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Report on the PAMINA Workshop on the Regulatory Role in Managing Uncertainties in the Safety Case for Geological Disposal of Radioactive Wastes
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Foreword

The work presented in this report was developed within the Integrated Project PAMINA: **P**erformance **A**ssessment **M**ethodologies **IN A**pplication 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.

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Report History

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Executive Summary

The European Commission's PAMINA Project (***P***erformance ***A***ssessment ***M***ethodologies ***in A***pplication to Guide the Development of the Safety Case), has the aim of improving and developing a common understanding of integrated performance assessment methodologies for various disposal concepts for spent fuel and long-lived radioactive wastes in different geological environments. The work is organised within five Research and Technology Development Components or RTDCs. Galson Sciences Limited (GSL) is responsible for the co-ordination and integration of RTDC2, which is designed to develop a better understanding of the treatment of uncertainty in performance assessment and the safety case. As part of RTDC2, Task 2.1.A is evaluating the approaches used by regulators in managing uncertainties in the safety case for geological disposal of radioactive wastes.

Under Task 2.1.A, the Swedish Nuclear Power Inspectorate (SKI), with assistance from GSL, organised and hosted a workshop to elicit views on managing uncertainties in a safety case for a geological repository. The workshop focused on a number of formal presentations, grouped into three sessions, which provided a stimulus for wider discussion of the issues:

1. **Uncertainties in the safety case**. This session addressed some of the key issues relating to the treatment of uncertainty that are faced by regulators, and included summaries of previous work in this area.

2. **Regulatory guidance on the treatment of uncertainties**. An important means for regulators to influence the treatment of uncertainties is through guidance. This session described some recent experiences in developing regulatory guidance.

3. **Regulatory review of uncertainty treatment**. Reviews and assessments of safety cases and license applications allow regulators to determine whether their requirements and expectations concerning the treatment of uncertainty have been met. This session described some recent review experience.

A final discussion session gathered together the points that had been raised throughout the workshop.

The workshop was held at the Nordic Sea Hotel in Stockholm, 10-11 June 2008. The workshop was attended by sixteen participants drawn from regulators and other organisations with close interests in the management of uncertainties in the safety case for geological disposal of radioactive waste.

The main messages arising from the workshop are:

- Participants felt that the workshop had been a useful exercise for learning more about what regulators in other countries are doing in terms of approaches to the treatment of uncertainties and the review of safety cases.

- Participants felt that there was now less emphasis than before being placed in the safety case on the traditional comparison between safety assessment calculation results and dose/risk criteria set by the regulator. 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.

- Some participants suggested that 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.

- Most regulators 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 licence applications.

- Most 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.

- Participants agreed that close dialogue between a regulator and a developer is beneficial to the development of a safety case and a licence application, but the dialogue must be controlled and documented and not lead to a compromise of a regulator's freedom to make decisions.

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1 Introduction

1.1 Background and Aims

Development of a safety case for the management of long-lived radioactive waste involves consideration of the evolution of the waste and engineered barrier systems, and the interactions between these and relatively complex, natural systems, such as climate change. The timescales that must be considered are much longer than the timescales that can be studied in the laboratory or during site characterisation. These, and other factors, give rise to various types of uncertainty e.g., on scenarios, models, and parameter values used in modelling, which need to be taken into account when assessing long-term performance of a geological repository. Owing to this range of uncertainties, it is important to follow a clear strategy for dealing with uncertainties when developing a safety case.

The European Commission's PAMINA Project (***P***erformance ***A***ssessment ***M***ethodologies ***in A***pplication to Guide the Development of the Safety Case), which has 26 partner organisations and runs from 2006 to 2009, has the aim of improving and developing a common understanding of integrated performance assessment methodologies for various disposal concepts for spent fuel and long-lived radioactive wastes in different geological environments. Galson Sciences Limited (GSL) is responsible for the co-ordination and integration of the Research and Technology Development Component "RTDC2" of the PAMINA Project. RTDC2 is designed to develop a better understanding of the treatment of uncertainty in performance assessment and the safety case.

Task 2.1.A of RTDC2 involves an evaluation of the approaches used by regulators in managing uncertainties in the safety case for geological disposal of radioactive wastes. Under this task, the Swedish Nuclear Power Inspectorate (SKI), with support from GSL, organised and hosted a workshop to elicit views from regulators on managing uncertainties in safety cases developed for geological disposal. The workshop focused on a number of formal presentations that provided a stimulus for wider discussion of the issues. The workshop was intended to provide a forum for discussion of how regulators can assess and compare quantitative and qualitative lines of reasoning and evidence in safety cases that are subject to uncertainties.

The workshop was held at the Nordic Sea Hotel in Stockholm on 10-11 June 2008. The workshop was attended by sixteen participants drawn from regulators and other organisations with close interests in regulatory management of uncertainties in safety cases for disposal of radioactive wastes (see Table 1.1 for the list of participants). The workshop was facilitated by Roger Wilmot (GSL), with Paul Hooker (GSL) taking the notes.

1.2 Workshop Participants

The list of workshop participants is presented in Table 1.1.

Table 1.1. List of Participants.

Name	Organisation
Robert Broed	Facilia AB, Sweden
Paul Hooker	Galson Sciences Limited, UK
Doug Ilett	Environment Agency, England & Wales
Petri Jussila	Radiation and Nuclear Safety Authority (STUK), Finland
Georg Lindgren	Swedish Nuclear Power Inspectorate (SKI), Sweden
Nuria Marcos	Saanio & Riekkola Oy, Finland
Martin Navarro	Gesellschaft für Anlagen- und Reaktorsicherheit (GRS) mbH, Cologne, Germany
Vincent Nys	Federal Agency for Nuclear Control (FANC), Belgium
Patrick O'Sullivan	Nuclear Energy Agency (NEA), Organisation for Economic Co-operation and Development
Kari Rasilainen	Technical Research Centre of Finland (VTT), Finland
Christophe Serres	Institut de Radioprotection et de Sûreté Nucléaire (IRSN), France
Shigeyuki Saito	Japan Nuclear Energy Safety Organization (JNES), Japan
Bo Strömberg	Swedish Nuclear Power Inspectorate (SKI), Sweden
Öivind Toverud	Swedish Nuclear Power Inspectorate (SKI), Sweden
Hans Wanner	Swiss Federal Nuclear Safety Inspectorate (HSK), Switzerland
Roger Wilmot	Galson Sciences Limited, UK

1.3 Workshop Agenda and Aims

The agenda for the workshop is provided below. The workshop comprised a series of short presentations and discussion periods. The aim of the presentations was to inform participants of new developments in different programmes and to act as background for discussion.

Agenda

Tuesday 10 June 2008

1300	**Introduction and Welcome**	Georg Lindgren - SKI
1315	**Overview and activities under PAMINA**	Roger Wilmot - GSL
	Uncertainties in the safety case	
1330	**The NEA perspective: Regulating the Long-Term Safety of Geological Disposal**	Betsy Forinash – NEA *presented by:* Patrick O'Sullivan - NEA
1400	Discussion and identification of key issues	
1430	*Tea / coffee*	
1500	**Uncertainties and optimisation**	Björn Dverstorp - SSI *presented by:* Bo Strömberg - SKI
1530	**Developing material to meet regulatory requirements and expectations**	Nuria Marcos - Saanio & Riekkola Oy
1600	**European Pilot Study – Summary of Uncertainty Treatment**	Christophe Serres - IRSN
1630	Questions and discussion	
1700	*Close*	
1900	*Dinner*	

Wednesday 11 June 2008

	Regulatory guidance on the treatment of uncertainties	
0830	**Development of new guidance in the UK**	Doug Ilett – Environment Agency
0900	**Developing a regulatory viewpoint in Belgium**	Vincent Nys - FANC
0930	*Coffee*	
1000	Discussion	
	Regulatory review of uncertainty treatment	
1030	**Regulatory review in Sweden**	Bo Strömberg - SKI
1100	**Dealing with uncertainty in the Swiss programme**	Hans Wanner - HSK
1130	**IRSN/ASN approach to managing uncertainties**	Christophe Serres - IRSN
1200	Discussion	
1230	*Lunch*	
1330	General discussion	
1430	Assessment of key issues and next steps	
1500	*Close*	

The presentations were arranged in three sequential sessions:

- **Uncertainties in the safety case**. This session addressed some of the key issues relating to the treatment of uncertainty that are faced by regulators, and included summaries of previous work in this area. A set of key issues for discussion was developed early in the workshop.

- **Regulatory guidance on the treatment of uncertainties**. An important means for regulators to influence the treatment of uncertainties is through guidance. This session described some recent experiences in developing regulatory guidance.

- **Regulatory review of uncertainty treatment**. Reviews and assessments of safety cases and license applications allow regulators to determine whether their requirements and expectations concerning the treatment of uncertainty have been met. This session described some recent review experience.

A final discussion session brought together the points that had been raised throughout the workshop.

1.4 Structure of this Report

This report is divided into the following sections:

- Section 1, above, provides some background and context to the workshop, and the workshop aims and agenda.
- Section 2 gives a flavour of each presentation and summarises the main points that arose from the discussions during the workshop.
- Section 3 summarises the conclusions in the form of key messages that arose from the workshop.
- Appendix A contains the workshop presentations.

2 Proceedings of the Workshop

Section 2 describes the workshop presentations and the discussions that took place after each presentation. Section 2.2 deals with the first session (Uncertainties in the Safety Case); Section 2.3 covers the middle session (Regulatory Guidance on the Treatment of Uncertainties); and Section 2.4 describes the last session (Regulatory Review of Uncertainty Treatment). A final round of general discussion closed off the workshop, and the main points are recorded in Section 2.5.

Only a brief outline of each presentation is given here. The main points from the discussions are described, and these are summarised as key concluding messages in Section 3.

2.1 Introductions

The workshop was opened by Roger Wilmot (GSL) on behalf of SKI and GSL. Georg Lindgren (SKI) then welcomed participants and introduced the workshop, describing its structure and objectives.

SKI and the Swedish Radiation Protection Authority (SSI) have interests in the workshop as the two organisations will be merged in July 2008 to form the Swedish Radiation Safety Authority (SSM), and SSM will need to assess the license application for a spent nuclear fuel repository that SKB plans to submit in 2010, either for Forsmark or Laxemar. In assessing the license application, SSM will need to deal in a transparent way with uncertainties associated with:

- Quantitative criteria: risk.
- Qualitative criteria: Best Available Techniques (BAT), optimisation, quality assurance and other confidence-building measures.
- Safety indicators.
- Questions on reasonable efforts, e.g. in the context of optimisation.

Following round-table introductions, Roger Wilmot gave an overview of the PAMINA Project and showed how Task 2.1.A fits into the overall project. Participants were reminded of the components to build a multi-factor safety case, namely the intrinsic safety functions of multi-barriers, and the safety assurance from arguments based on multiple lines of reasoning. The focus in the workshop should be on the safety assurance angle, noting that there are two key strands to safety assurance:

- Performance assessment, based on dose and risk calculations.
- Alternative lines of reasoning that build confidence in safety.

2.2 Uncertainties in the Safety Case

There were four presentations in the session on uncertainties in the safety case.

2.2.1 The NEA perspective on regulating the long-term safety of geological disposal

In the absence of Betsy Forinash (NEA), Patrick O'Sullivan (NEA) gave the presentation. Since the Cordoba Workshop in 1997 on Regulating the Long-term Safety of Radioactive Waste Disposal (Cordoba Workshop, 1997), NEA has continued to monitor developments in this area, culminating in various projects and documents, of which the following are especially relevant to the topic at hand:

- Consideration of Timescales in Assessing Post-Closure Safety (2006).
- Regulating the Long-Term Safety of Geological Disposal: Towards a Common Understanding of the Main Objectives and the Bases of Safety Criteria (2007).

The NEA presentation was developed largely from the conclusions of these two documents, which have resulted from work done by NEA's Integration Group for the Safety Case (IGSC) and from the NEA's Regulator Forum Project on Long-Term Safety Criteria (LTSC), respectively. Findings from the LTSC Project indicate that there are differences between national disposal programmes about what is meant by safety and how numerical safety criteria are established, although the project concluded that there was no reason to expect that these differences would lead to significant differences in terms of the radiological impacts from a geological disposal facility. The differences can be difficult to explain to the public and other stakeholders.

In the long term, uncertainties are unavoidable, and this means there are practical limitations as to how long anything meaningful can be said about the protection provided by a repository system. The types and treatment of uncertainties over different assessment time-frames should be identified, as they can affect regulatory criteria and the scope of the safety case.

Complementary safety indicators can be useful for avoiding certain biosphere assumptions. The challenge is to identify appropriate reference values to achieve a reasonable assurance of safety. Other means of building confidence in the safety argument include stepwise decision making, using optimisation and/or BAT, and having monitoring and performance confirmation programmes during the early phase of a repository lifetime.

A follow-up meeting to the Cordoba Workshop is planned to take place in January 2009 in Japan.

2.2.2 Discussion and identification of key issues

During discussion of the use of natural radionuclide fluxes as complementary safety indicators, mention was made of the IAEA co-ordinated research project on alternative safety indicators[1]. For example, natural ^{226}Ra concentrations and fluxes can be useful safety indicators when compared with estimated releases of ^{226}Ra from a repository.

Germany has proposed some new additional indicators of safety for long time-frames based on considering the isolation capacity of the repository. The indicators are used to estimate the radiological perturbation of the natural system at the boundary of the isolating rock zone and in shallow aquifers. For instance, the concentrations of U and Th released from the repository are compared with the natural concentrations of U and Th at the boundary of the isolating rock zone. Fixed criteria are proposed for each indicator. The approach is limited to natural radionuclides. The need to protect non-human species is considered in some national regulations, e.g. Switzerland and the UK.

Roger Wilmot took the opportunity to facilitate a discussion on the key issues that would serve to tie together subsequent discussions during the workshop. A variety of points arose as a result of the discussion:

- Complementary safety indicators, such as natural radionuclide concentrations and fluxes, provide useful alternative lines of reasoning.
- The roles of BAT and optimisation in a safety case are important for demonstrating ways of minimising radiological impacts.
- There are difficulties in managing the uncertainties associated with changing *in-situ* properties, and therefore safety functions, of engineered barriers during an assessment time-frame.
- Qualitative uncertainties need to be managed differently to quantitative uncertainties.
- Is it acceptable that regulatory criteria, such as dose constraints, risk targets and risk guidance levels, are different in each country?
- Public acceptance of a safety case is different to regulatory acceptance of a safety case.
- The achievement of safety principles in the safety case requires a process of confidence building, to complement dose/risk calculations.
- A regulator might find it a challenge to frame and communicate regulatory advice on licensing to government.

[1] Safety indicators for the safety assessment of radioactive waste disposal, IAEA-TECDOC-1372, IAEA, Vienna, 2003.

The key issues agreed for further discussion were:

- BAT/optimisation.
- Assessment time-frames.
- Complementary safety criteria.
- Confidence in the safety strands or pillars of the safety case.
- Regulatory advice/recommendations.

These key issues ran as continuous threads throughout the workshop discussions.

2.2.3 Uncertainties and optimisation - Sweden

In the absence of Björn Dverstorp (SSI), Bo Strömberg (SKI) presented SSI's views on BAT and optimisation in the context of geological disposal of radioactive wastes. The SSI regulations define optimisation as keeping radiation doses to people as low as reasonably achievable, economic and social factors being taken into account. BAT are defined as the most effective measures available to limit the release of radioactive substances and the harmful effects of the releases on human health and the environment which does not entail unreasonable costs. BAT forms part of the Swedish Environmental Code. BAT and optimisation are considered to be complementary requirements to dose/risk standards. BAT and optimisation ensure that everything is done as well as reasonably possible. Where a conflict between BAT and optimisation arises, the measures that satisfy BAT should be prioritised. After a million years, alternative safety criteria have to be used.

Regulatory review and government decisions on SKB's research, development and demonstration (RD&D) programme takes place every three years, the last RD&D review being in 2007. A key question is: how detailed should the BAT and optimisation measures be as provided by the repository developer/implementer? Various constraints (societal, economical and technical) play a part in the regulator's decision making on the levels of BAT and optimisation that are necessary for an acceptable safety case.

Regulatory review of SKB's RD&D programme is a legally binding process that requires SKB to follow government recommendations.

2.2.4 Discussion

Although at first sight it might appear that SSI is out of step with other countries applying a constrained optimisation approach, the SSI approach is close to the French one, which develops design options of repository components to help demonstrate safety/confidence in a given time-frame.

A question arose concerning whether a modification in design would lead to a change in the strategy for achieving safety. If the application of BAT were to require a

significant change in repository design (e.g. switching from KBS3-V to KBS3-H), then not only the design but the disposal concept would be different, and this would require a different safety case.

2.2.5 Developing material to meet regulatory requirements and expectations – Finnish case study

Nuria Marcos of Saanio & Riekkola Oy explained how information is developed in Finland to meet the regulatory requirements and expectations in Guide YVL 8.4: Long-term safety of disposal of spent nuclear fuel, issued by STUK in 2001. The regulatory requirements focus on safety analysis of different scenarios to support the safety case. Posiva has developed a main evolution scenario that does not envisage release of radioactivity from the repository within the assessment time-frame. Several assessment scenarios were described to encompass uncertainties regarding possible releases through perturbation of the expected evolution scenario by human intrusion, earthquakes, canister defects, buffer erosion, and glacial melt water making contact with the canisters.

In addition to being used to calculate annual dose rates, activity release rates are used as input into the stylised biosphere model in order to calculate activity concentrations in environmental media such as soils and water bodies. From these, landscape (areal) doses are derived in order to compare with regulatory constraints.

2.2.6 Discussion

It was apparent from the discussion that there is a move to require the developer not only to use a value for risk derived from the safety analysis results, for direct comparison with a regulatory risk target, but also to use the information from the safety analysis of different scenarios as support for the safety case. This support takes the form of disaggregated annual dose rate results, and transparent identification of the risk drivers, uncertainties and assumptions.

2.2.7 European Pilot Study – summary of uncertainty treatment

Christophe Serres (IRSN) gave an overview of the European Pilot Study on the Regulatory Review of the Safety Case for Geological Disposal of Radioactive Waste. The case study on Uncertainties and their Management concluded that although regulatory frameworks differ considerably between countries, regulatory practice and attitudes towards the achievement and demonstration of safety differ to a much lesser extent. Another overall conclusion was that the developer of a geological repository should adopt a staged approach, and keep the regulatory authorities informed and involved in major decisions on the development of a disposal facility and the safety case.

2.2.8 Discussion

Discussion highlighted the problem of assigning criteria for assessing the degradation of engineered barrier materials with time. It was suggested that the approaches used for understanding degradation processes in near-surface repositories could add value to the treatment of such processes in geological facilities for high-activity wastes. The application of strict quality control measures in the fabrication of components would minimise defects and unwanted changes in the safety functions of a canister/buffer system.

2.3 Regulatory Guidance on the Treatment of Uncertainties

Two presentations were made in this session.

2.3.1 Development of new guidance in the UK

Doug Ilett of the Environment Agency explained how there is a public consultation process underway to seek comments on the recent revision of the UK guidance on requirements for authorisation for geological disposal facilities on land[2]. The guidance explains that a developer should establish and maintain a register of significant uncertainties, develop a clear forward strategy for managing each significant uncertainty (through avoidance, mitigation, or reduction), and assess whether uncertainties can be reliably quantified. Guidance is provided for different approaches to treating uncertainties. The guidance expects that the uncertainties that can be quantified will be considered in a risk assessment, and the resultant numerical estimates of risk compared to a risk guidance level. Uncertainties that cannot be reliably quantified include those associated with future human actions, and these could be managed by means of separate "what-if" scenarios. There will also be increased programmatic uncertainties as a result of the long timescale of the UK repository programme (however, these do not contribute to the risks generated from performance assessment).

2.3.2 Discussion

Doug Ilett noted that it is up to the developer to decide how to manage the risks and uncertainties associated with possible human intrusion. There is no assessment method in the UK guidance. Equally, it is down to the developer to set the appropriate assessment time-frame for applying the risk guidance level, as there is no time cut-off in the guidance.

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[2] Deep Geological Disposal Facilities on Land for Solid Radioactive Wastes: Guidance on Requirements for Authorisation, Draft for Public Consultation, Environment Agency and Environment & Heritage Service, 15 May 2008.

2.3.3 Developing a regulatory viewpoint in Belgium

Vincent Nys (FANC) described the regulatory situation for the proposed near-surface disposal facility in northeast Belgium. The licence authorisation, expected around 2010, will require a safety case that should describe how the long-term safety strategy has been implemented through the disposal concept and should provide confidence in the long-term safety of the facility. The safety case should justify the decision for a release of regulatory control after the institutional control period. In this perspective, the identification and management of uncertainties is key for confidence building. Regulatory guidance is currently being prepared. The specific regulatory framework will have three levels: Level 1, Strategy document that states the fundamental principles, and describes the authorisation process; Level 2, Disposal Specific Guidance that develops the safety strategy that has to be followed for a certain disposal type; and Level 3, Specific guidance on human intrusion, seismicity, groundwater impacts, etc.

Near-surface disposal guidance comprises a safety approach and specific requirements. Confidence in long-term safety can be achieved by the implementation of the safety approach and demonstration that the repository will perform as expected. The developer will be required to manage the uncertainties that occur over different timescales and to demonstrate that containment, isolation, stability and expected performance are met in the long term. An example of such uncertainty management was presented from the seismic guidance.

2.3.4 Discussion

It became clear from the discussion of the Belgian presentation that FANC would not expect the safety argument to be implemented solely on the basis of a dose/risk calculation; qualitative arguments demonstrating the preservation of safety functions over time are also important. A general question is always present – what is acceptable safety? Although there is a dose constraint in Belgium, arguments for safe containment over time will help provide the necessary levels of confidence in the safety case.

A safety approach that relies on a containment period followed by a period of uncertainty where qualitative arguments are needed to provide confidence in safety may pose the question of whether a numerical risk requirement for the long term is relevant. Most participants thought that keeping a numerical risk constraint as a safety indicator is necessary. However, there was a difference of opinion on whether risk criteria for the long term should or could be harmonised between countries. Although regulators might, in an ideal world, welcome common safety criteria to facilitate communication with stakeholders, the actual concerns of lay audiences may lie elsewhere. For example, the public in Sweden appear to be most concerned about unexpected processes that could affect long-term performance of the repository, e.g. an unknown corrosion mechanism affecting copper canister integrity. The establishment of trust between the regulator and stakeholders is considered a key goal.

A discussion of the multi-function concept, as applied in France, highlighted some potential assessment difficulties. Different engineered barrier system (EBS) components might have the same safety function, whilst some EBS components might have several safety functions. The EBS components will degrade at different rates and therefore their safety functions will change at different times. Once the EBS barriers have degraded and their safety functions are no longer operating, the safety case is reliant on the natural geological barrier, and uncertainties associated with the host rock will therefore require particular regulatory attention.

2.4 Regulatory Review of Uncertainty Treatment

Three presentations were made in this session.

2.4.1 Regulatory review in Sweden

Bo Strömberg (SKI) presented the regulatory review approach to SKB's licence application, planned for submission in June 2010. The review is likely to take at least two years. Support for the regulatory review will come from expert groups (e.g. INSITE for site investigations of the host rock; OVERSITE for site investigations of the biosphere; BRITE for EBS issues; groups for spent fuel and radionuclide chemistry, and safety assessment methodology issues; and a NEA review team); independent modelling capability to assess groundwater flow, radionuclide transport, and evolution of repository conditions; quality assurance review; and experts on specific technical and scientific issues.

The SKI-SSI SR-Can summary review report is due out in English mid-2008. Its contents were outlined. The appendices contain a list of contributions from external reviewers (the external review reports are open-file and published now); examples of quality deficiencies; and international statements about deliberate human intrusion. The SR-Can review concluded that the safety assessment methodology is mainly consistent with regulatory requirements, but developments are needed in some areas, e.g. better justification of criteria/target values; scenarios with overlapping failure of safety functions; uncertainty and sensitivity analysis; biosphere modelling; more work to demonstrate BAT; and quality assurance. Prior to licensing, better knowledge is needed on long-term processes such as buffer erosion, stress-corrosion cracking and creep of the copper shell, and oxygen penetration with glacial melt waters.

The safety functions in SR-Can form the basis of further regulatory preparation. Areas requiring further analysis have been identified, such as large-scale rock mechanical models, propagation of fractures, spalling and formation of new fractures, permafrost depth and freezing point for the buffer, and microbial processes. Areas for additional review capability have also been identified, e.g. for microbial processes.

2.4.2 Discussion

Discussion clarified some points. The reason for poor uncertainty analysis in SR-Can was lack of time. The codes used by SKB in SR-Can are verified to varying degrees of comfort, but it is the duty of SKB to verify the codes to acceptable levels. SKB has a single report containing the data used in its assessment.

2.4.3 Dealing with uncertainty in the Swiss programme

The presentation by Hans Wanner (HSK) dealt with uncertainty in the Swiss HLW programme. The regulatory guidelines HSK-R-21 are to be replaced by regulatory guidelines HSK-G03 at the end of September 2008. HSK-G03 will require 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. As in the feasibility demonstration for high-level waste disposal, the implementer may also use "what-if" cases/parameter variations and consideration of reserve FEPs.

Conservative assumptions need to be applied when setting radionuclide solubility limits and sorption coefficients, e.g. the K_d values for Nb and Am sorption onto bentonite. "What-if" cases use assumptions which are not scientifically justified, but serve to demonstrate the robustness of the repository system, e.g. high water flow in the geosphere (100-fold increase), transport along transmissive discontinuities in host rock, increased fuel dissolution (10- and 100-fold), and decreased transport distance in the geosphere. Reserve FEPs are FEPs that are not considered in order to be conservative, e.g. co-precipitation of radionuclides with secondary minerals from spent fuel, glass and canister corrosion is a process that is likely to occur in practice, but it is not included for conservative reasons; likewise for the sorption of radionuclides onto canister corrosion products, and irreversible sorption of radionuclides.

Reducible uncertainties are termed 'open questions' in the review of the feasibility demonstration and require further research. The term 'open question' was misunderstood by some stakeholders, who thought they were impacting the feasibility demonstration in a detrimental way. Non-reducible uncertainties require pessimistic assumptions in order to avoid under-estimation of possible radiation exposures.

2.4.4 Discussion

The HSK-G03 guidelines requires that uncertainties in data, processes and models have to be reduced 'as far as necessary', but does not say what is necessary. The developer has to explain how to reduce uncertainties, e.g. sensitivity analysis may show that an uncertainty has a negligible impact on safety. The implementer must decide what is necessary to be done to reduce uncertainties. It need not do what is judged to be unnecessary. To facilitate this process, a close dialogue with HSK is

needed in order to be in tune with regulatory thinking on issues such as geochemical modelling.

2.4.5 IRSN/ASN approach to managing uncertainties

Christophe Serres (IRSN) gave an overview of the regulatory approach in France for managing uncertainties associated with a safety case for a geological repository. The presentation focused on the regulatory process (principles of the ASN Safety Guide, key safety issues, and stepwise reviewing process), uncertainties from the Dossier 2005 Argile, and some perspectives on dealing with the remaining uncertainties.

The Safety Guide provides guidance for site selection and design, which is a first step to reduce uncertainties. Key safety issues include the geological and hydrogeological characteristics of the site, the geochemical confining capacity of the site, the main perturbations of the disposal components and their influence on the containment function, and the technical feasibility of the seals. Retrievability impacts on the design concept will be considered.

Review of Dossier 2005 Argile highlighted a number of remaining uncertainties, which include the identification of faults in the Callovo-Oxfordian clays at ANDRA's Bure site, and the role of faults in possible radionuclide migration. Further studies are needed also on the long-term performance of concrete, the *in-situ* behaviour of seals, and biosphere modelling. High-resolution 3-D seismic reflection experiments were conducted in the Toarcian clays in the IRSN Tournemire experimental station to test whether this method would help identify faults in the clays at the Bure site. The seismic results failed to detect faults that were proven in the rock-cores drilled through the Toarcian clays. A combination of techniques is therefore required to identify and characterise faults in the Callovo-Oxfordian clays at Bure. IRSN performed a "what-if" scenario calculation to assess the impact of undetected faults on radionuclide migration; this was done to resolve disagreement between ANDRA's experts and those for IRSN.

Proposed approaches to dealing with the remaining uncertainties at Bure include the following: cross-characterisation methods adapted to site features (3-D seismic methods plus inclined boreholes); long-term *in-situ* experiments to evaluate the behaviour of the engineered disturbed zone and chemical interactions in the EBS; *in-situ* demonstration tests on the performance of seals and cement; and modelling of probable scenarios using conservative assumptions, and less probable altered and "what-if" scenarios.

2.4.6 Discussion

It was noted how the spatial variability of faults and fractures in clay sequences can be a potentially significant uncertainty in site characterisation. Because it is difficult to detect faults in clay rocks, even by using sophisticated geophysics, a regulator might expect the developer to treat and quantify such heterogeneities through specific scenarios ("what-if", less probable.…). Improvements in detection techniques would

thus be valuable with regard to the types of situations (i.e. fault location and properties) to be considered in long-term evolution scenarios. More generally, such issues should be addressed in terms of the overall safety strategy and design choices made by the implementer.

2.5 General Discussion

Discussion of the regulatory review process highlighted some general points. First, the regulator does not need to replicate the full safety assessment produced by a developer (a situation that pertained earlier in the UK). Instead, the regulator is concerned with reviewing the RD&D programme or safety case submitted by a developer, and in doing so it would use its own capabilities to assess and evaluate key processes and uncertainties. Following a review, a regulator is in a position to require the developer to carry out what it considers to be necessary further research, site characterisation or assessment.

There is the question of when should the regulator request a developer to do a piece of research rather than doing it itself. Research pursued by a regulator or regulatory support organisation is likely to be focused on obtaining improvements in scientific and technical knowledge as a basis for effective reviews and for maintaining and developing regulatory competence. In addition, a regulator may carry out some 'seed' research in order to demonstrate to the developer that a research area should be investigated in more detail. HSK places importance on its experts staying at the forefront of science and performing quality 'independent' research.

Although a developer has the primary responsibility to verify its codes, the question of how much involvement should a regulator have in code verification was posed for discussion. During the WIPP Compliance Certification Application (CCA), the US Environmental Protection Agency (EPA) requested the Department of Energy (DOE) to re-run the DOE code using EPA-preferred parameter values. Although this was not a code verification exercise, it circumvented the problem that the EPA had no code to carry out its own independent tests. On the other hand, HSK has the strong view that it should use a different code to the one used by the developer to model radionuclide migration, in order to verify what the developer has done. Use of its own code enables HSK to perform parameter value variations, independent of the developer. STUK plans to use a simple code to verify what Posiva has modelled. IRSN has its own specific codes to test assumptions and verify the magnitudes of different effects modelled by ANDRA. Although IRSN along with the Commissariat à l'Énergie Atomique (CEA), AREVA and Électricité de France (EDF) have jointly developed codes for modelling reactor criticality for nuclear power plants in order to have the best codes that France can produce, it was felt that this approach was less viable for modelling an open system for radionuclide migration, with its many uncertainties and assumptions. SKI has its own codes and an independent capability for modelling radionuclide transport and performance assessment. This is important for verifying the SKB results and for discussion of the different assumptions buried in the codes, which can give rise to different results. GRS favours the use of open-source software

that can be modified in-house and development of its own codes; this gives GRS flexibility to investigate alternative assumptions and physical models in an independent way. The Environment Agency has limited resources in-house and therefore relies on consultants to run codes when necessary. Code development occurs partly through participation in international code verification exercises using set problems.

The discussion of code verification threw up the question of how distant or close should the regulator be to the implementer during the development of the safety case to avoid compromising its review process during a licence application stage. Although the onus for developing the safety assessment, safety case and licence application rests with the developer, it is the regulator that grants the licence or authorisation, and it is the regulator, not the developer, which has to defend and justify to the public and other stakeholders the decision to dispose of waste. Stakeholders must recognise that although a regulator must not be compromised in any way and should have freedom to make decisions once a licence application is submitted, it nevertheless needs detailed knowledge of the safety assessment and safety case in order to review the application and defend its decision to grant or recommend a licence or authorisation. Ideally, regulatory decisions should not be bound by any commitments made to the developer prior to receipt of the application. Basic scientific knowledge can be jointly gained and commonly understood, but it is used differently by the developer and regulator.

The comment was made that a pre-application review procedure means, by necessity, that a regulator will advise or require a developer at various intervals to do specific pieces of research or investigation, and this appearance of working together needs to be explained to stakeholders in order to avoid misunderstanding during the licensing procedure. A regulator might pose questions and requirements to the developer via regulatory review, but the regulator should not provide the answers.

A formal process of staged authorisation is outlined by the Environment Agency in its draft revised guidance on requirements for authorisation for deep disposal, with a series of formal hold-points to be decided by the regulator. If adopted by the UK Government, this regulatory process will formalise the need for dialogue between the Environment Agency and the developer.

A brief closing discussion involved round-table commentaries on what had been usefully gained from the workshop. The commentaries are as follows:

- Hans Wanner thought that the workshop had been a useful exercise, from which he had learned some new things; meeting with other regulators is a good way to facilitate discussion on specific topics of concern.

- Patrick O'Sullivan observed that regulators appear to be giving increasing emphasis, in assessing long-term performance, to a consideration of BAT, optimisation and safety functions and less emphasis to performance assessment calculations of dose and risk, and wondered what the implications

are going to be for a safety assessment in the future if calculated doses or risks are no longer seen as the primary indicators of performance and safety.

- Christophe Serres agreed that this development of thinking is occurring amongst many regulators, and that harmonisation on dose and risk criteria was not the priority, but more effort should be focused on developing alternative criteria.

- Shigeyuki Saito thought the workshop experience had provided useful information for the generic disposal concepts being developed in Japan.

- Nuria Marcos thought that the general shift from considering a safety assessment to a safety case was an interesting development in the context of the practicalities that arise from the 2001 Guide YVL 8.4 in Finland.

- Kari Rasilainen considered that national safety criteria act as the starting point for national safety cases; in Finland this means both dose rate- and release rate-based criteria.

- As a modeller and code developer, Robert Broed thought the workshop had provided a bigger picture with some food for thought on how to answer questions on uncertainty.

- Martin Navarro thought that it was useful to hear views on reducing the emphasis on numerical safety criteria and on developing alternative arguments in a safety case.

- Petri Jussila gained useful information from the presentations and especially from the discussion on codes and independent modelling.

- Doug Ilett valued the chance to see what is happening in more advanced programmes, and to share thoughts on different regulatory approaches.

- Bo Strömberg thought that the size of the PAMINA workshop had been good for regulator interaction, and thought that this type of EC meeting was a valuable forum for open discussion. He was encouraged by learning about the review strategies in Switzerland and France, and felt that these gave some confirmation of the SKI approach to reviewing a safety case.

- Paul Hooker thought the workshop was informative and a good way to check that the strategies used by regulators to review a safety case are in harmony with each other.

- Georg Lindgren noted that the use of dose/risk numbers was still an important way to build a safety assessment and to evaluate the integrated effects of different processes for optimisation.

Finally, Georg Lindgren wrapped up the workshop by thanking participants for attending, and acknowledging the work of Gisela Hytte (SKI) in making the local arrangements.

3 Conclusions

The principal messages derived from the discussions during the workshop are summarised as follows:

- Participants felt that the workshop had been a useful exercise for learning more about what regulators in other countries are doing in terms of approaches to the treatment of uncertainties and the review of safety cases.

- Participants felt that there was now less emphasis than before being placed in the safety case on the traditional comparison between safety assessment calculation results and dose/risk criteria set by the regulator. 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.

- Some participants suggested that 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.

- Most regulators 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 licence applications.

- Most 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.

- Participants agreed that close dialogue between a regulator and a developer is beneficial to the development of a safety case and a licence application, but the dialogue must be controlled and documented and not lead to a compromise of a regulator's freedom to make decisions.

Finally, it was clear from the round-table commentaries at the end that the workshop format was effective.

Appendix A Workshop Presentations

Appendix A provides access to the eleven presentations, in the order that they were delivered during the workshop.

Lindgren - SKI introduction:

Wilmot – PAMINA:

NEA:

Dverstorp – SSI:

Marcos – Finland:

Serres – European Pilot Study:

Ilett – Environment Agency:

Nys – FANC:

Stromberg – SKI:

Adobe Acrobat Document

Wanner – HSK:

Adobe Acrobat Document

Serres – IRSN: