso Díaz-Terán</td>
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1. **What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?**

The Spanish programme for High Level waste disposal is at the stage of general feasibility studies. There are no definite plans at present to move into a new development stage.

The aim of ongoing activities in this field is the consolidation and update of the knowledge already acquired, taking advance of the new international developments.

2. **What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?**

The only acceptance criteria established by the Spanish Regulatory Body up to now is either that the individual equivalent effective dose does not exceed $10^{-4}$ Sv.y$^{-1}$, or that the individual annual risk does not exceed $10^{-6}$.

There are no specific requirements on the treatment of uncertainty.

3. **How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.**

Three different types of uncertainties are considered:

- **System evolution uncertainty**, related to the prediction of the future evolution of the barriers of the system and the Biosphere.

- **Conceptual uncertainty**, related to the incomplete understanding of the nature of the processes involved in repository evolution.

- **Data uncertainty**, due to the limited amount of data available and the variability of the different input parameters to the models.

The previous classification already constitutes an example.
4. How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.

Each one of the three previous types of uncertainties has been dealt following different approaches:

- **System evolution uncertainty.** In addition to the Reference Scenario, other scenarios are defined and evaluated to study the sensitivity of the system performance to alternative assumptions on future system evolution.

- **Conceptual uncertainty.** Calculations are performed for different conceptual models and variants derived from the Reference Scenario.

- **Data uncertainty.** This uncertainty is considered through the use of probability distributions in the probabilistic calculations. The acceptability of results is assessed by comparing the average dose to the dose acceptance criterion (see question above)

For the two first types of uncertainty, the doses calculated are compared for each scenario, or in general, for each calculation case, to the dose criterion (there is not consideration for the probabilities of the scenarios). In all scenarios considered (with the exception of some intrusion scenarios) the calculated dose complies with the acceptance criterion.

In the Safety Assessment of a repository in clay (ENRESA 2003) the following scenarios were defined and analysed to address the uncertainty in the system evolution: Reference Scenario, Climatic Scenario, Deep Well Scenario and Poor Sealing Scenario.

In ENRESA 2003 many variants of the Reference Scenario were analysed using alternative models when there were significant conceptual uncertainties: different canister durations, constant spent fuel matrix alteration rate instead of the alpha radiolysis model, simultaneous failure of all the canister instead of failure spread over a long time period,…

In ENRESA 2003 data uncertainty is explicitly included in the probability distributions used in the probabilistic calculations.
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5. **How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.**

The treatment of uncertainties is so far very limited in scope. Safety Assessments have been performed for synthetic sites, created on the base of limited data available for the Spanish favourable areas. Due to the lack of a real site, data must be taken from the literature or be based on the limited information obtained during the site searching programme. This leads in general to defining wide ranges of values for most host rock parameters, to cover the different potential sites.

Near field barriers are better defined in the preliminary repository concepts. Although R&D programmes have already provided a significant amount of data, much uncertainty remains due to the open decisions on the final design and the fitting to the geological environment. As a consequence, for the near field models an enlarged range of data taken from the bibliography has been adopted, leading also to quite wide ranges of values of near field parameters.

Example: Bentonite is considered as buffer material in the disposal drifts for the Spanish repository concepts in granite and clay. On the base of bibliographic data, small ranges were assigned to the diffusion accessible porosities of bentonite, narrow ranges were assigned to the pore diffusion coefficients (Dp) and much greater ranges (up to several orders of magnitude) to the distribution coefficients of many chemical species.

Taking into account the stage of the Spanish programme, great uncertainties are judged unavoidable, but this has a beneficial effect, because the large uncertainty ranges considered ensure that potential combinations of parameter values that would lead to high doses can be identified. Uncertainties will be reduced at later stages when site specific information become available and engineered barriers properties are better known.

Since generic synthetic sites are used in Spanish Safety Assessments there are significant uncertainties regarding the future evolution of the system, which is analysed through different scenarios. Covering a wide spectrum of future evolutions is useful at the current stage of the Spanish programme because it provides information that can help for site selection. At later stages, when a site becomes available, the number of potential future evolutions of the system can be reduced.

Due to limitation in knowledge, there can be different alternative conceptual models to represent a given process. To deal with this uncertainty, calculations are performed with the different models in order to identify their relevance for the global system (for instance, two alternative models of matrix alteration are considered: time decreasing matrix alteration due to alpha radiolysis and a small constant alteration...
rate in reducing conditions in presence of H2). Hopefully, progress in scientific knowledge will allow to select the right model, and decrease the model uncertainty.

6. **What approach to system Performance Assessment is preferred / appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of “fuzzy mathematics”; others)?**

In Spanish Safety Assessment exercises the probabilistic approach is preferred, although deterministic calculations are performed too, taking the best estimate (most likely) values for the latter. Then, deterministic calculations may be considered realistic in general, but for uncertain favourable processes which, in general, are not considered (for example: the hindering by hydrogen build up of radiolytic spent fuel matrix oxidation is ignored)

Deterministic calculations are performed using highly detailed codes. The calculation chain is formed by a set of individual calculations with manual transfer of the results from one code to the next one. As a consequence, a complete deterministic calculation can take several days and requires a significant human effort.

Probabilistic calculations allow including explicitly the parameter uncertainties in the calculations. In addition, all the models used in the global calculation are implemented in a single input file for computer code (GoldSim) and a calculation requires little human effort.

The self-contained probabilistic models, together with the fast algorithms used in GoldSim allow performing many calculations in a short time period. As a consequence, sensitivity and uncertainty calculations are performed following the probabilistic approach.

The consistency between probabilistic and deterministic approaches has been verified at a general, informal level.

For the reasons exposed (less human effort and treatment of parameter uncertainty) the probabilistic approach is preferred, nevertheless the deterministic approach is judged also necessary, as it allows a more detailed and rigorous representation of the processes and of the geometry of the system.

7. **How does the Performance Assessment conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.**

The purpose of the sensitivity analysis is to understand how the system works and which parameters have a strong influence on results (mainly doses) and which are less relevant. This sensitivity analysis is performed through a set of parameter
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<th>Organisation(s):</th>
<th>Enresa</th>
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<tr>
<td>Responsible Person(s):</td>
<td>Jesús Alonso Díaz-Terán</td>
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<td>Date:</td>
<td>9 January 2007</td>
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Variation and “what-if” calculations. In the parameter variation calculations values are changed by a small factor, while in the “what-if” calculations radical assumptions are usually made (no solubility, no sorption,…) leading to much greater parameter changes.

Uncertainty analysis is understood as the quantification of the effect of the uncertainties in the assessment bases on the system performance indicators (essentially individual dose). This is being done through probabilistic assessment.

The previously identified three classes of uncertainties are treated in the PA in different ways:

- Calculations are performed for several scenarios in addition to the Reference Scenario.
- Probabilistic calculations are performed using alternative models when there are significant conceptual uncertainties (i.e. alternative fuel alteration models,…).
- Parameter uncertainties are included in the probability distributions used in the probabilistic calculations, allowing to transmit the uncertainty to the results (doses).

In the Safety Assessments already performed by Enresa a limited post-processing of the probabilistic results has been done: only mean doses and percentiles have been used. No formal analyses of which parameters control the uncertainties in the results have been done, but it is considered an interesting topic for the future.

#### 8. What supporting arguments are available / relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.

Spanish Safety Assessment exercises for repositories in granite and clay were done assigning wide ranges of values to most parameters, and doses were found to be well below the acceptance criteria. None of the individual runs of the probabilistic calculations leads to doses greater than 3% of the reference value (1E-4 Sv/yr).

We think that the previous result is a strong argument to show that there is no potential combination of values of the uncertain parameters that could lead to unacceptable results, and no efforts to further reduce uncertainties are necessary. This may be satisfactory for the current stage of feasibility studies. Nevertheless in future stages, in particular when the safety authorities and the public opinion need to be confronted and comforted, this is not enough. We think that it will be necessary to demonstrate that a strong scientific base is available, that the uncertainties are identified and properly managed, and that every reasonable effort to reduce them has been made (this would be a very long and gradual process, extended to the whole
Uncertainty management is intimately linked to the issue of confidence. The main element is the existence of a sound scientific programme subject to QA principles. The progress in terms of scientific understanding and data shall have to be submitted to critical analysis at different levels (assessment team, collaborating experts, overview groups, peer reviews, safety authorities). The step by step processes also plays an important role here, as the long time frames assure that new people come in and have a fresh look to the different issues. The third aspect is the robustness of the system (this mean that the system is a) reasonably predictable and b) forgiving in case of deviation, i.e. not very sensitive to uncertainties). Regarding the formal uncertainty analysis, both methodological approaches and mathematical methods are of fundamental importance.

Since no site has been selected in the Spanish programme, there are great uncertainties in all geosphere data. Uncertainties in near field barriers are smaller, but remain significant.

The Safety Assessment exercises for repositories in both granite and clay rock were done assigning wide ranges of values to most parameters, and doses were found to be well below the acceptance criteria. None of the individual runs of the probabilistic calculations leads to doses greater than 3% of the reference value (1E-4 Sv/yr).

In the future, when more data (mainly site specific) become available, uncertainty ranges are expected to decrease but remain bounded by those already used. Doses will be bounded by the estimates already performed too. As a consequence, we do not think that uncertainties could jeopardise the project in future stages of development.

Up to now, none of the uncertainties considered jeopardize the acceptability of the repository.
11. **How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.**

Uncertainty and sensitivity analyses have been very useful to identify the processes and parameters that control the long term repository evolution and its capability to isolate the radionuclides and delay their transport.

These methods have allowed to rank the importance of radionuclides, processes and parameters for the performance of the repository system. For instance, in the transport in the near field of a repository in granite it has been identified that for most radionuclides the main parameters are the distribution coefficients (Kd) and the equivalent water flow in the granite (Q_F), while the importance of the other parameters (Dp and 0 and solubility limits) is in general much smaller. Obviously these results are radionuclide-specific.

12. **What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.**

Enresa has practically no experience on this subject and we believe that the best way is to follow a systematic approach, identifying explicitly each type of uncertainty (3 types in the Enresa case) and how has been treated each one in the Safety Case.

13. **With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.**

We, as users of probabilistic approaches, think that an important weakness is the definition of pdf’s. We think this is an important field for improvement, and it is one of the reasons why we proposed a task on expert judgement elicitation. At a general level, in our opinion the methods to define pdf’s are of high priority.

The development of a methodology to extract as much information as possible from the fully probabilistic calculations would be useful. In particular, a systematic approach to identify the parameters that control the uncertainty in the results (doses) would help to focus R&D efforts. In the past, Enresa took place in the NEA PSA Group, and sustained an important activity in that area, which led to the proposal of a large number of sensitivity methods. Nevertheless, they did not prove to be very useful in safety assessment exercise. We think it is important to have a new verification of the potential usefulness of those, or new sensitivity analysis methods.
Another area which in our opinion needs developments is the change of scale. This is in particular the case for the modelling of the far field, especially in the integrated performance assessment, where parameter values for coarse models must be selected on the base of field data.

At a very high level, we think it would be very interesting to delineate an integrated and consistent view on the way to implement an appropriate management of uncertainty and how to show it: requirements, methods and tools.

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<th>14.</th>
<th>Any other comments?</th>
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<th>15.</th>
<th>What are the key references that support your response?</th>
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<tr>
<td>Enresa response is based on the Spanish Safety Assessments exercises for spent fuel repositories in granite (ENRESA 2000) and clay (ENRESA 2003). Both documents are available only in Spanish.</td>
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</table>
1. What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?

Detailed site characterisation stage, see section 1.1 of SKB TR-06-09 for more details.

2. What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?

See response from SKI.

3. How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.

All responses below are based on experiences and results from the SR-Can safety assessment project, the main report of which, SKB TR-06-09, was published in November 2006.

Several reports produced in the SR-Can project, with their names in bold, are referred to below. All these are primary references of central importance for the assessment and are published together with the SR-Can main report. See further the SR-Can main report, SKB TR-06-09 section 2.2.1, for a complete list of, and full references to these reports.

In SR-Can, the following broad definitions/classifications are used.

System uncertainty concerns comprehensiveness issues, i.e. the question of whether all aspects important for the safety evaluation have been identified and whether the analysis is capturing the identified aspects in a qualitatively correct way, e.g. through the selection of an appropriate set of scenarios. In short, have all factors, FEPs, been identified and included in a satisfactory manner?

Conceptual uncertainty essentially relates to the understanding of the nature of processes involved in repository evolution. This concerns not only the mechanistic understanding of a process or set of coupled processes, but also how well they are represented in a possibly considerably simplified mathematical model of repository evolution.

Data uncertainty concerns all quantitative input data used in the assessment. There are a number of aspects to take into account in the management of data uncertainty.
These include correlations between data, the distinction between uncertainty due to lack of knowledge (epistemic uncertainty) and due to natural variability (aleatoric uncertainty) and situations where conceptual uncertainty is treated through a widened range of input data. The input data required by a particular model is in part a consequence of the conceptualisation of the modelled process, meaning that conceptual uncertainty and data uncertainty are to some extent intertwined. Also, there are several conceivable strategies for deriving input data. One possibility is to strive for pessimistic data in order to obtain an upper bound on consequences in compliance calculations, another option is the full implementation of a probabilistic assessment requiring input data in the form of probability distributions. These aspects are further discussed in a dedicated Data report, an important reference for the SR-Can assessment.

4. How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.

There is no clear distinction between a quantitative PA and a wider safety case in SR-Can. All relevant calculations are seen as part of the safety case. The following can be said about the treatment of different kind of uncertainties:

**System uncertainty**

System uncertainty is generally handled through the proper management of FEPs in the SR-Can FEP database according to the established routines described in the SR-Can FEP report. The database structure and FEP management routines have been set up to assure that the following information is obtained:

- A sufficient set of initial conditions. This is obtained by including all initial state FEPs in the database. These are, however, often formulated in general terms and have to be expressed in a way that is specific to the KBS-3 system. This is done through the systematic documentation of a reference initial state in accordance with the description in the Initial state report and by using that reference initial state as a starting point for alternative initial states.

- A sufficient set of internal, coupled processes. This is obtained by including in the assessment all relevant process FEPs in the database. It is important to note that the database already from the start includes the result of several earlier exercises aiming at process identification for the KBS-3 concept. Influences between processes are handled, in the Process reports, by systematically going through a set of defined physical variables that could mediate influences and by the systematic treatment of boundary conditions for each process. Hence, in addition to including FEPs describing influences and couplings, the procedures for process documentation are set up in a way that enforces a systematic search for such
A sufficient set of external influences. This is obtained by including in the assessment all relevant external FEPs and by structuring the documentation of these in the Climate report in a format similar to that used for the internal processes.

Scenario selection

Another aspect of system uncertainty concerns the selection of a sufficient set of scenarios, through which all relevant FEPs are considered in an appropriate way in the analysis. The selection of scenarios is a task of subjective nature, meaning that it is difficult to propose a method that would guarantee the correct handling of all details of scenario selection. However, several measures have been taken to build confidence in the selected set of scenarios:

- A structured and logical approach to the scenario selection;
- The use of safety function indicators in order to focus the selection on safety relevant issues;
- The use of bounding calculation cases to explore the robustness of the system to the effects of alternative ways of selecting scenarios, including unrealistic scenarios that can put an upper bound on possible consequences;
- QA measures to ensure that all FEPs have been properly handled in the assessment;
- The use of independent reviews.

Conceptual uncertainty

The handling of conceptual uncertainty for internal processes is essentially described in the Process reports. For each process, the knowledge base, including remaining uncertainties, is described and, based on that information, a handling of the process in the safety assessment is established. Alternative conceptual models are sometimes formulated, and of these the model yielding the highest consequences is frequently chosen for compliance calculations. (Uncertainty regarding influences between processes can be seen as either system uncertainty or conceptual uncertainty, it is described as system uncertainty above.)

Through the use of a defined format for all process descriptions, it is assured that the processes and their associated conceptual uncertainties are described in a consistent manner. External reviews of central parts of the process documentation have also been performed.
Conceptual uncertainty for external influences is handled in a more stylised manner, essentially through the definition of a sufficient set of scenarios and by using state-of-the-art models for the quantification of external influences, e.g. ice models for the modelling of glacial cycles. Another method is the use of bounding cases that ensure that the consequences are overestimated.

Data uncertainty

Data uncertainties are handled according to established routines described in the Data report. Quality assurance is obtained through the use of a template for data uncertainty documentation, through clearly defined roles for participating experts and generalists and by the use of external reviews prior to finally establishing input data for the assessment.

Modelling

An essential part of the assessment concerns the quantification of both repository evolution and dose and risk consequences through mathematical modelling. Apart from requiring appropriately defined models that represent relevant conceptualisations of the processes to be modelled and quality assured input data, this step requires:

- good model documentation, including results of code verification and results of benchmarking against other models;
- procedures to detect and protect against human error in the execution of the models.

A dedicated SR-Can Model summary report describes models used in the assessment and provides references to more detailed descriptions of the models. Mapping of processes to models, provides an overview of the models used. A guiding principle is that models and data should be documented in sufficient detail to allow calculations to be reproduced and audited.

Human errors can be prevented e.g. by formal procedures for checking that input data are correct and by the use of alternative, often simplified, models for crucial aspects of quantification. An example of the latter is given in calculations of radionuclide transport and dose.
5. How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.

No general answer can be given to such a question.

For each process of importance for long-term safety, a treatment in the safety assessment is established based on the available knowledge following a pre-defined template, see section 6.3 of SKB TR-06-09 for an introduction. Numerous examples are provided in the SR-Can Process reports SKB TR-06-18, TR-06-19, TR-06-22 and TR-06-23.

Not only the level of knowledge dictates the treatment, but also the importance of the uncertainty to safety. For example, the longevity of the fuel cladding is uncertain, but this is in most situations not important for safety. Therefore, the barrier function of the cladding is disregarded.

6. What approach to system PA is preferred / appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of “fuzzy mathematics”; others)?

Most of the calculations in SR-Can are deterministic. Probabilistic calculations are used essentially as a means of handling data uncertainty and spatial variability in the modelling of radionuclide transport and dose.

This is partly controlled by regulatory requirements. The primary compliance criterion is a risk limit, requiring some kind of probabilistic approach, see further section 2.9 of SKB TR-06-09. However, it is also a requirement that the assessment results are presented in a disaggregate fashion so that main risk contributors can be clearly identified.

7. How does the PA conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.

Sensitivity analysis is in SR-Can generally understood as a determination of how sensitive a certain calculation endpoint is to variations in input parameters. For example, several hydraulic interpretations of a particular site were provided from the site modelling. Each of these gave different input distributions of hydraulic parameter for radionuclide transport calculations. A separate Monte Carlo calculation was done for each interpretation, but it was not possible to assign probabilities to the different interpretations. This is thus an example of an analysis of sensitivity of dose consequences to different hydraulic interpretations. This and several other examples are documented in section 10.5.7 in SKB TR-06-09. See also
Sensitivity analysis may also be understood as the process of assigning, to uncertain input variables, a measure of importance with respect to a resulting calculation endpoint, e.g. through rank correlations. This is briefly discussed in section 10.5.10, subheading “Sensitivity analyses”.

Uncertainty analysis is understood as the quantification of output uncertainty when input uncertainty has been quantified, usually by means of Monte Carlo calculations with given input distributions. For example, the results of the probabilistic base case calculation in Figures 10-16 and 10-17 in SKB TR-06-09 quantifies the uncertainty in annual dose for the input distributions given in Table 10-3.

8. **What supporting arguments are available / relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.**

A number of confidence related issues are discussed in section 13.3.5 of SKB TR-06-09.

9. **What measures other than numerical analysis can be utilised to manage the uncertainties (e.g., methodological, QA, etc.)? Please provide examples.**

Essentially methodological approaches to manage qualitative uncertainties, see further response to question 4.

10. **What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?**

Important examples include:

a. The extent of buffer erosion/colloid release when exposed to dilute groundwaters during glacial conditions.

b. The hydraulic interpretations of the candidate sites.

c. The extent of thermally induced spalling in the host rock near the deposition holes.

Of these, the first, if unresolved, may delay the completion of the current program stage.
11. How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.

See the concluding chapter 13 of the SR-Can main report, SKB TR-06-09. In particular, feedback to canister design, to repository design, to site investigations, to RD&D programme and to future safety assessments is provided in sections 13.5 through 13.9.

12. What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.

So far the results have been communicated to regulators and experts. No “best” technique can be identified, but several approaches are used as appropriate, for example:

- Data uncertainty as simple box-and-whisker plots or cumulative distribution functions, see e.g. Figures 9-25 and 9-30 of SKB TR-06-09.
- Output data uncertainty for a particular calculation case as percentiles of dose as a function of time, see e.g. Figures 10-16 and 10-17 of SKB TR-06-09.
- Impact of conceptual uncertainty as comparisons of mean values as a function of time of probabilistic calculation results using different assumptions, see e.g. several Figures in section 10.5.7 of SKB TR-06-09.
- For a distinction between epistemic and aleatoric uncertainty, see SKB TR-06-09, section 10.5.1, first subheading.

In addition, a clear verbal description/interpretation of the results is often more important than the particular technique used when presenting the numerical results.

13. With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.

Several aspects of the handling of uncertainty in the SR-Can project can and will be further developed but no particular issues suitable for a cross-programme working group come immediately to mind. (We are not actively planning for participation in RTDC2).
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<th><strong>PAMINA RTDC-1 Work Package 1.2: Questionnaire for RTDC-1 Participants</strong></th>
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<td><strong>Organisation(s):</strong> SKB</td>
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<td><strong>Responsible Person(s):</strong> Allan Hedin</td>
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<td><strong>Date:</strong> 11 January 2007</td>
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<td><strong>14. Any other comments?</strong></td>
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<td><strong>15. What are the key references that support your response?</strong></td>
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<td>Long-term safety for KBS-3 repositories at Forsmark and Laxemar – a first evaluation. Main report of the SR-Can project. SKB TR-06-09, available through <a href="http://www.skb.se">www.skb.se</a></td>
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1. **What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?**

Two types of repositories are foreseen in Switzerland: (i) a repository for the disposal of spent fuel (SF), vitrified high-level waste (HLW) and long-lived intermediate-level waste (ILW) and (ii) a repository for the disposal of low- and intermediate-level waste (L/ILW) arising from the operation and decommissioning of Swiss nuclear power plants and from medicine, industry and research.

Regarding the repository for SF, HLW and ILW, Project Opalinus Clay (Entsorgungsnachweis) was submitted to the Federal Government at the end of 2002. This feasibility study had the aim to demonstrate that a safe repository for SF / HLW / ILW can be implemented using current technology and that a site with the required properties for construction and for long-term safety exists within Switzerland. After an extensive review process followed by a three-month public consultation phase, the Swiss Government (the Federal Council) announced its approval of the project on 28th June 2006.

In the case of the repository for L/ILW, an advanced project at Wellenberg, Canton of Nidwalden, had to be abandoned on political grounds after the population of the Canton of Nidwalden rejected the plans for the proposed underground investigation gallery in 2002.

Partly as a consequence of this set-back, the Federal Office of Energy is currently defining a site selection process for repositories for all waste categories, which is expected to enter into force in 2007.

The basis for the answers to this questionnaire is Project Opalinus Clay (Nagra 2002a, b, c).

2. **What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?**

The principles and protection objectives that a final repository for radioactive waste in Switzerland must meet are defined in Guideline R-21 (HSK & KSA 1993), issued jointly by the Swiss Federal Nuclear Safety Inspectorate (HSK) and the Federal

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1 This German term translates into English as “demonstration of disposal feasibility”.

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<th>Organisation(s):</th>
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<td>Responsible Person(s):</td>
<td>J. Schneider</td>
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<td>Date:</td>
<td>19 December 2006</td>
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Section: Protection Objectives

- **Protection Objective 1**
  
  The release of radionuclides from a sealed repository subsequent upon processes and events reasonably expected to happen, shall at no time give rise to individual doses which exceed 0.1 mSv per year.

- **Protection Objective 2**
  
  The individual radiological risk of fatality from a sealed repository subsequent upon unlikely processes and events not taken into consideration in Protection Objective 1 shall, at no time, exceed one in a million per year.

- **Protection Objective 3**
  
  After a repository has been sealed, no further measures shall be necessary to ensure safety. The repository must be designed in such a way that it can be sealed within a few years.

No time cut-off is specified for post-closure assessments. HSK/KSA suggest that "...dose and risk calculations should be carried out for the distant future, at least for the maximum potential consequences from the repository...". It is however recognised that, in view of uncertainties, dose calculations for the distant future are to be interpreted as indicators, and should be based on the use of "... reference biospheres and a potentially effected population group with realistic, from a current point of view, living habits ..."

Regarding the treatment of uncertainty in models and datasets, R-21 states:

"When calculating dose or risk, the applicant has to give the possible ranges of variation of the relevant data. He also has to give the range of variation in the results following from these data. Conservative assumptions are to be made, where uncertainties remain. Uncertainties which are due to incomplete knowledge of the properties of the repository system and to incomplete understanding or simplified modelling of release and migration mechanisms have also to be estimated."

There is also a paragraph in R-21 related to optimisation ("safety enhancing measures"): "Even if compliance with Protection Objectives 1 and 2 is demonstrated, the radiological consequences from the repository have to be reduced by appropriate measures as far as feasible and justifiable with current status of science and technology. However, owing to the uncertainties involved in determining potential
3. **How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.**

In Project Opalinus Clay, a distinction is drawn between, on the one hand, completeness uncertainty, which can be reduced and to some extent avoided by appropriate FEP management (see Nagra 2002c), but can neither be quantified e.g. in terms of probabilities nor entirely eliminated, and on the other hand uncertainties regarding the evolution and performance of a system which are explicitly addressed in the safety assessment by means of a wide range of assessment cases. These latter uncertainties are in turn classified according to the following scheme:

- **Scenario uncertainty** is uncertainty in the broad evolution of the repository and its environment. This can also be considered as the uncertainty related to inclusion, exclusion or alternative realisations of FEPs that may affect this broad evolution.

- **Conceptual uncertainty** is uncertainty in the assumptions or conceptual model used to represent a given scenario or set of FEPs, including uncertainty related to the existence of plausible alternative conceptual models.

- **Parameter uncertainty** is the uncertainty in parameter values used in a model. Parameter uncertainty can be due to spatial variability and evolution over time of relevant properties and to uncertainty in the extrapolation of observations from laboratory or natural system conditions and scales of space and time to the conditions and scales relevant to the repository and its environment. Parameter uncertainty can also arise from uncertainty in the models used to interpret the raw data used to derive the parameters required for SA.

One example is how the consequences of future human actions were evaluated. First, this was regarded as a separate scenario. Within this scenario the following conceptualisations were considered: (i) a borehole penetrating the repository (near hit, direct hit); (ii) extraction of groundwater from a deep well in an aquifer above the Opalinus Clay host rock; (iii) abandoned repository. These conceptualisations were then evaluated with different parameter sets to assess the effect of parameter uncertainty. See also the figure in the answer to Question 4.

4. **How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.**

Specific measures to reduce completeness uncertainties in Project Opalinus Clay
include:

- the use of international FEP lists as checklists against which to compare the assessment basis, assessment cases and the models used for their evaluation;

- the systematic consideration of potential interactions between FEPs;

- providing appropriate guidelines, in order to encourage the responsible experts to take into account all relevant sources of information and to consider all possible sources of uncertainty;

- the use of peer review by internationally acknowledged experts for all key technical reports.

As mentioned in the response to Question 3, adhering to certain principles in siting and design can also reduce completeness uncertainty (e.g. designing for simplicity and robustness).

Other uncertainties were treated primarily by defining and analysing a wide range of assessment cases - i.e. specific model realisations of different possibilities or illustrations of how a system might evolve and perform. The cases each address the impact of some particular uncertainty or combination of uncertainties (the insensitivity of a system to completeness uncertainty in some aspects of evolution and performance was also tested in Project Opalinus Clay by means of "what-if?" assessment cases). The categorisation of uncertainties according to the scheme shown in the response to Question 3 provided a basis for organising the cases. Thus, scenarios were represented by groups of individually analysed cases. Within each scenario group, sub-groups of cases addressed alternative possibilities arising from conceptual model uncertainties. Individual cases within each subgroup addressed alternative possibilities arising from parameter uncertainties. This hierarchy of assessment case groupings is illustrated in the following figure (Fig. 3.7-3 in Nagra 2002a):
Uncertainties in the evolution of the biosphere and future human actions that may change exposure to contaminant releases and that could disturb a disposal facility, being less readily characterised than uncertainties in the evolution of the engineered barrier system and geological environment of a repository, were treated as separate scenarios using a stylised approach (see also answer to Question 3).

Finally, some uncertainties were treated using model assumptions or simplifications that are conservative, meaning that they tend to over-estimate evaluated doses or risks. This approach was used, for example, where there was no adequate model or database to evaluate the impact of a particular FEP, but simply omitting the FEP or treating it in some highly simplified manner was confidently expected to lead to conservative results.

In the safety case for Project Opalinus Clay, it was argued that the outcome of the safety assessment has shown that the remaining uncertainties and open questions that have been identified through a systematic and comprehensive procedure do not put safety in question. Although there are many steps to be taken before a repository is definitively sited in Switzerland, there is ample time to continue investigations that address a wide range of uncertainties and to iterate on the repository design.

An RD&D Plan is currently being developed that takes into account the findings from Project Opalinus Clay and its review.

5. How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.

The knowledge base for Project Opalinus Clay includes results from laboratory and
field experiments and from observations of natural systems. The most important elements are summarised in Tab. 8.2-1 of the Safety Report Nagra 2002a. This includes in many instances multiple lines of evidence.

The level of knowledge dictates the treatment of uncertainty to the extent that:

- if an uncertainty can be show, e.g. by qualitative argument or sensitivity analyses, to have a negligible impact on system evolution and performance, then it may be possible to disregard it in the definition and analysis of assessment cases (example: effects of corrosion of structural elements in highly compacted bentonite blocks avoided by design, see Tab. 3.4-1 in Nagra 2002c);

- if a potentially significant uncertainty can be quantified - e.g. in terms of upper/lower bounds on a parameter, a probability density function or a set of alternative plausible models or scenarios, and suitable models and databases are available, then its impact can be investigated by defining and analysing corresponding assessment cases (example: sorption values on bentonite and on Opalinus Clay given in terms of reference-case values, lower limit, upper limit);

- if a potentially significant uncertainty cannot be quantified because suitable models and/or databases for its analysis are not available, then a conservative or pessimistic approach may be adopted to bound the effect of the uncertainty (example: conservative omission of sorption of radionuclides on canister corrosion products places an upper bound on the effect of this type of uncertainty);

- if a potentially significant uncertainty cannot be quantified, then a stylised approach may be appropriate (example: future human actions).

6. What approach to system PA is preferred / appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of “fuzzy mathematics”; others)?

The use of conservatism has been discussed in the response to earlier questions. In general, some degree of (conservative) simplification in assessment modelling is necessary in view of the complexity of the system modelled and the limited understanding of some processes, and in view of the need to produce defensible bounding estimates of consequences. More detailed and realistic modelling of subsets of FEPs is, however, carried out in order to assess the impact of simplifications and to support parameter selection (e.g. use of mechanistic sorption models to support the selection of $K_{ds}$ for assessment models).
The emphasis in Project Opalinus Clay was on the one-by-one (“deterministic”) analysis of assessment cases, since these were considered to give a clear illustration of the impact of individual uncertainties and design variations (or limited combinations of these uncertainties and variations) on system performance. Providing guidance regarding key uncertainties that need to be reduced, avoided or their impact mitigated at future project stages was one of the aims of the safety assessment for Project Opalinus Clay.

Probabilistic calculations were, however, also used to explore systematically the consequences of different combinations of parameters that fall within the ranges of uncertainty. Probabilistic calculations were used to enhance system understanding, to ensure that no unfavourable combinations of parameters were overlooked, and to test whether there were sudden or unexpected changes in performance as parameters were varied, which might not have been detected using a deterministic approach.

7. How does the PA conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.

Sensitivity analyses are explorations of how a modelled system responds to variations in parameter values or model assumptions. In Project Opalinus Clay, sensitivity analyses were performed both deterministically (i.e. with the models and parameter values defining each calculation individually specified by the safety assessor to investigate the impact of particular uncertainties) and probabilistically (i.e. with parameter values randomly sampled from probability distribution functions). One example of a sensitivity analysis is the calculated dose as a function of canister breaching time, which showed that canister breaching time is an insensitive parameter (Fig. 6.7-4 in Nagra 2002a).

Uncertainty analysis is seen as the broader activity of identifying and quantifying uncertainties, and evaluating their potential impacts. As noted earlier, the results of sensitivity analysis can guide the approach adopted to the treatment of specific uncertainties in the safety assessment (see the response to Question 5). Sensitivity analysis is thus a tool used by the broader activity of uncertainty analysis.

8. What supporting arguments are available / relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.

Supporting arguments (i.e. arguments not directly related to the outcome of the evaluation of assessment cases) that address uncertainties include arguments to support the exclusion from the analyses of uncertainties judged to be irrelevant, and to support the conservatism of the treatment of other uncertainties. As mentioned earlier, such arguments can come from sensitivity analyses. They can also come from qualitative reasoning (e.g. processes such as sorption on waste degradation products can only be beneficial to performance, and so their exclusion is conservative). An
example for a line of argument supporting the statement that in Opalinus Clay, diffusion will be the dominating radionuclide transport process, is the existence of measured diffusion profiles of natural tracers in Opalinus Clay, which can be explained by assuming diffusion was the only transport mechanism in the past ~ 1 Ma (see following figure).
Isotope concentration profiles in porewater across the Opalinus Clay (OPA) and adjacent rock strata due to diffusion that occurred for 0.25, 0.5 and 1 Ma. Taken from Nagra 2002a (Fig. 4.2-14).
The existence of reserve FEPs - i.e. FEPs that are considered likely to occur and are beneficial to safety and are deliberately and conservatively excluded from quantitative analysis because suitable models and / or databases are unavailable - constitutes a complementary qualitative line of argument enhancing confidence in long-term safety. An example for a reserve FEP is the delayed release of radionuclides from corroding metallic materials in the ILW (all radionuclide releases from ILW were treated as being instantaneous).

Another line of argument is that remaining potentially important uncertainties not comprehensively addressed in the safety assessment are "under control", meaning that there is an adequate strategy to address them, e.g. by further RD&D during future stages. It is pointed out in the Project Opalinus Clay safety report that it is not possible, nor is it necessary, to eliminate uncertainties completely in order to make a safety case that is adequate to support a positive decision to proceed to the next programme stage.

9. What measures other than numerical analysis can be utilised to manage the uncertainties (e.g., methodological, QA, etc.)? Please provide examples.

Measures include those adopted to promote completeness (see the response to Question 4), siting and designing the repository according to principles such as robustness and simplicity with the aim of reducing uncertainties and their impact, and measures to promote the quality of the analyses (e.g. through the prevision of systematic reviews of work and reports, validation of models and databases, verification of computer codes, reliable and traceable procedures for running the codes, etc.). Design and assessment principles are given in Tabs. 2.6-1 and 2.6-2 in Nagra (2002a). The QA measures applied throughout Project Opalinus Clay are summarised in Appendix 8 in Nagra (2002b).

10. What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?

In Project Opalinus Clay, it was found that uncertainties in the initial characteristics of the disposal system are relatively small (with the exception of some alternative system or design options). Key uncertainties concern mainly the rates of processes affecting the evolution of the engineered barriers and a range of phenomena that may perturb the geological setting and, in particular the impact of repository-generated gas, which is not readily transported in this particular host rock. The highest calculated doses arose in scenarios illustrating the release of radionuclides affected by human actions. Project Opalinus Clay concluded that, despite an analysis of a wide range of assessment cases that was derived in a careful and methodical way, the safety assessment did not identify any outstanding issues or uncertainties with the potential
One of the important results of the safety assessment for Project Opalinus Clay, including the associated uncertainty analysis, was the identification of features of the disposal system that are key to providing long-term safety. These features, which include, for example, the host rock, which has a low hydraulic conductivity, a fine, homogeneous pore structure and a self-sealing capacity, thus providing a strong barrier to radionuclide transport and a suitable environment for the engineered barrier system, are termed the "pillars of safety". Although the pillars of safety are already considered well understood, a conclusion of the project was that further understanding of phenomena directly related to their evolution and performance will strengthen future iterations of the safety case.

In communicating the different types of uncertainties, it was found useful to have developed, as part of the safety case, a clear strategy for the evaluation and treatment of uncertainties, including a definition of the different types of uncertainties (see answer to Question 3). In explaining this strategy, the figure shown in the answer to Question 4 worked quite well. To illustrate with a few selected examples how the effects of uncertainties were evaluated within the scheme shown in that figure, the following figure was found useful (Fig. 5.7-1 in Nagra 2002a):
### PAMINA RTDC-1 Work Package 1.2: Questionnaire for RTDC-1 Participants

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<th>Organisation(s):</th>
<th>Nagra</th>
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<tr>
<td>Responsible Person(s):</td>
<td>J. Schneider</td>
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<tr>
<td>Date:</td>
<td>19 December 2006</td>
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| Range of influence of possible deviations from the expected evolution of the disposal system (Fig. 5.7-1 in Nagra 2002a). Black bars – transport through host rock, gray bars – transport through tunnels/ramp/shaft and seal system, red bars – “what if?” cases. |

#### Deviations

<table>
<thead>
<tr>
<th>Climate</th>
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<td>- Alternative climates</td>
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<td>- Glaciation</td>
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<th>Geological characteristics</th>
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<tr>
<td>- Alternative hydraulic conditions</td>
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<tr>
<td>- Rapid transport of volatile $^{14}$C in OPA</td>
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<tr>
<td>- Heterogeneous flow in OPA</td>
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<tr>
<td>- Reduced path length in OPA</td>
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<tr>
<td>- Decay during transport in confining units</td>
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<tr>
<td>- $K_d$($^{129}$I) = 0 in OPA and Bent.</td>
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<th>SF/HLW</th>
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<tr>
<td>- Bentonite alteration</td>
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<td>- Initial canister defects</td>
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<td>- Early canister breaching</td>
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<td>- Waste matrix dissolution</td>
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<tr>
<td>- Redox front propagation in bentonite</td>
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<tr>
<td>- Increased glass dissolution</td>
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<tr>
<td>- Gas-induced release of dissolved radionuclides</td>
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<tr>
<td>- Gaseous release of $^{14}$C</td>
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<td>- Convergence-induced release</td>
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<td>- Gaseous release of $^{14}$C</td>
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<td>- Convergence-induced release</td>
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<td>- Oxidising conditions</td>
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<td>- Alternative discharge area</td>
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<tr>
<th>Human Actions</th>
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<tr>
<td>- Borehole penetration</td>
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<td>- Deep groundwater extraction</td>
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<td>- Repository abandonment</td>
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13. *With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.*

This question is biased: It implies that it is clear that there are gaps of understanding of how uncertainty should be treated. In Project Opalinus Clay, it was claimed that the treatment of uncertainties was adequate for the project stage.

14. *Any other comments?*

15. *What are the key references that support your response?*


1. **What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?**

In the UK there has recently been a period of consultation regarding the options for long-term radioactive waste management, undertaken on behalf of Government by an independent Committee on Radioactive Waste Management (CoRWM). It was the recommendation of CoRWM to implement deep geological disposal, and this recommendation has now been endorsed by the Government. In the mean time, in order to be able to continue to provide advice on the conditioning and packaging of wastes to waste producers, Nirex has developed a generic phased geological repository concept. This questionnaire is answered with respect to this concept, i.e. a generic viability study.

2. **What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?**

In the context of the long-term safety of a deep radioactive waste repository in the UK, the Environment Agency, in conjunction with the Scottish Environment Protection Agency and the Department of the Environment for Northern Ireland, published Guidance on Requirements for Authorisation (GRA) [1] in 1997. This replaced earlier advice published in 1984 and sets out guidance on the principles and requirements against which the Agencies and associated regulatory authorities would assess any application for authorisation under the Radioactive Substances Act 1993 for the operation of a waste repository.

The GRA includes a set of four principles and eleven requirements covering all aspects of the design, construction, operation and closure of a deep waste repository in the context of long-term safety. Of most interest are the following:

Requirement R1 is applicable in the period of regulatory control over the disposal site, lasting at most a few hundred years. It states:

> 'In the period before control is withdrawn, the effective dose to a representative member of the critical group from a facility shall not exceed a source-related dose constraint. Also during this period, the effective dose to a representative member of the critical group resulting from current discharges from the facility aggregated with the effective dose resulting from current discharges from any other sources at the same location with contiguous boundaries shall not exceed an overall site related..."
The GRA goes on to state that the Government accepts the NRPB’s advice that the source-related dose constraint should not exceed 0.3 mSv yr\(^{-1}\). In common with practice for controlling discharges from operating nuclear facilities, the concept of a critical group is identified.

Requirement R2 is applicable in the period after a repository has been operated and sealed and control is withdrawn. It states:

‘After control is withdrawn, the assessed radiological risk from the facility to a representative member of the potentially exposed group at greatest risk should be consistent with the risk target of 10\(^{-6}\) per year ...’

This requirement introduces the concept of a potentially exposed group. Noting that this is more appropriate than the critical group in the context of long-term potential exposures, an exposed group is defined in the GRA as:

‘... any group of members of the public within which the exposure to radiation is reasonably homogeneous: where the exposure is not certain to occur, the term potentially exposed group is adopted’.

Although the main emphasis in Nirex’s assessments of the groundwater pathway has been on Requirement R2, consideration is also given to issues relevant to Requirement R5, which states:

‘The overall safety case for a specialised land disposal facility shall not depend unduly on any single component of the case.’

UK regulatory guidance \[1\] specifies, ‘The developer should … present the range of possible doses which each potentially exposed group may receive, together with the probability that the group receives any given dose.’ The regulatory guidance also states the requirement to consider ‘all situations that could give rise to exposure’ and Nirex has tended to fulfil this requirement by conducting probabilistic assessments and by considering a range of scenarios.

3. How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.

The main uncertainties identified by the Nirex post-closure safety assessment team in Nirex’s Generic post-closure Performance Assessment (GPA) \[2\] are as follows:

- Data uncertainty: near-field solubility, near-field sorption, effect of organic complexants on solubility and sorption, far-field sorption, inventory, biosphere factors, groundwater travel time, groundwater flux through...
• Model uncertainty: gas generation and migration, waste container corrosion, groundwater pathway models.

• Scenario uncertainty: evolution of the near field, criticality events, evolution of geosphere and biosphere (e.g. climate change).

• Uncertainty regarding human behaviour: start of post-closure period, human intrusion.

This assessment does not use a timeframes presentation, nor does it consider time-dependencies explicitly. Rather, the possible variation of a parameter in time is included implicitly in the uncertainty (in probabilistic calculations) for that parameter. Some stakeholders have challenged this approach and hence it is proposed that future assessments, based on a timeframes presentation, may use a more sophisticated treatment of the time-variation of parameter values, rather than treating time variation within parameter uncertainty.

4. How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.

Strategies for handling uncertainty tend to fall into the following broad categories:

1. Demonstrating that the uncertainty is irrelevant i.e. uncertainty in a particular process is not important to safety because, for example, safety is controlled by other processes.

2. Addressing the uncertainty explicitly, for example using probabilistic techniques.

3. Bounding the uncertainty and showing that even the bounding case gives acceptable safety.

4. Ruling out the uncertain process or event, usually on the grounds of very low probability of occurrence, or because other consequences, were the uncertain event to happen, would far outweigh concerns over the repository performance (for example a direct meteorite strike).

5. Explicitly ignoring uncertainty or agreeing a stylised approach for handling an uncertainty (for example the ‘reference biospheres’ approach developed by the IAEA BIOMASS project).

The preferred treatment of a particular uncertainty will depend on the context of the
### 5. How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.

A key driver for a deep geological repository as an option for the long-term management of radioactive waste, is to remove the large uncertainties associated with leaving the waste accessible to humans over very long timescales. This is because there is substantially more uncertainty over the future of society than there is over whether the geosphere will perform its desired role of isolating the waste from such future societies. This is reflected in the relative timescales of geological change versus social change.

There is considerable confidence that a well-chosen geological site will be relatively stable for a long time into the future and provide continuing safety from the radioactive material. However, it is also important to recognise that there is substantial uncertainty associated with certain events and processes operating in a radioactive waste repository system on a timescale of a million years or more. Therefore the treatment of that uncertainty is an essential part of a performance assessment to show that, although the uncertainty in some processes may be acknowledged to be large, actually it can be shown that it is acceptable i.e. despite substantial uncertainty a strong safety case can be made.

There is insufficient knowledge about some of the uncertainties to avoid the need for expert judgement when handling uncertainty in performance assessments. Systematic frameworks and modelling processes provide tools to help the experts, but there will still be situations where judgements need to be made. Expert judgement plays a key role in handling data uncertainty and may be combined with the available empirical data to elicit a full data set or manage the consequences of uncertainty associated with the available data.

Expert judgement is based on scientific/technical understanding and experience, supplemented with appropriate evidence. However, there is still scope for different experts to have different views and for two groups to reach different conclusions regarding an elicited data set, even when they are both using the same empirical
evidence. Ideally such a situation, if it occurred, should be resolved by discussion between the experts, or with an independent third party if necessary. Disagreement between experts can be one of the main reasons for undermining public confidence in any decision-making process. This emphasises the importance of peer review throughout the performance assessment process and the value in maintaining flexibility in the modelling process to allow the testing of alternative view-points. Where there is more than one expert view, it may be best to conduct two parallel sets of calculations to determine the relative impacts of the conflicting views.

In documenting a performance assessment it is important to ensure that all data and model inputs are traceable. This will mean being clear on the extent and role of expert judgement, for example recording all expert input in an appropriate database that can be easily linked to the models generated, thus creating an audit trail for the impact of such judgements.

6. **What approach to system PA is preferred / appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of “fuzzy mathematics”; others)?**

In the main, Nirex adopts a probabilistic approach to system PA. This is influenced by the regulatory requirement to identify risks from different repository evolution scenarios and ensure that risks to an individual are summed over all relevant situations.

Nirex considers that the possible evolution of a repository system can be addressed in terms of the following:

- a base scenario that provides a broad and reasonable representation of the natural evolution of the system and its surrounding environment (i.e. includes all those FEPs that are considered more likely than not to persist for a significant part of the assessment period); and

- a number of variant scenarios that represent the effects of probabilistic events (i.e. those FEPs which may or may not occur).

Any FEPs not considered within the base scenario must either be screened from the assessment basis (with a justification for their irrelevance or insignificance) or considered within a variant scenario. Consideration within a variant scenario does not necessarily imply explicit representation of a specific FEP, many FEPs have a similar impact on system performance.

The base scenario is assumed to have a probability of unity. Variant scenarios are assumed to occur with a probability of less than unity. In calculating combined risks from the base and variant scenarios, the conditional risk from the base scenario is
assigned a weight of unity and the conditional risks associated with the variant scenarios are assigned weights of less than unity. Note, there is no requirement to ensure that the total probability of all scenarios sums to unity, hence the preference for the term ‘weight’ rather than ‘probability’. It is noted, that this in itself, will lead to a conservative estimate of the overall risk.

The scenarios approach leads to an understanding of what is important in terms of the performance of a repository system and hence allows resources to be focused on those aspects most important to safety.

In previous studies screening of scenarios has been carried out using expert judgement on the basis of certain scenarios being physically unreasonable or having an insignificant impact. In order to make such judgements it is necessary to have a suitable framework to ensure that a consistent view is taken in the decision-making process.

In the Nirex approach, the methodology of subsuming replaces that of screening. (Although where a scenario is considered to be immaterial to the system performance it will be regarded as screened from the assessment basis; and individual FEP influences may be screened within the conceptual model development process.) The overall aim is to apply a principle of caution to subsume scenario representations at the highest possible level (for example, into the base scenario whenever appropriate) and hence to treat explicitly only those scenario representations which cannot be subsumed. All subsuming decisions are based on the principle of caution, while reserving the option to revisit a decision if it becomes too onerous. This philosophy has the advantage of making the assessment tractable and focusing effort on the most important areas in terms of safety implications. All subsuming decisions must be fully justified and will form part of the auditable record of the assessment.

Subsuming of scenario representations involves considering a specific scenario representation in relation to a more general case. If the specific scenario representation has a conditional risk which is similar to or lower than the general case it can be subsumed into the general case. For example, any variant scenario with a conditional risk less than or equal to the base scenario can be subsumed into the base scenario. This will always be conservative, regardless of the probability of occurrence for the variant scenario, as the base scenario is taken to have probability one.

Uncertainties in data can be quantified in terms of ‘probability density functions’ (PDFs) that give the relative likelihood of different parameter values. The PDFs can be based solely on measured values, or, more usually, are generated at a formal elicitation in which measured values are supplemented by the judgement of suitably qualified and experienced experts on the basis of various research data, and can take
into account any scarcity of data, uncertainty or bias from measurements.

With the uncertainty quantified as PDFs, a probabilistic assessment can be carried out using Monte-Carlo methods. In such an assessment, a computer model is run many times (each run is called a realisation) with different sets of parameter values. In each realisation, the values of the parameters are chosen at random from the PDFs representing the range of possible values. This is a probabilistic approach and it ensures that wide ranges of possible parameter values are considered within a performance assessment. Statistical analysis of the results of a probabilistic calculation can be used to explore the sensitivity of the performance measure e.g. risk to the uncertain model parameters.

The probabilistic approach is also consistent with current regulatory guidance in the UK, as an important regulatory requirement is the calculation the expectation value of risk for comparison with the regulatory risk target. The expectation value of risk is obtained by averaging the calculated risk from each probabilistic realisation.

The probabilistic approach is used to address most of the uncertainties in Nirex’s post-closure assessments of the radiological risk from the groundwater pathway.

The challenge is then to be able to communicate this understanding of the relative impact of the uncertainties in a transparent manner. It is often helpful to include other presentations e.g. deterministic sensitivity studies and ‘What if?’ calculations to improve the understanding and communication of the results of a performance assessment.

In performance assessment modelling, it is often necessary to make a number of simplifying assumptions, either because insufficient data are available or the modelling capability cannot represent some feature of the system in full detail. The aim is to address issues as realistically as possible, whilst erring on the side of caution. Therefore, some simplifications involve taking a conservative view, i.e. assumptions are made such that radiological risk will tend to be over- rather than under-estimated. Conservative assumptions are often the best way of addressing issues without introducing unnecessary complexity into the models.

However, this approach of making conservative assumptions can sometimes lead to models which, although robust from a safety point of view, are physically unrealistic. Also, it is important to note that the probability that all parameters in a system take their most pessimistic values is, in general, negligible, so that a calculation that assumes this would give a significant overestimate of the consequence and therefore provide a poor basis for making decisions.
7. How does the PA conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.

The probabilistic approach ensures that many possible combinations of model parameters are considered; it is therefore a key approach to treating uncertainty in post-closure assessments. However, it is sometimes helpful to consider variations in a particular parameter systematically in order to understand the impact it has on long-term safety. This can be achieved by conducting deterministic sensitivity studies. From a modelling point of view, a deterministic calculation is one that takes fixed parameter values and is run once only, as opposed to a probabilistic calculation which takes sampled parameter values and is run many times. A series of deterministic calculations is usually carried out as part of a sensitivity study with the values of a number of key parameters varied systematically within their uncertainty range. A ‘matrix’ of calculations are carried out so that the effect of the different values for the different parameters in combination can be investigated. For example, if four parameters are varied, each taking one of two values (a high value and a low value) then 16 ($2^4$) calculations would be carried out in total.

The impact of parameter uncertainties on consequences can be demonstrated by comparing a calculation with best estimates for particular parameters with worst case estimates. In this context, a worst case estimate usually means that a parameter is given the worst credible value i.e. there is a low probability of the actual value being worse. ‘What if?’ calculations can be carried out to investigate the effects of specific values of some parameters. Conceptual model uncertainty can also be addressed in this way, by performing ‘What if?’ calculations for a small number of alternative conceptual models for the system i.e. to ascertain whether the uncertainty matters.

8. What supporting arguments are available / relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.

Generally, a performance assessment will include a range of quantitative performance indicators, together with alternative lines of reasoning and qualitative considerations, such as the intrinsic quality of the repository design, to build understanding in the overall repository performance and hence determine whether it satisfies the relevant safety requirements.

Qualitative arguments can include:

- Comparisons with natural analogues, i.e. occurrences of materials or processes which resemble those expected in a proposed geological waste repository, for example the Maqarin site in Jordan which provides a natural analogue for a cementitious repository.

- Showing consistency with independent site-specific evidence, such as
observations in nature or palaeohydrogeological information.

- Evidence for the intrinsic robustness of the repository system, for example demonstrating that relevant features and processes are well understood, often supported by evidence from underground research laboratories.

- Describing the passive safety features of the repository and demonstrating that the design uses best practice scientific and engineering principles.

- The safety case may also include more general arguments related to radioactive waste management, and information to put the results of performance and safety assessments into perspective. For example, for the Nirex concept a repository at a depth below ground of about 650m is assumed. Such a depth offers a number of benefits to the long-term management of radioactive waste that would be of relevance to the safety case.

There is also a role in many performance assessments for semi-quantitative arguments, for example applying physical and chemical understanding of the system to build more simple models to give an insight of repository system behaviour.

Qualitative arguments may be particularly important in performance assessments conducted at the earlier stages of a repository development programme. At these stages the focus is on building understanding of the processes that could affect the performance of a repository and on explaining how the repository concept will be able to provide safety over very long time periods. There may also be insufficient data at this stage to justify complex calculations, therefore other methods are required to build confidence in the viability of the proposals. Assessments at this stage are also more likely to be communicated, at least in summary form, to wider, non-technical audiences for whom qualitative arguments may be more meaningful than detailed, complex calculations.

A safety case contains a number of different elements, and is an integration of arguments and evidence that describe, quantify and substantiate the safety, and the level of confidence in the safety, of a radioactive waste management facility. A performance assessment in support of a safety case will include a range of quantitative performance indicators, together with alternative lines of reasoning and qualitative considerations, such as the intrinsic quality of the repository design, to build understanding in the overall repository performance and hence determine whether it satisfies the relevant safety requirements.

Information crucial in the safety case relates to:

- Arguments for groundwater-flow predictability.
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<tr>
<td>Responsible Person(s):</td>
<td>Mike Poole</td>
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<td>Date:</td>
<td>27 November 2006</td>
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- Retention of potentially released radionuclides
- Predictability of groundwater composition
- Mechanical/geological predictability of the repository formation such that the integrity of the rock structure would not be impaired
- Absence of resources (mineral, water, oil, etc) – or other uses of the host rock

Regarding consideration of geoscientific arguments for safety:

- The most important argument is to present a clear understanding of past geological evolution at the particular site, consistent with the global understanding of geological evolution. Efforts should be made to achieve a broad consensus on this from many independent experts.
- The supporting arguments are seldom based on a single piece of evidence. It is the chain of arguments rather than individual arguments that is important.
- A primary interest is in “reasonable” predictability of the geological system. It is recognized that most geological systems evolve with time, but all details of this are not needed for demonstrating safety. However, there is a need to find well-reasoned bounds for the future evolution.
- Generally, the same type of arguments can be applied for different rock types. The strength of arguments and the time scale of validity, however, vary between host rocks and types. The arguments work better in “simple” systems.
- Sharing experiences between different programs is crucial in assessing strengths and weaknesses in “own” arguments

The confidence with which groundwater flow models can be used is, in part, dependent on the process adopted to develop those models from site-specific data. A scientific programme supporting successive stages in the siting of a disposal facility will evolve as more information becomes available and understanding is refined. It is therefore important that there is demonstrable integration between the data on which understanding is founded, the models that represent that understanding, and the experts involved in both. It is also important that the level of confidence in the models is clearly established.

The development of a conceptual model of the system or subsystem is key to the integration of site characterisation information into a performance assessment. A conceptual model should capture the behaviour of the system and provide the link...
between the underlying data and the numerical models that are used to assess the performance of various components of a repository system. It must be based on, and consistent with, the underlying data, and is progressively refined as more data become available. Conceptual models define key aspects of the numerical groundwater flow models (e.g. the geometry of the system, boundary conditions and time dependency) and also provide the context within which to derive effective parameters to input into these numerical models.

9. **What measures other than numerical analysis can be utilised to manage the uncertainties (e.g., methodological, QA, etc.)? Please provide examples.**

Performance assessment calculations should be carried out under an appropriate Quality Assurance regime (such as ISO 9001). It is important that all the data used in a performance assessment are wholly traceable and a source reference available. Likewise, all assumptions should be well documented and any potential biases acknowledged.

As well as relying on QA procedures to give confidence in the results, there is also value in demonstrating an understanding of the system at several levels of complexity, so that the results of complex computer calculations can be supported by simpler models. For example, in the Nirex 95 and Nirex 97 assessments, a simple analytic model of the safety functions of the multiple barrier system was shown to give a good approximation to the results of the more complex modelling for the groundwater pathway. Confidence can be provided in the results of the complex numerical models by showing that similar results may be obtained on the basis of simple models whose basis may be more easily explained and that can be shown to capture the essential features of the system.

10. **What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?**

At the current, generic, stage of the Nirex programme, the arguments that demonstrate that the system can be implemented with existing technology are presented in the ‘Viability report’ – which is a statement about why Nirex believes its concept is viable [3]. This report identifies the following outstanding uncertainties:

- C-14 has been identified as a key issue in the PGRC. Calculations have been carried out to scope the potential impact of C-14 for two alternative scenarios. In the first of these it is assumed that C-14 all dissolves in groundwater and is released to the biosphere in solution; in this case the calculated risk is well below the regulatory target. The second scenario assumes that carbon-14 is released as gas and all methane generated is
released directly to the biosphere as gas, taking no account of any delay in the geosphere. In this case, the calculated risk is significantly over the regulatory target. In practice, some of the gas could dissolve in groundwater and the migration of gas in the geosphere would depend on the site geology. In many geological settings, some form of gas retardation may be expected.

- Nirex has an ongoing programme of research on C-14, which is improving our understanding of these issues. Further work is still required, which includes: work to assess the extent to which gas would dissolve in groundwater; work to assess the extent to which different geological environments have the potential to retard gas migration; and work to reduce uncertainties in the rates and quantities of gaseous C-14 generated.

- Non-aqueous phase liquids (NAPLs) are challenging because they can have a greater capacity for uptake of some radionuclides and may migrate more rapidly through the geosphere than groundwater. NAPLs would only leave a repository vault if there was sufficient pooled in the vault to overcome the forces that prevent such materials entering narrow fractures in the host rock.

11. How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.

Once the uncertainties have been quantified, by carrying out scoping calculations either with a probabilistic system model or with deterministic analyses, it is possible to ascertain to which of the uncertainties the performance of the concept is most sensitive, which then can inform

- future research needs – research can be target into trying to reduce the uncertainties that really matter. These research needs, if significant (i.e. costly or time-consuming), may affect the future programme.

- design optimisation – the design of the facility could be modified such that key uncertainties are reduced or engineered out.

12. What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.

As noted above, the regulatory guidance in the UK leads the developer to a probabilistic approach, so such an approach is of most value in communicating the uncertainties to the regulators.

Communication of the uncertainties to non-technical stakeholders is more of a
challenge. Many researchers have discussed how risk and uncertainty is perceived by non-experts; how the way risk and uncertainty is presented and reported in the media can affect people’s perception of it; and how the context in which a risk arises and previous experiences and events can also affect people’s perception of the risk.

Scientific uncertainty can undermine public confidence in environmental and technological projects. However, one of the ways that scientists can undermine confidence in their work is by maintaining an exaggerated sense of certainty. Therefore, it is important to be open and honest about uncertainty, and to explain how it is managed and why it is still possible to have confidence in the assessments and the proposed facility.

Explicitly stating the uncertainties associated with assessments will enable stakeholders to develop more informed responses to the situation. It will also help them to engage in the debate and feed back important information about their issues of concern. This could influence the scenarios that are assessed or enable measures to be put in place to lessen the socio-economic impacts of any uncertainties or risks.

13. With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.

Nirex believes that the technical challenges of an appropriate treatment of uncertainty are well understood. The main gaps in terms of the treatment of uncertainty relate to the way in which it is communicated and/or perceived. These are particularly important issues because no matter how much effort is put into a consistent and defensible treatment of uncertainty in a performance assessment, if we are not able to communicate it to stakeholders in such a way that they engage with it, then it is only of limited value. Expert judgement and data elicitation are particular areas in which some stakeholders do not necessarily understand or buy in to our approach.

14. Any other comments?

None.
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<td>Responsible Person(s):</td>
<td>Mike Poole</td>
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15. What are the key references that support your response?


A15 United States - SNL-WIPP

PAMINA RTDC-1 Work Package 1.2: Questionnaire for RTDC-1 Participants

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1. What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?

The Waste Isolation Pilot Plant (WIPP) is operational. It was first certified on May 18, 1998, and the first waste shipment was received March 26, 1999.

2. What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?

The WIPP-specific Certification Criteria of 40 Code of Federal Regulations (CFR) 194 require that a probabilistic risk assessment be performed and dictates how the “Performance Assessment” (PA) must be conducted. These criteria also detail how uncertainty must be treated.

The following requirements pertain to system parameters:

- Probability distributions for uncertain disposal system parameters must be developed.
- The entire range of the probability distributions must be sampled.
- It is assumed that future drilling practices and technology will remain consistent with current practices.

With regard to repository performance, the following principal regulations exist:

- Features, Events, and Processes (FEPs) that have less than a 1 in 10,000 chance of occurring during 10,000 years do not need to be considered in performance assessment. Probabilities this small would tend to be limited to phenomena such as the appearance of new volcanoes outside of known areas of volcanic activity, and the EPA saw no benefit to public health or the environment from trying to regulate the consequences of such highly unlikely events.
- The results of the performance assessments must be assembled into complementary, cumulative distribution functions (CCDFs) that represent the probability of exceeding various levels of cumulative release.
- The number of CCDFs generated must be large enough such that the
maximum CCDF generated exceeds the 99\textsuperscript{th} percentile of the population of CCDFs with at least 0.95 probability.

- It must be demonstrated that there is at least 95 \% level of confidence that the mean CCDF meets containment requirements.

The containment requirements of 40 CFR 191.13 specify a 10,000 year performance period. A period of 10,000 years was considered long enough to distinguish geologic repositories with relatively good capabilities to isolate wastes from those with relatively poor capabilities. This period was considered short enough so that major geologic changes would be unlikely and repository performance might be reasonably projected.

In addition to complying with radionuclide release limits, the WIPP must comply with individual and groundwater release protection standards. To demonstrate compliance with these standards, PA results are used, along with other tools, in the compliance assessment, and the uncertainty is accounted for in a manner similar to that in the PA.

For a complete listing of regulations that pertain to the WIPP, go to the website [http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr194_04.html](http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr194_04.html). Sections 194.25, 194.26, 194.28, and 194.32 all pertain to how uncertainty must be handled in performance assessment.

### 3. How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.

The performance calculations for WIPP involve using the results from a set of deterministic, process-level models to construct response surfaces that are subsequently used by a probabilistic, process-level model (CCDFGF) to estimate potential releases. All uncertainty in the process level models is considered epistemic and is associated with the lack of knowledge about the precise values of the model parameters. This uncertainty is represented by three hundred sets of values (sampled using Latin hypercube sampling) for the parameters and running the models for each set. A fixed set of scenarios is applied to the process level models. These scenarios represent the repository in an undisturbed state and in various states following drilling intrusions into the repository. CCDFGF simulates releases from the repository over a 10,000-year period following closure of the facility. The timing and location of intrusion events, the type of waste encountered by drilling events, penetration of brine pockets and the way in which the boreholes are plugged are all treated as stochastic events in CCDFGF. CCDFGF generates 10,000 possible futures for each of the 300 sets of results from the process-level models. Uncertainties regarding the scenarios that are modelled or associated with the structure and assumptions of the process level models are not considered in the PA calculations.
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We assume that there are no uncertainties associated with the models (conceptual, numerical, etc.). However, we do address uncertainty modelling assumptions. Examples include: instantaneous equilibrium and batch reactor chemical environment for chemistry models, brines have access to all actinides, etc. Thus, some model uncertainties are accounted for through assumptions and modeling approaches. These assumptions are generally conservative in nature.

4. How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.

The epistemic uncertainties associated with parameters are defined by distributions that are assigned to the parameters. These are propagated through the deterministic models by sampling the distributions with a Latin hypercube method to generate 300 sets of parameters, and then running the models for each of these sets. Aleatory uncertainty associated with potential drilling intrusions into the repository are modelled as stochastic events. Ten thousand possible futures are generated for each of the 300 sets of parameters and a single CCDF is generated from the 10,000 futures. Thus, the model results consist of 300 CCDF curves. Variability across the 300 curves is interpreted as uncertainty in the probability of a release of a given magnitude rather than the uncertainty in the magnitude of release at a given probability. The wider scope of safety issues would probably consider risks to the workers involved in the construction, maintenance and use of the facility, risks to those handling the waste, transportation risks, etc. These risks are not considered in the WIPP PA but are addressed separately.

5. How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.

A screening process was used to identify the potentially significant FEPs that could have an impact on the performance of the repository. These were then either explicitly represented in the process level models or implicitly accounted (e.g., via modelling assumption) for in one or more of the scenarios that the models simulated. All uncertainty in the deterministic process-level models was assumed to be due to uncertainty in their parameters, and that uncertainty was either quantified from data, when available, or by using subjective methodologies. The level of information on which to base the assignment of the distributions of possible values varied greatly among the parameters. The level of knowledge was an important consideration in assigning both the shape and the variance of a distribution.

When knowledge about parameters is small and these parameters have been identified by the regulator or modellers as potentially significant to the performance of the disposal system, a conservative approach is sometimes taken.
6. What approach to system PA is preferred / appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of “fuzzy mathematics”; others)?

The regulations under which WIPP operated require a probabilistic risk assessment be performed. In addition, the regulations specify that certain kinds of releases, e.g. those associated with groundwater, always be considered independent of the potential magnitude of those releases. The releases associated with groundwater require using relatively complex models. Some simplification was required, however, due to computational limitations. Therefore, the calculation of releases relies on the use of response surfaces generated from running a limited set of scenarios across 300 sets of parameters.

The WIPP PA, like many risk assessments, is a mixture of both conservative and realistic approaches. The process-level models are compromises between striving for realism and the constraints imposed by limitations on computer resources and data availability. In the case of the hydrologic models, for example, these compromises influence the scale and resolution of the grid being simulated. The selection of parameters is thus made with the knowledge of limitations imposed by scale and resolution of the models, which can lead to the assignment of “appropriate” values rather than simply “realistic” values. In some cases the regulator for the site has dictated the range of values to be covered by distributions, and these invariably tend to be conservative in the sense of maximizing releases. In other cases the modellers may choose to use conservative values, particularly when the consequence of doing so is small compared to the effort it would take to provide, and have approved by the regulator, more realistic values.

7. How does the PA conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.

The evaluation of uncertainty in the model projections is used to support the conclusion that the facility will meet compliance requirements. Uncertainty in the results is assumed to be due to uncertainty about the parameters used in the process-level models. This uncertainty is propagated using Monte Carlo methods.

Thus far, sensitivity analyses have been conducted using regression analysis on the inputs and the results generated by the uncertainty analysis. Although this approach limits the kinds of analyses that can be performed, the computational requirements of the WIPP PA system prevent the consideration of the specialized and more extensive sampling designs required by some alternative methods. In addition, the use of regression techniques has been adequate in terms of identifying the dominant
8. **What supporting arguments are available / relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.**

The models and their parameters have been subjected to external peer review. The distributions assigned to the model parameters have been scrutinized and approved by the regulators of the facility. Public confidence in the long-term safety of the repository is derived through trust in the regulators for the facility, the US Environmental Protection Agency (EPA) and the New Mexico Environment Department (NMED). Confidence by the regulators is gained by providing full access to the data, codes and methods used to perform the PA; by estimating uncertainties on the projections using establish methods; by performing tests to verify and validate the codes; by maintaining an approved Quality Assurance (QA) program to enforce the utilization of approved codes and data and to provide documentation that describes the various analyses conducted in the PA; and by using additional analyses beyond the baseline PA to examine the impact of assumptions, requirements, parameters, and methods used in the PA.

Furthermore, the project includes public stakeholder input through a variety of different opportunities. These opportunities include interactions through technical exchanges with the regulators and DOE, formal public comment periods, a WIPP hot line, and independent technical oversight.

Finally, the DOE must apply for recertification every five years. In the original certification application and subsequent recertification applications, the DOE must document how uncertainty and other issues are handled. The WIPP is a licensed and operational facility because the regulator reviewed the original certification application and subsequent recertification application and approved both.

9. **What measures other than numerical analysis can be utilised to manage the uncertainties (e.g., methodological, QA, etc.)? Please provide examples.**

A parametric uncertainty analysis, such as that done for WIPP PA, can only provide an estimate of the quality of the assessment within the bounds of the modelling framework, assumptions and the uncertainties assigned to the parameters. In other words, the uncertainty analysis expresses the range of possible releases or risks given that the conceptual models capture all the important process and events affecting the future of the repository, that the conceptual model has been properly implemented in code, that the numerical methods applied to solve the computer models are implemented properly and of adequate precision, that the assumptions made in developing the models are reasonable, that the parameters used are appropriate for the scale of the implementation, that the code and its inputs are protected from unauthorized changes, etc. Thus, by itself it cannot provide an estimate of the
validity of those calculations. Confidence in the validity of the calculations must be established through a variety of other means. Lack of such confidence can result in the perception among reviewers, regulators and the general public that the uncertainties in the predictions far exceed those reported. Thus efforts to demonstrate the overall credibility of the approach used in the assessment are likely to be important. These efforts include such things as configuration control for all related computer files, documentation of changes and their impacts, verification and validation of the models, use of formalized methods for assessing uncertainties subjectively, peer review down to the level of the code, etc. Putting these additional activities under QA can help to confirm that the approved methodologies are being used. However, care must also be taken to help ensure that the requirements and delays imposed by QA do not detract from the quality of the assessment.

For the WIPP project, the regulator recognized the overall uncertainty of the performance predictions. EPA states in 40 CFR 191.13(b), “Performance assessments need not provide complete assurance that the requirements of §191.13(a) [the release limits] will be met. Because of the long time period involved and the nature of the events and processes of interest, there will inevitably be substantial uncertainties in projecting disposal system performance. Proof of the future performance of a disposal system is not to be had in the ordinary sense of the word in situations that deal with much shorter timeframes. Instead, what is required is a reasonable expectation, on the basis of the record before the implementing agency, that compliance with §191.13(a) will be achieved.” It is important for all participants of the project to recognize that there will always be uncertainties relating to long-term predictions and that the best practice to account for these uncertainties uses both quantitative and qualitative methods that are defensible, justified, reproducible and reasonable.

10. What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?

The key long-term performance measure for the WIPP is the total cumulative release of radioactivity to the environment. Solid waste material removed from the repository by the drill bit and shearing forces of the drilling fluids during a drilling intrusion account for an overwhelming majority of the total releases. These solid waste materials are termed “cuttings and cavings.” Uncertainty in total normalized releases is largely due to uncertainty in waste shear strength. In fact, shear strength accounts for more than 88% of the variability in total releases. The uncertainty in the volumes of cuttings and cavings is primarily controlled by shear strength. The second most important variable is a “solubility multiplier” that represents uncertainty in solubilities for all actinides in the +III oxidation state. This variable accounts for approximately 2% of the variability in total releases. The drill string angular velocity, also used in computing cuttings and cavings, contributes to about 1% of the
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variability of total releases. Each of the remaining parameters explain less than 1% of the variability in the total releases.

PA models are modified to incorporate changes to repository design, contents, and uses. The simplest way to receive approval from the regulator for the model changes is to implement them in a “bounding” manner. However, if this is the only approach taken to introduce change, the system that is modeled and the performance predicted will not resemble the actual performance of the repository, and, it may appear that a change will have a large, adverse impact on the performance of the repository when in fact it may not. Care must be taken to implement future changes with the best science and engineering information available.

11. **How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.**

During late site characterization and early PA development, the project performed a systems prioritization where PA tools were used to determine the sensitivity of parameters under investigation to PA outputs. This information was used to prioritize experimental and other site characterization work that was ongoing with the intent of developing or justifying PA parameters. Highly sensitive elements were given priority while less sensitive elements were reduced or eliminated. This prioritization resulted in better management of resources and expedited the final PA and compliance certification application.

After the site was operational, sensitivity assessments, operational efficiency changes and other drivers led the project to investigate many PA related elements such as ground water level anomalies in the WIPP vicinity and refinements in models and computer codes to increase efficiencies and assess changes to the repository designs. This type of information is necessary for periodic compliance recertifications and change requests.

12. **What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.**

The focus of WIPP PA has always been on the presentation of the CCDFs for the releases, primarily because those are the key to showing compliance with the governing regulations. In the graph below the total normalized releases computed for two assessments are compared and shown relative to the release limits set by regulations.
13. With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.

14. Any other comments?

Sandia is a multi program laboratory operated by Sandia Corporation, a Lockheed Martin Company, for the United States Department of Energy’s National Nuclear Security Administration under Contract DE-AC04-94AL85000.
15. *What are the key references that support your response?*

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### United States – USDOE-Yucca Mountain Project

**PAMINA RTDC-1 Work Package 1.2: Questionnaire for RTDC-1 Participants**

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1. **What stage is the radioactive waste disposal programme at in development (concept assessment, general siting, detailed site characterisation, final licensing to start construction / operation, operations)?**

The Yucca Mountain Project is to submit a license application in 2008 to the U.S. Nuclear Regulatory Commission (NRC), to obtain a construction authorization.

2. **What are the principal regulatory compliance requirements for long-term safety of the waste disposal system, particularly those that pertain to treatment of uncertainty?**

The U.S. Environmental Protection Agency (EPA) and the NRC are currently in the process of developing the standards that will apply to the disposal of high-level radioactive wastes in the potential repository at Yucca Mountain (proposed 10 CFR Part 63 [64 FR 8640]). In the Supplementary Information published with the rule, the NRC has stipulated the application of a probabilistic framework for total system performance assessment (TSPA):

Demonstration of compliance with the postclosure performance objective specified at § 63.113(b) requires a performance assessment that quantitatively estimates the expected annual dose, over the compliance period and weighted by probability of occurrence, to the average member of the critical group. Performance assessment is a systematic analysis of what can happen at the repository after permanent closure, how likely it is to happen, and what can result, in terms of dose to the average member of the critical group. Taking into account, as appropriate, the uncertainties associated with data, methods, and assumptions used to quantify repository performance, the performance assessment is expected to provide a quantitative evaluation of the overall system’s ability to achieve the performance objective. (64 FR 8640)

Note that the NRC not only anticipates that there will be significant uncertainties (proposed 10 CFR 63.101), but the NRC also requires the TSPA take into account uncertainties in characterizing and modeling the barriers (proposed 10 CFR 63.114). Furthermore, proposed 10 CFR 63.113(b) (64 FR 8640) requires a demonstration of
The expected annual dose is the expected value of the annual dose considering the probability of the occurrence of the events and the uncertainty, or variability, in parameter values used to describe the behavior of the geologic repository (the expected annual dose is calculated by accumulating the dose estimates for each year, where the dose estimates are weighted by the probability of the events and the parameters leading to the dose estimate). (64 FR 8640)

The regulatory guidelines also require a demonstration of reasonable expectation in the compliance calculations vis-à-vis the following acceptance criteria:

- Does not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence;
- Focuses performance assessments and analyses on the full range of defensible and reasonable parameter distributions rather than only upon extreme physical situations and parameter values

The EPA has recently proposed public health and safety standards in proposed 40 CFR Part 197 (64 FR 46976), with which the potential repository at Yucca Mountain must comply. The EPA has also specified the application of a probabilistic framework where uncertainties associated with scenarios, models, and parameters are explicitly incorporated into the performance assessments for demonstration of compliance. The regulation specified by the NRC in proposed 10 CFR Part 63 (64 FR 8640) is intended to implement EPA’s standards and be consistent with the EPA requirements.

3. How have the main types of uncertainties been classified for consideration (e.g., scenario, model, parameter, others)? Please provide examples.

The assessment of long-term performance for the potential high-level radioactive waste repository at Yucca Mountain is a complex endeavor. It requires modeling various coupled hydrologic, geochemical, thermal, and/or mechanical processes taking place within the engineered and natural barriers over extended periods of time. In addition, the future evolution of the geologic and environmental conditions surrounding the disposal facility must also be considered, albeit in a somewhat stylized manner. Such integrated assessments of the future behavior of the disposal system via a total system performance assessment (TSPA) model are often
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complicated by uncertainties which arise due to incomplete understanding, limited information, and/or paucity of data. These uncertainties may be further categorized as follows:

- Scenario uncertainty
- Model uncertainty
- Parameter uncertainty and/or variability.

Scenario uncertainty stems from the fact that future evolution of geologic and environmental conditions surrounding the disposal facility, over tens of thousands of years, is inherently unpredictable. Scenarios of plausible future states of the system, and their likelihood of occurrence, must therefore be inferred from direct and/or indirect field evidence and incorporated into the performance assessment analyses. An example of an uncertain scenario is volcanic activity resulting in upward magma flow to the repository horizon and damage to waste containers.

Model uncertainty includes uncertainty in conceptual models and assumptions, uncertainty in mathematical descriptions of these conceptual models, as well as uncertainty in numerical implementations in computer codes. Because of incomplete understanding and characterization of FEPs, multiple plausible alternative conceptual models may be considered equally likely or defensible. This is often the major source of model uncertainty. Translation of a conceptual model into a mathematical model also results in uncertainties because of simplifications and approximations commonly employed to make the problem tractable. An example of model uncertainty is the representation of unsaturated flow at Yucca Mountain using the active fracture model. Conceptually, the problem involves simplifying the characterization of water flow through a complex fractured rock mass using a simple dual-continuum fracture-matrix model. Additional uncertainty is introduced through the assumptions inherent in mathematical representations of fracture-matrix interaction and numerical solution of the governing equations, and calibration to field conditions using only a limited amount of data.

Parameter uncertainty may be categorized either as aleatory uncertainty, or as epistemic uncertainty. Aleatory uncertainty arises due to the inherent unpredictable nature of future events (as random processes/chance occurrences) and cannot be reduced by further collection of information after the repository system is designed. The time of an igneous or seismic event, or the number of waste packages destroyed in an igneous event, are examples of aleatory variables in the TSPA analyses. Aleatory uncertainty is also referred to as stochastic uncertainty, irreducible.
uncertainty or natural randomness (variability). Epistemic uncertainty arises due to lack of knowledge about the true, non-random, values of parameters and can be reduced by additional information. Model parameters such as spatially-averaged values of hydraulic conductivity are examples of epistemic variables in the TSPA analyses. Epistemic uncertainty is also referred to as subjective uncertainty or reducible uncertainty.

The presence of uncertainty in the inputs of the TSPA model (i.e., scenarios, mathematical and conceptual models, and parameters) results in the output of the model being uncertain as well. A probabilistic framework has been adopted in the Yucca Mountain project for translating uncertainties in model inputs to corresponding uncertainties in model predictions. This approach is also consistent with the regulatory standards proposed by the NRC and the EPA.

4. How have the different types of uncertainty been dealt with in the quantitative PA, and how have they been dealt with as part of the wider safety case? Please provide examples of each.

Question 6 answers the PA part fully. The safety case part is currently being planned, but not yet done. Perhaps uncertainties will be discussed in the safety case in a less technical manner as was previously done in sections 5.2.4.3.3 through 5.2.4.3.6 of the Yucca Mountain Final Environmental Impact Statement, which can be read at http://www.ocrwm.doe.gov/documents/feis_a/vol_1/eis05_bm.pdf. In these four sections there is a general discussion of uncertainties, specific discussions disclosing quantified and unquantified uncertainties, and a discussion of the main results of uncertainty and sensitivity analyses.

5. How much knowledge is there to define the main uncertainties, and how does the level of knowledge dictate the treatment of the uncertainties? Please provide examples.

A systematic methodology is employed where the level of knowledge dictates how uncertainty is characterized. If enough data are available from (a) field, laboratory and/or numerical experiments, (b) historical sources or (c) analog sites, then probability distributions are fitted to the data. Maximum entropy approaches are used to derive distributions when only a limited amount of information is available about the variable of interest. Formal expert elicitation protocols are applied to create subjective distributions when no site-specific information is available. Finally, Bayesian updating is used to combine old information (e.g., expert elicitation from a previous TSPA) with new measurements (e.g., results of recent field experiments). Documents have been written that provide guidance on how
6. What approach to system PA is preferred / appropriate and why (e.g., conservative versus realistic; deterministic versus probabilistic versus deterministic complemented by probabilistic; simplified versus complex modelling; use of “fuzzy mathematics”; others)?

The approach is to strive for a realistic (i.e., unbiased) characterization of uncertainty where possible and to adopt a conservative approach where realism is difficult to defend.

The regulatory requirements prescribe a probabilistic framework for incorporating the effects of uncertainties in scenarios, conceptual models, and/or parameters on evaluation of long-term system behavior. It has been extensively used in probabilistic risk analyses for evaluating the safety of nuclear reactors and power plants. Several probabilistic performance assessments have also been carried out within the U.S. radioactive waste disposal program. These include a series of performance assessment studies for the disposal of transuranic waste at the Waste Isolation Pilot Plant, as well as a series of calculations performed for the disposal of high-level radioactive waste at Yucca Mountain by the DOE and the NRC.

Monte Carlo simulation, the most commonly employed technique for implementing the probabilistic framework in engineering and scientific analyses, is a numerical method for solving problems by random sampling. This method allows a full mapping of the uncertainty in model parameters (inputs) and future system states (scenarios), expressed as probability distributions, into the corresponding uncertainty in model predictions (output), which is also expressed in terms of a probability distribution. Uncertainty in the model outcome is quantified via multiple model calculations using parameter values and future states drawn randomly from prescribed probability distributions. Monte Carlo simulation is also known as the method of statistical trials because it uses multiple realizations of the inputs to compute a probabilistic outcome.

The probabilistic modeling approach is computationally burdensome because it requires several hundred model calculations for each scenario of interest. However, it also provides important information not available from a deterministic “best-guess” or “worst-case” calculation. The benefits of probabilistic modeling include (1) obtaining the full range of possible outcomes (and the likelihood of each outcome) to quantify predictive uncertainty and (2) analyzing the relationship between the uncertain inputs and the uncertain outputs to provide insight into the
A Monte Carlo analysis of the TSPA model involves the following four steps:

1. Select imprecisely known model input parameters to be sampled
2. Construct probability distribution functions for each of these parameters
3. Generate a sample set by selecting a parameter value from each distribution
4. Calculate the model outcome for each sample set and aggregate results for all samples.

These steps are briefly described below.

Selecting Imprecisely Known Model Input Parameters To Be Sampled – The TSPA model consists of approximately 2,000 parameters, many of which are uncertain and/or variable. A determination as to which of these have a significant range of uncertainty or variability, affect the response of the performance measure(s) of interest, and thus need to be statistically sampled during model calculations, is made during the development of individual process models and/or abstractions thereof.

Constructing Probability Distribution Functions for Each Parameter – The probabilistic framework employed in Monte Carlo simulations requires that the uncertainty in model inputs be quantified using probability distributions. A variety of methods is used in the TSPA process for developing proper input distributions:

- fitting parametric distributions to measured, historical or analog data,
- using maximum entropy approaches to assign probability distributions based on minimal information about range/shape, and
- eliciting subjective judgment of domain experts using formal protocols and aggregating them to create composite distributions
- using Bayesian updating as an objective framework for combining old information (e.g., expert elicitation) with new data (e.g., field measurements)

Generating a Sample Set by Selecting a Parameter Value from Each Distribution – The next step in the Monte Carlo process requires generating a number of equally likely input data sets, which consist of parameter values randomly sampled from the prescribed range and distributions. An improved form of random
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<td><strong>Organisation(s):</strong></td>
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<td>U. S. Department of Energy (US DOE), Office of Civilian</td>
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<tr>
<td>Radioactive Waste Management, Las Vegas, Nevada</td>
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<tr>
<td>(“Yucca Mountain Project”)</td>
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<td><strong>Responsible Person(s):</strong></td>
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<td>Peter Swift and Srikanta Mishra, Lead Laboratory/Sandia</td>
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<td>National Laboratories, Albuquerque, New Mexico.</td>
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Sampling is the Latin hypercube sampling procedure, where the range of each parameter is divided into several intervals of equal probability and a value is selected at random from each interval. Latin hypercube sampling, which is employed in TSPA, helps achieve a more uniform coverage of the uncertain parameter range as compared to purely random sampling. The issue of interdependence or statistical correlation between parameters is also important from the perspective of maintaining the necessary dependence between random variable pairs. The sampling algorithm used in TSPA ensures that any desired correlation between input parameters is retained.

### Calculating Outcomes for the Sample Set and Aggregating Results for All Samples

In this step of the Monte Carlo methodology, the model describing the behavior of the system for the scenario of interest is evaluated for each of the randomly generated parameter sets. This is a simple operation consisting of multiple model calls, where the outcome (i.e., annual dose as a function of time) is computed for each sampled parameter set. One key consideration in this step is ensuring that enough simulations have been performed to obtain a stable solution via statistical tests of convergence, as well as parametric and non-parametric estimates of the reliability in statistical measures of model output. Once all of the required model runs have been completed, the overall uncertainty in the predicted outcome can be characterized by (1) summary statistics such as the mean and median and (2) the cumulative probability distribution.

Recall that the uncertainty in system performance (total system or subsystem), caused by the aleatory variables cannot be reduced, and the uncertainty caused by epistemic variables can be reduced by collection of additional information. Thus, interest centers on quantifying the uncertainty that can be reduced (reducible uncertainty), and further, to identify the important drivers of this reducible uncertainty, by the methods of sensitivity (uncertainty importance) analyses. This requires computing the reducible uncertainty and, therefore, maintaining a distinct demarcation between the aleatory and epistemic variables whenever that is practicable. The corresponding computational strategy involves selecting a sample of the all the epistemic variables, and, calculating for this sample, the expected performance over the set of aleatory variable(s). This procedure is repeated for other samples of epistemic variables, so that one obtains, the expected performance of the system (the expectation being only over the aleatory uncertainties such as timing of igneous event) for a set of samples of epistemic variables.

With respect to the nature of models used (i.e., simple versus complex), the GOLDSIM used by DOE for TSPA calculations allows models of any level of
7. **How does the PA conduct and differentiate between sensitivity analysis and uncertainty analysis? Please provide examples.**

Uncertainty analysis refers to the translation of uncertainties in model inputs into the corresponding uncertainties in model outputs. As noted earlier, uncertainty analysis is carried out using Monte Carlo simulation. Results are presented in terms of: (a) probabilistic time history of subsystem (e.g., mass release) and total system (e.g., annual dose), (b) corresponding statistics (e.g., mean, median, 5th and 95th percentiles of time histories), (c) dominant radionuclides contributing to mean dose.

Sensitivity analysis involves examining the sensitivity of the TSPA model results (and their uncertainties) to the uncertainties and assumptions in model inputs. This is accomplished using (a) regression analysis to determine the most important contributors to the spread in probabilistic model results, (b) classification tree analysis to identify those variables controlling extreme outcomes in the full suite of probabilistic results, and (c) entropy analysis to quantify the strength of input-output association for non-monotonic patterns. Note that these are global sensitivity analysis techniques that rank the uncertainty importance of various uncertain inputs by taking into account both the degree of uncertainty in the input and input-output sensitivity. This is different from the standard one-parameter-at-a-time local sensitivity analysis which captures only the input-output sensitivity at a reference point.

The TSPA sensitivity analyses are carried out using results from the probabilistic calculations at a fixed point in time, with the sampled inputs corresponding to each of the realizations being treated as independent variables and the computed outputs being treated as dependent variables. Note that the outputs can either be total system-level performance measures, such as annual dose rate to a receptor, or they...
Regression Analysis – In performance assessment studies, multiple linear regression modeling is commonly used to identify input variables that contribute the most to the calculated uncertainty (variance) in the performance measure. The primary technique for regression modeling is stepwise linear regression using rank transformations of the input and output values. The indicators for determining the relative importance of the input variables are the partial rank correlation coefficient and the standardized regression coefficient. Both of these indicators are calculated during stepwise regression modeling. The partial rank correlation coefficient for a particular input variable measures the correlation between the output and the selected input variable, after the linear influences of the other variables in regression have been eliminated. The standardized regression coefficient is related to the fraction of the total explained variance in the regression model that can be attributed to the variable of interest.

Classification Trees Analysis – Linear regression is useful for analyzing entire spectra of output data. However, analyzing small categories of output data may require a more specialized approach. Classification tree analysis is a categorical method for determining what variables or interactions of variables drive output into particular categories. Those realizations that yield the highest and lowest outcomes are grouped into high and low categories. Classification tree analysis will then provide insight into what variable or variables are most important in determining whether outputs fall in one or the other category. This leads to the extraction of useful decision rules such as “IF $x_1 < a$ AND $x_2 > b$ THEN dose > 90th percentile”.

Mutual Information (Entropy) Analysis – This approach is particularly useful for detecting non-monotonic input-output relationships. It involves constructing a contingency table that has entries of nonnegative integers giving the number of observed events for each combination of input variable ($x$) state and output variable ($y$) state. The mutual entropy (information) between $x$ and $y$ is a measure of the reduction in uncertainty of $y$ due to knowledge of $x$ (or vice versa). It can be computed by counting the number of occurrences of various states of $x$ alone, $y$ alone, and $xy$ together. The strength of association in the contingency table is quantified using the $R$-statistic, which is a generalization of the coefficient of linear (monotonic) correlation.
8. **What supporting arguments are available / relevant to address uncertainties and provide confidence in long-term safety? Please provide examples.**

Confidence is enhanced by demonstrating robust multiple barriers, using natural analogs where appropriate, showing that a detailed characterization of the repository has been performed at the component and system levels, comparing intermediate results from the system-level model with process model results, comparing with other comparable system-level analyses where appropriate, peer reviews, and also institutional actions including performance confirmation monitoring, site controls, QA, and assuring a safety-conscious work environment.

9. **What measures other than numerical analysis can be utilised to manage the uncertainties (e.g., methodological, QA, etc.)? Please provide examples.**

Showing that a reasonable estimate has been made insofar as data has allowed, and where there was a sparsity of data, conservative estimates have been made to avoid underestimating risk.

10. **What are the main uncertainties with regard to key performance measures / objectives and the purpose of the safety case at its current status? What is the likelihood that the uncertainties may jeopardise the project at a later stage?**

In the DOE’s Site Recommendation was accompanied by a “Yucca Mountain Science and Engineering Report (2002, sections 1.4.3; 4.1.1 and 4.4.5), uncertainties and their importance are discussed. But these analyses are now out of date and new analyses to support licensing are in progress. We do not believe that the remaining uncertainties preclude submittal of a license application. Link to internet for the cited document: [http://www.ocrwm.doe.gov/documents/ser_b/index.htm](http://www.ocrwm.doe.gov/documents/ser_b/index.htm)

11. **How are the uncertainty analysis results and other measures of uncertainty management used to derive conclusions and focus future work (e.g., programme decisions, R&D priorities, design requirements or modifications, license submissions)? Please provide examples.**

Long-term performance assessment of geologic disposal systems are significantly impacted by uncertainties arising from ignorance or imperfect knowledge about future events, processes and/or parameters as well as differences attributable to geologic heterogeneity. In the Yucca Mountain project, a systematic and comprehensive methodology has been developed for dealing with these uncertainties in a manner consistent with regulatory requirements. To that end, the combination
of uncertainty and sensitivity analyses techniques described above facilitates the quantification of uncertainty bounds on predicted radiological and non-radiological consequences, as well as the identification of key processes and parameters governing disposal system response for the proposed Yucca Mountain repository.

12. **What works best in communicating the different types of uncertainty to regulators and to other stakeholders (e.g., alternative approaches to presentation of results, etc.)? Please provide examples.**

Regulatory requirements include consideration of uncertainty, and the mean is the primary regulatory metric. Given regulatory expectations for evaluations of stability of the mean and uncertainty in the mean, we generally display the mean with the full distribution of results from which it is derived, along with selected quantiles such as the 5th and 95th percentiles. This seems to satisfy almost all non-technical audiences.

13. **With reference to the responses to previous questions, what are the gaps in understanding of how uncertainty should be classified, managed, analysed, supported with qualitative argument, presented, used to derive conclusions about future work, communicated, etc. that could usefully be considered as part of RTDC2, and why are these gaps important.**

In the US regulatory framework the classification and management of uncertainty is addressed jointly by both the regulator and the implementer. The DOE believes the approach it has taken is adequate and appropriate to support the decision-making process associated with DOE’s submittal of the license application.

14. **Any other comments?**

No.

15. **What are the key references that support your response?**

The CFRs mentioned above are part of the Code of Federal Regulations available on the internet at http://www.gpoaccess.gov/cfr/index.html. A reference was given in parts 4 and 10, above.