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Swedish Radiation Safety Authority

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Workshop on Regulatory Review and Safety Assessment Issues in Repository Licensing

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SSM perspective

The Swedish Radiation safety Authority (SSM) is currently developing project plans for the review of the Swedish Nuclear Fuel and Waste Management Co's (SKB) planned license application for a spent nuclear fuel repository in Forsmark and an encapsulation plant in Oskarshamn. In support of the development of these project plans, SSM has carried out several international workshops during 2010 on detailed technical review issues including radionuclide transport, earthquakes, properties of the spent fuel and on copper corrosion and buffer erosion. The workshop reported here addresses general safety assessment issues and review strategy.

The objectives of the workshop were:

- to learn from other programmes' experiences on planning and review of a license application for a nuclear waste repository,
- to offer newly employed SSM staff an opportunity to learn more about selected safety assessment issues and
- to identify and document recommendations and ideas for SSM's further planning of the licensing review.

These workshop objectives were met. Besides providing a useful orientation for newly employed SSM staff, the results of the workshop, documented in this report, have proven valuable to SSM in its preparations for the licensing review. Key results include advice on areas where SSM would benefit from developing its projects plans further, suggestions for specific activities such as staff training to make SSM better prepared for the licensing review and, not least, the exchange of valuable experiences from regulatory review projects in the United States, Great Britain and Finland.

Project information

SSM's project leader and contact person: Björn Dverstorp
SSM's project reference: SSM 2010/3239

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1 Introduction

1.1 Background and objectives

The Swedish Radiation Safety Authority (SSM) is in the process of developing a project plan for the licensing review of a spent nuclear fuel repository. SSM expects to receive the license application from the Swedish Nuclear Fuel and Waste Management Company (SKB) on 15 March 2011. In preparation for the licensing review, SSM has already carried out several workshops during 2010 on detailed technical review issues including radionuclide transport, the impacts on a repository of earthquakes, properties of the spent fuel, and on copper corrosion and buffer erosion. The workshop described here was organised to address more general issues regarding regulatory review of SKB's safety assessment and overall review strategy.

The objectives of the workshop were:

- to learn from other programmes' experiences on planning and review of a license application for a nuclear waste repository,
- to offer newly employed SSM staff an opportunity to learn more about selected safety assessment issues, and
- to identify and document recommendations and ideas for SSM's further planning of the licensing review.

1.2 Workshop organisation

The workshop was held at Krägga Herrgåd on 30 November – 1 December 2010. Participants included SSM staff and invited speakers with experience in the planning and conduct of regulatory reviews for other waste disposal programmes. A list of participants is included as an appendix. Several participants come from organisations that have planned and carried out regulatory reviews in other countries.

The workshop comprised a series of presentations on licensing reviews undertaken for different programmes and on safety assessment issues, and working group discussions on a set of themes relating to the planning of a licensing review. The workshop closed with a plenary discussion of the topics raised and lessons learned. The workshop programme is included as an appendix.

The workshop was chaired by Björn Dverstorp (responsible for the technical workshop programme) and Bo Stromberg of SSM. Scientific support for workshop organisation and summary reporting was provided by Roger Wilmot of Galson Sciences Ltd (GSL).

1.3 Report structure

This remainder of this report is structured as follows:

- Section 2 summarises the programme and scope of the presentations.
- Section 3 comprises reports from the rapporteurs of the three Working Groups and a summary of the subsequent discussions.
- Section 4 summarises the plenary discussion.
- Appendix 1 contains the list of participants.
- Appendix 2 contains the workshop programme.
- Appendix 3 contains summaries of the oral presentations.

Copies of the presentations are available from SSM.

2 Presentations

2.1 Introductory remarks

Following a welcome and introductory remarks from Johan Anderberg (Head of Department, Radioactive Materials, SSM), Björn Dverstorp (SSM) gave a presentation on *Preparing for a Swedish licensing review*.

2.2 Licensing review

The first major group of presentations focused on the planning and conduct of licensing reviews in different waste disposal programmes.

The US Nuclear Regulatory Commission (NRC) has been undertaking a licensing review for the construction of a geological disposal facility at Yucca Mountain. The planning and conduct of key components of this review were summarised in three presentations from staff at the Center for Nuclear Waste Regulatory Analyses (CNWRA), Southwest Research Institute:

Budhi Sagar: *Safety assessment aspects*

Jude McMurry: *Natural barriers system*

Hundal "Andy" Jung: *Engineered barrier system*

Joel Geier (Clearwater Hardrock Consulting) gave a presentation on *Reviewing alternate conceptual models for the geosphere* describing why a consideration of alternative models is important and different approaches to their review dependent on the information presented.

Daniel Galson (Galson Sciences Ltd) gave a presentation on *Lessons learned from regulatory review of BNFL's 2002 post-closure safety case for the LLWR near Drigg*, which described the review methodology and how the outputs from the review were used.

Yvonne Tsang (Uppsala University) gave a presentation entitled *Checklist for review of scientific arguments*, which used experience from the review of SR-Can and proposed checklists of questions relating to data, models, safety functions, repository evolution, radionuclide transport and consequence analysis.

Mick Apted (Intera) gave a presentation on *Approaches to Issue Resolution within the Context of Regulatory Reviews: Experience from the US Process*, which used examples of a risk-informed approach from the NRC's independent safety evaluation to show how regulatory confidence could be developed.

Summaries of these presentations are included in Appendix 3.

2.3 Safety assessment issues

A second group of presentations focused on some of the key issues relevant to regulatory review of safety assessments.

Neil Chapman (Chapman & Co Consulting) gave a presentation on *Addressing the very-long term hazard potential of spent fuel in the regulatory review process*. This examined some of the principles underlying geological disposal and regulations and how these principles might apply in the very long-term, when there are very large uncertainties about disposal system behaviour.

Claudio Pescatore (OECD/NEA) gave a presentation on *Very long time scales in safety assessment* which also considered very long time-scales and discussed the potential implications of the ingrowth and external exposure to gamma-emitting daughters and also the chemical toxicity of spent fuel.

Ryk Klos (Aleksandria Sciences) gave a presentation on *Role of the biosphere – a measure of protection*, which described the specific requirements for dose and risk evaluation, the approaches that SKB has used in previous assessments and some of the issues to be considered in review.

Jussi Heinonen (STUK) gave a presentation on the *Regulatory review of Onkalo: Integration of long-term safety requirements and construction practises*, which highlighted the step-wise approach to characterisation and construction and the corresponding stages of regulatory review and licensing.

Roger Wilmot (Galson Sciences Ltd) gave a presentation on *Future human actions: their role in a safety case*, which summarised how future human actions could affect a disposal system, applicable regulations and issues concerning siting and markers.

Summaries of these presentations are included in Appendix 3.

3 Working Groups

Part of the workshop was spent in group discussions, with three working groups organised to consider a series of themes and associated questions. The objective of the working group discussions was to elicit advice as input to SSM's further planning of the licensing review. Each group was asked to address at least two of the following themes:

Theme 1: Potential weighting issues

- How can the relative importance of operational safety, construction safety and long-term safety be judged / weighted? Are there foreseeable conflicts between these phases? Which?

- Sufficiency of data gathering for long-term safety assessment vs. construction/operation safety assessment?

Theme 2: Optimisation and BAT

- Practical approaches for assessing optimisation and Best Available Techniques (BAT): how far should SKB have gone in their search for the best solution?

- What arguments for sufficiency are expected/acceptable?

Theme 3: Acceptable uncertainties at this decision point

- In what areas are unresolved issues expected (for example, data gathering for additional site characterisation, development and testing of engineered barrier components, incompletely understood processes)?

- What issues have to be resolved at this stage in the licensing process and what issues can wait until later decision points (application to start construction, test operation, routine operation, etc.)?

- What criteria could be used for assessing SKB's plans for handling unresolved issues?

Theme 4: Review methodology

- What criteria should SSM use for evaluating scientific soundness of methods and arguments in SKB's safety case?

- How to handle divergent views on critical scientific issues in the scientific community? Role of expert elicitation in the review process?

- Approaches for resolution of divergent views within the review organisation? Experiences from other programs?

- How are "critical review issues" best identified (pre-established from regulation, experience, previous assessments, established from preliminary review of license application, combination)? What makes an issue critical? How is resolution of an issue decided?

- Organisational issues: Experiences from actual reviews in other programmes?

A rapporteur for each working group presented the discussions and any conclusions to the workshop. A summary of these presentations is given here, together with a note of points raised in discussion.

3.1 Working Group 1

Participants:

Carina Wetzel (Chair)
Roger Wilmot (Rapporteur)
Claudio Pescatore
Jussi Heinonen
Hundal "Andy" Jung
Anders Wiebert
Bengt Hedberg
Maria Nordén

Themes discussed:

Working Group 1 considered the questions posed under Theme 2 Optimisation and BAT and under Theme 1 Potential Weighting Issues.

3.1.1 Optimisation and BAT

The Working Group started by discussing the general concepts of optimisation and BAT to ensure that there was common ground to the discussion of how their application could be assessed. Although different terminologies are in use in different countries, it was generally felt that the overall concept of reducing dose but taking account of costs (optimisation) is universal. It was recognised that SSM had introduced the comparable concept of BAT to reduce speculation regarding exposure pathways and the calculation of dose in the long-term, while still using quantifiable measures of performance for the comparison of alternatives.

Both optimisation and BAT are about the justification of decisions and the documentation should describe the alternatives that were assessed in reaching a decision and the reasons for a particular choice being made. The group considered that a failure to identify credible alternatives for key decisions would be an issue, but also felt that the level of documentation and justification should be proportionate to the importance of the decision or selection of alternatives.

The group was unsure about where the responsibilities of SSM and the Environmental Court lie with respect to the assessment of alternative approaches to waste management (e.g., KBS3 vs deep boreholes) and also with respect to other high-level alternatives such as the selection of Forsmark or the use of vertical rather than horizontal emplacement.

Although both optimisation and BAT imply some degree of quantitative assessment, the group did not consider that quantitative review criteria could be set to determine whether a decision was reasonable. Such criteria would require that a cost-benefit assessment (value-of-life) could be applied to the future. Nevertheless, the group would expect illustrative calculations to support arguments and decisions and, in the case of BAT, a justification of the performance measure used.

The group noted that SSM and its predecessors have included optimisation and BAT in regulations and guidance for some time but was unsure whether clear messages about regulatory expectations have been provided to SKB. The group therefore felt that a failure to fully meet expectations might reflect an absence of documentation rather than being symptomatic of flaws in SKB's programme. It was generally felt that identification and evaluation of alternatives, and a traceable and justifiable record of decisions were good engineering practise. The group considered that SKB should be able to respond promptly to any requests for clarification of key decisions.

3.1.2 Potential weighting issues

One of the questions posed for Theme 1 was "*How can the relative importance of operational safety, construction safety and long-term safety be judged / weighted?*" The group considered what a weighting of these issues in a review would imply, and noted that, prior to any "weighting", all aspects of the safety case must satisfy respective criteria. In other words, the operational safety case must show the facility is safe to operate, and the post-closure safety case must show that long-term criteria are met. There are potential conflicts when optimisation or BAT considerations in one phase conflict with considerations in another phase. For example, an increase in the amount of "foreign" material used for rock support to provide operational safety could have a deleterious effect on long-term safety of the repository. If all the relevant criteria are met, the group felt that any application of "weighting" could suggest that SSM considered one or other system to be "too safe". Using the same example, weighting long-term safety more than operational safety would require that less rock support should be used. It would, however, be difficult to argue for any increase in risks to present-day workers in favour of lessening uncertain risks to future populations.

SSM's guidance suggests that where there is conflict, BAT (performance) should take precedence over optimisation (dose). From its discussions, however, the group concluded that that BAT vs optimisation considerations should only apply within a phase, not between phases.

The second question posed under Theme 1 related to "*Sufficiency of data gathering for long-term safety assessment vs construction / operation safety assessment?*" The group focused its discussion on data collection rather than on the sufficiency of data.

It was noted that the periods over which long-term safety and construction / operation safety need to be considered overlap because there will be parts of the facility where waste has been emplaced and tunnels closed while other parts are still under construction. There is a possibility of monitoring the system after waste emplacement, but the group considered that the collection of data for long-term safety assessment must be complete prior to any waste emplacement commencing. Data gathering for long-term safety could continue during the initial phase of construction, but this would require a clear identification of data needs and commitments by SKB for timely data gathering. These commitments should be reinforced by licence conditions from SSM to ensure that the long-term safety case is complete and acceptable prior to emplacement of any waste.

The view was also expressed that the collection of data after emplacement would only be of value if the possibility of retrieval was both acceptable and practical. It was also noted, however, that, even without provision for retrieval, further data could be of value for optimising later phases of construction and operation.

3.1.3 Discussion

During the presentation, there was further discussion concerning what SSM required in terms of the documentation of optimisation and BAT. In the USA, for example, there was no requirement to optimise or justify decisions, but it was noted that this was related to the regulatory regime and that good engineering practice included the justification of design decisions. SSM noted that there had been consultation meetings with SKB concerning the regulations and what was expected and that the application of optimisation and BAT should be familiar to them. There remained a question as to whether SKB had considered a sufficient range of alternatives.

3.2 Working Group 2

Participants:

Bo Strömberg (Chair)	Mick Apted
Ryk Klos (Rapporteur)	Jan Linder
Budhi Sagar	Jinsong Liu
Daniel Galson	Björn Dverstorp

Themes discussed:
Working Group 2 considered the questions posed under Theme 4 Review Methodology and Theme 1 Potential Weighting Issues. Review Methodology received the most attention. Theme 2 Optimisation and BAT was also touched on in the discussion.

3.2.1 Review methodology

Initial discussion focused on the idea of a *Scientific Checklist* as described during the workshop presentation by Yvonne Tsang. Such a checklist was considered to be of use in helping to define the contents of a safety case, but not necessarily in conducting the review itself. From a regulatory point of view, particularly in the context of determining the acceptability of the licence application, it was realised that there is a distinction to be drawn between the "best possible" science and "good enough" science to fulfil the requirements of the licence application, taking into account the anticipated future developments at the site.

This discussion highlighted the practical purpose of the safety case and corresponding review. It was suggested that there is more in common with engineering concepts than a purely scientific understanding of the system. An engineering "bounding analysis" was suggested as an option for the review, which would give an appropriate level of detail. The ideal combination would be a review of "scientific soundness" combined with engineering judgements.

In respect of optimisation and BAT, it was pointed out that SKB has yet to demonstrate their use of BAT. At the time of the SR-Can assessment, no optimisation was reported. The reporting in SR-Site of optimisation and the use of BAT will require review of topics that SSM has not yet had to review in detail. There has been some debate within SSM on BAT and on how much SKB should present in the licence application. SSM understands that there will be stand-alone documents on the themes of site selection and the development of the disposal method in the series of documents published in support of SR-Site.

The Working Group was generally of the opinion that any critical issues could be identified now, before the licence application was submitted – this can be achieved by a top-down review of the potential failures of the safety function of the barrier systems. SR-Can endeavoured to perform such a review, but was not systematic. The group suggested that SSM should be able to identify the top ten most significant candidate issues before the review started. To do so was seen as being highly beneficial since this would focus attention on the key *safety issues*. This kind of experience had helped inform the NRC's review of the Yucca Mountain licence application.

The question of whether there are currently any "show-stoppers" was raised. At the time of SR-Can, the critical issues were:

- critical defect in individual canisters,
- the potential of earthquakes to disrupt the engineered barriers, and
- the possibility of buffer erosion leading to the release of radionuclide-bearing colloids.

However, it was noted that the critical issues identified at the time of SR-Can may have been satisfactorily resolved. It remains to be seen whether new critical issues are determined during the review process for the licence application.

Several themes relating to how the review might be organised were discussed. In common with the SR-Can review there are two threads – one is a straightforward review of the SKB licence application, but the importance of a parallel *numerical review* was also noted. Simple calculations can be used to review an issue concerning understanding of the SKB case as well as to perform preliminary investigations of critical issues. The use of such a process in informing the proponent of where additional calculations were required was also noted from the regulatory review of the 2002 safety cases for the low-level radioactive waste repository (the LLWR) near the village of Drigg in the UK.

SSM noted that application of their independent modelling capability was useful in helping to identify the right questions to ask during the SR-Can review. There were Quality Assurance (QA) issues in SR-Can in that not all of the data were clear or well justified. This was particularly evident when SSM attempted to shadow the SKB results using their own implementation of SKB's models (as described in the SR-Can documentation) using data taken from SKB's reports.

Another role identified for independent modelling is to determine how reliable the SKB modelling is, whether all the necessary documentation is available, and to determine the extent to which SKB has documented their modelling assumptions. The aim is to help SSM to check for any deficiencies in SKB's modelling.

SSM plans to carry out QA reviews of SR-Site. From UK experience, this was found to be essential at an early stage of the review, particularly with respect to critical issues. In the US, both random QA checks and vertical in-depth QA reviews were carried out.

The training of staff in the necessary regulatory review focus was emphasised as being of great value in both the US and UK review processes. A focus on safety is important since it allows the review to minimise the amount of discussion on issues that are unimportant to safety. The early development of an outline of the review report would provide a framework for the review team, so that individual reviewers could better understand how their contributions would fit into the bigger picture.

The issue of consistency emerged during this part of the discussion. In determining confidence in the safety case it was suggested that, say, "99% certainty" be the aim and that the review would be complicated if one participating expert in a particular area worked to a standard of "99.99%", whereas another in the same field worked to "70%". It was clear, therefore, that all participants should have a clear understanding of the aim and standards of the review strategy, i.e., that the team needs to be aware of the necessary and sufficient degree of certainty. Whether it was necessary for the whole team to be "trained" or whether only the team leader was sufficient was discussed.

A major topic of the discussion was "issue resolution" during the review. Three possible instances were identified:

- where SKB's documentation provides insufficient detail,
- where there is a difference of opinion between members of the review team, and
- where issues are identified by third parties (e.g. non-governmental organisations).

With respect to the latter point, it was realised that any comments by third parties should also be covered by SSM's review. From the US perspective, it is clear that the regulator has to be able to say that any issues arising were considered in the review. Otherwise it is the responsibility of SKB to deal with any rebuttals as are required. The more formal legal framework in the US was found to be useful in this respect. The three-person tribunal (the Nuclear Safety Licensing Board) was able to rule on the degree of importance of review issues and had the power to dismiss "frivolous" issues put forward by third parties.

Both the US and UK reviews included the equivalent of what in the US review was known as requests for additional information (RAIs). Again, the legal framework in the US was seen as having a useful function in sharpening the wording of the RAIs. The need for the RAI was subject to internal review to ensure that the need for the additional detail was properly justified. As a second step, the RAI was subject to a legal review where, it was found, the wording was likely to be further improved. The role of the legal profession was seen as a positive aspect of the US review.

The final point concerns internal review team disagreements. In the experience of the review of the 2002 safety cases for the LLWR, it was found that such conflicts were generally not *safety* related. From the US perspective it was noted that divergent issues were usually the result of features at the tail of the distribution of risk. More often than not, conflicts during the Yucca Mountain review process arose when a topic could be ruled of lesser importance and the associated expert was uncomfortable with the downgraded influence of their "pet subject". The example cited was of glass dissolution, where the importance was diminished by the overall small quantities of vitrified material in the waste stream.

It was agreed that the best way to resolve disputes is for the experts of the team to discuss matters together. In practice it has been found that the majority of conflicts were resolved amicably. The NRC has a written procedure for the resolution of internal review team disputes. The results of the dispute resolution process are documented, but this procedure only comes into play *if* the issue can be shown to impact the safety case. This documentation is for internal discussion, but the fact, and resolution, of the dispute is reported in published documentation. The three-person Licensing Board adjudicates on such matters. There was a difference of opinion within the Working Group on the need for, and indeed wisdom of, publicising such internal review disputes.

3.2.2 Potential weighting issues

SSM stated that this matter arose from the need to ensure that long-term safety would not be compromised by activities during the construction phase (a few decades) and operational phases (one century). The example given was of the drilling of too many boreholes during construction and operation which would leave the repository in a state incompatible with that assumed as the initial condition in the safety case. SSM recognises that the review of operational safety will require greater detail than hitherto. SSM needs to be confident that SKB can operate the repository and leave it in the planned initial state.

The Working Group concluded that measures that compromised long-term safety could be acceptable if they saved lives or avoided extreme doses during the pre-closure phase, provided always that safety criteria are met. Before any new activity or process is carried out, its impact should be reviewed in terms of the impact on long-term safety. This should be made a condition of the granting of the licence to construct / operate.

3.2.3 Discussion

In the discussion, there were questions concerning the identification of critical issues and the extent to which SKB had been systematic in identifying these. It was noted that there may be important differences between the issues identified as critical within a safety assessment and those that are critical to an overall safety case. The former may be systematically identified through sensitivity and uncertainty analyses to determine which components, FEPs (features, events and processes) or parameters have most effect on safety. It is more difficult to take a structured approach to deciding what is critical to a safety case. Although SKB should be expected to identify what it considers to be critical, SSM will have its own views on the critical issues, not least because resource constraints may limit the detailed review to these.

3.3 Working Group 3

Participants:

Shulan Xu (Chair)
Joel Geier (Rapporteur)
Yvonne Tsang
Jude McMurry
Neil Chapman
Pål Andersson
Georg Lindgren
Mikael Jensen
Karin Olofsson

Themes discussed:

Working Group 3 considered the questions posed under Theme 3 Acceptable Uncertainties at this Decision Point, and Theme 4 Review Methodology.

3.3.1 Acceptable uncertainties at this decision point

The working group started by discussing the meaning of "this decision point", as this influences what types of uncertainties are acceptable.

In principle SSM will only make a recommendation to the government and environmental court, but in practice SSM is the main entity with resources to make an informed recommendation, so this recommendation is expected to carry considerable weight in the actual decision. The licence to build a repository can be granted with conditions that SKB will need to meet in order to proceed with waste emplacement. SSM takes a risk, however, that SKB will empty the nuclear waste fund prematurely if their plans for disposal turn out to be impractical. Hence SSM needs to be convinced that the safety case is adequate.

In what areas are unresolved uncertainties expected?

SSM's INSITE review group produced an inventory of unresolved issues relating to the geosphere, at the end of surface-based site investigations. SSM's complementary review group for the biosphere, OVERSITE, also identified key issues. These provide a starting point for assessing which unresolved uncertainties can be expected at the time of licence application.

Uncertainties regarding the fracture model and state of stress at depth are expected to remain high until underground data are available.

SKB's criteria for choosing canister emplacement locations, to avoid critical "discriminating" fractures, is currently a concept but has not been tested. This criterion and methods for ensuring that it is met will need to be proven underground.

Feasibility of the engineered barriers remains a key concern that is likely to be carried into the construction phase. A critical question is, can SKB actually build the engineered barriers as an industrial process while meeting the quality assurance requirements that are assumed in the safety assessment? Concerns persist, for example, regarding methods for welding of canisters and emplacement of bentonite blocks and canisters; demonstrations of these methods to date have been of a "hand-crafted" nature rather than as industrial processes that can be sustained for thousands of waste packages.

What issues have to be resolved at this stage in the licensing process and what issues can wait until later decision points?

The working group considered that the licence to begin underground construction is a key decision point, so the threshold for acceptance needs to be quite high. The later decision points in the process (application to start construction, test operation, routine operation, etc.) provide possibilities for SSM to attach conditions at this stage of licensing. However, by approving a licence for this stage, SSM takes on a significant degree of risk regarding the feasibility of a repository at this site. If SKB ultimately cannot build a repository to specification, the nuclear waste fund may be exhausted leaving few resources for an alternative solution.

SKB must show that they have an adequate plan for data gathering during construction to cover identified uncertainties in open issues. Their plan must give confidence that they have an approach that will close remaining issues. SKB must also show that they have *at least* a plausible path for solving the remaining issues for constructability.

The only excuse for not resolving a critical safety assessment issue prior to licensing is that there is no way for SKB to resolve it before they go underground. This could arise from an objective lack of knowledge regarding the rock itself. If there are parts of the safety case that depend on being able to find rock with particular properties, this is acceptable, but evidence should show a strong likelihood of success.

Issues relating to fabrication of the canister should be resolved as no additional information can be expected to be gained by going underground. Likewise, validation of the bentonite erosion model against experimental data does not require underground access at the site. Long-term experiments in surface facilities, other underground laboratories, or even a demonstration portion of the repository may be necessary to check time-dependent effects, but as proponent has chosen the timing of the licence application, lack of time cannot be used to excuse significant gaps in the safety case.

How can SKB's plans for handling unresolved issues be assessed?

The working group considered the term “unresolved issue” in this context to mean only what the proponent does not know at the time of the licence application. Based on what the proponent knows at this point, they need to provide a convincing safety case.

SSM will need a clear target for each issue, as to what is meant by “resolution of the issue.” For example, if the issue regarding bentonite erosion is to be resolved, there should be a clear idea of what is expected. Then SSM will need to evaluate if SKB has a method that could achieve this within a set period. Does SKB have alternatives if the primary method fails? Would they need to redesign if it fails? If these questions cannot be answered in the affirmative, SSM should ask for more development of the methodology before approving the licence application.

3.3.2 Review methodology

Approaches for resolution of divergent views within the review organisation? Experiences from other programmes?

Peer review might be helpful to settle internal differences of opinion as to whether an issue is sufficiently important to impact the safety case.

A formal approach used for irreconcilably divergent professional views in the US programme is “differing professional opinion”. This goes on public record and can be used in legal proceedings. This approach is used only after attempts have been made at resolution within the organisation. It is only used for issues that are seen by the dissenting professional as safety-critical. It is available only to reviewers with a professional standing for the issue in question (so, for example, a geologist would not have the option of giving a differing professional opinion on stress corrosion cracking in the waste package).

How to handle divergent views on critical scientific issues in the scientific community? Role of expert elicitation?

Expert elicitation can be used as a method for assessing divergent views in the scientific community. The review organisation can use a process of calibration (expert ranking), to assess if individual experts tend to be outliers with respect to accepted opinion.

However, the working group considered that it is better not to discount divergent views, even in such cases. The key question is to evaluate if a divergent opinion actually affects overall acceptance of the safety case. Where there is diversity of scientific opinion that could be significant for safety, SKB ought to account for alternative models.

Expert judgement must be traceable. One should only turn to expert judgement when there is something unknown.

How to ensure completeness in the identification of critical review issues?

How are "critical review issues" best identified (pre-established from regulation, experience, previous assessments, established from preliminary review of licence application, combination)?

The working group answered, "Yes to all of the examples." In other words, all of these are important bases for identifying critical review issues, so a combination of all should be used.

How are critical issues best identified? What makes an issue critical?

The primary question is, does it affect safety? Constructability must also be considered, but is secondary for this stage.

What criteria should SSM use for evaluating soundness of methods and arguments in SKB's safety case?

The safety case should be transparent to a qualified individual in SSM. SKB has the responsibility of showing that, for all substantial scientific issues, the safety case meets scientific peer review,.

3.3.3 Discussion

In the discussion, it was noted that validation of models of engineered barriers may require data from extended timescale tests. SSM could consider licence conditions to ensure that these are undertaken at an appropriate scale.

There was further discussion concerning the treatment of divergent views within the review. Some considered that differing professional opinion could be problematic for the regulatory approval process. Where the differing opinions are critical to the safety case, the explicit justification of divergent views would help ensure that regulatory decisions could be defended.

4 General Discussion

A general discussion was held on the issues raised in the presentations and working groups, with the aim of identifying key lessons that could be used by SSM in developing the Review Plan for SR-Site.

The following summary is not presented sequentially, but is structured according to several themes that arose from the discussion:

- Issue identification
- Guidance to reviewers / training
- End product of review

Issue identification

Several of the presentations had noted the importance of identifying review topics and the key issues prior to the review, and some of the possible approaches to identifying these were discussed in the working groups. Several potential sources were identified.

INSITE had used an issue identification and resolution process during the examination of SKB's site characterisation programme, and outstanding issues from this could be used as an input to the review. It was noted that not all of these issues could be addressed through surface investigations and associated modelling and a lack of resolution in SR-Site should not necessarily be regarded as critical. This highlighted the importance of being able to maintain a list of issues for review in later stages of the licensing process, perhaps through the setting of conditions.

SKB is understood to have compiled a database of comments on SR-Can. This would be a useful tool for SSM, although it was noted that the list would include minor comments that are of little relevance to safety. Work since SR-Can and changes to SKB's assessment approach could also mean that some issues would no longer be relevant. These points were not regarded as problematic, but did highlight the fact that the list should be used as an input to the Review Plan rather than as a definitive list of issues for review.

SSM, and its predecessor organisations, has been reviewing SKB's programme and undertaking independent research for many years and there should therefore be a general understanding of the key issues. A preliminary list of issues has been compiled, but this may need to be updated. The set of standard questions developed by the NEA for international peer reviews could provide the basis for checking the completeness of the application/safety case. A preliminary review stage would be useful in refining the list of key review issues.

Guidance to reviewers / training

Several of the presentations had described how reviewers had been issued with review guidance and, in the case of the NRC review, specific training. Some of these points were raised again in discussion.

There was discussion of the role of check-lists as guidance to reviewers. Some felt that generic check-lists could have some value, but that more specific guidance would be required. Such specific guidance would not be dissimilar to a detailed set of review issues, and deriving this guidance and determining the key issues would be related tasks. An outline of the review document, with a set of key questions for each chapter, was mentioned as a potentially useful starting point for reviewers.

In addition to guidance on the topics for review, reviewers would require guidance on the types of outputs required from the review and on the procedures for the review, including communication. This type of guidance could perhaps be provided through training, at least of task leaders, if not all reviewers.

One specific topic on which guidance will be required is interaction with SKB. During the review, such interaction would need to be transparent and open, and documentation would need to be available to the national consultation as well as to all reviewers. Proposals for SKB to make initial presentations of the safety case to SSM and its consultants received strong support.

SSM considered that there were useful lessons to learn from the way in which the NRC had managed cases where there were divergent views between reviewers.

End product of review

It was noted that in previous reviews by SSM and its predecessors, the emphasis has been on weak areas and what SKB could improve. The review of SR-Site, however, must determine whether a target has been reached, and SSM needs to establish what that target is. This will allow SSM to respond to the application, in terms of recommendations to Government, rather than just undertake another review.

There was wide-ranging discussion of this issue, with three key aspects:

- Expectations for this stage of review
- Feasibility and BAT
- The role of licence conditions

Expectations for this stage of review need to be defined both in terms of what SSM needs to establish and what the overall outcomes of the review process might be. SSM has a responsibility to ensure that it has confidence in the licence application, but has yet to define how to determine this.

There was discussion about the importance of “scientific soundness” and how this could be established, and it was noted that the judgements that must be applied here may be different to those applied in the safety assessment in which conservative approaches might be used. It is important that SSM has confidence in the scientific soundness of the safety case at this stage because SKB may not revisit the fundamentals of the safety case in later stages of the licensing process. Some uncertainties will remain at least until there is information from the underground, but the fundamentals of the safety case must be clear at this point.

One key observation was that if a conclusion cannot be reached or a decision made, then the decision must be "No", although it was also noted that the focus must be on safety significance and not on a lot of details about the science where they are unimportant to safety.

One suggested approach for deciding what is required from the review would be to consider the various possible conclusions and recommendations and to then determine what types of information would be needed in support of these. Which aspects of the application must be satisfied before continuing, which aspects could be delayed, which aspects might be subject to licence conditions? Similarly, if conditions are applied to a licence, what information is needed in support of these conditions?

Feasibility and BAT were discussed because concerns have been raised that SKB has not yet demonstrated that the initial conditions for the disposal system, particularly the properties of the bentonite buffer, can be achieved. There were differing views about how SSM should treat this issue, with some feeling that an assessment of feasibility should be made as part of the review. Others felt that it remained SKB's responsibility to assume the risk of proceeding if there were issues concerning feasibility that had not been resolved or demonstrated. It was noted that SSM could appear foolish if it transpired that the repository could not be built as specified and licensed, but it was also noted that there would inevitably be uncertainties that could not be resolved at this stage. There was general agreement that licence conditions would be an appropriate means of maintaining regulatory control over these and other aspects of SKB's forward programme.

The question of feasibility is related to the assessment of BAT, and whether the techniques proposed by SKB are the best available. SSM has provided guidance on the application and reporting of BAT, but the regulatory review is not straightforward and will by necessity contain subjective elements. It was suggested that this would be an area where SSM could usefully develop internal guidance for its review prior to the receipt of the licence application.

The role of licence conditions

The ability to establish licence conditions was regarded as an important outcome of the review. Licence conditions could allow SSM to require particular approaches and the provision of additional information and thereby influence SKB's forward programme. Licence conditions might also be used in relation to inspection during construction and operation.

It was noted that SSM has experience of licensing facilities, including SFR and CLAB as well as nuclear reactors. There may be lessons that could be learnt from these in the way in which licence conditions are applied and monitored.

Licence conditions will provide a means of regulatory control during later stages of the licensing process. It was noted that some of the issues that will be the subject of licence conditions will be topics where SSM considers there to be potential risks to the project. For example, the feasibility of canister emplacement and meeting the assumed initial conditions is an area where SKB may have to proceed with a significant level of uncertainty and where SSM could use licence conditions to monitor and control further stages of the licensing process. Although SSM would need some confidence in the feasibility before letting SKB proceed, it is important that the recommendations to Government made as a result of the review make these areas of risk clear.

Appendix 1 List of participants and affiliations

Invited speakers

Budhi Sagar (CNWRA, United States)
Jude McMurry (CNWRA, United States)
Hundal “Andy” Jung (CNWRA, United States)
Roger Wilmot (Galson Sciences Ltd, United Kingdom)
Daniel Galson (Galson Sciences Ltd, United Kingdom)
Joel Geier (Clearwater Hardrock Consulting, United States)
Yvonne Tsang (Visiting Professor at Uppsala University, Sweden)
Ryk Klos (Alexandra Sciences, United Kingdom)
Claudio Pescatore (OECD/NEA, France)
Jussi Heinonen (STUK, Finland)
Neil Chapman (Chapman & Co Consulting, Switzerland)
Mick Apted (Intera, United States)

SSM staff

Johan Anderberg (Head of the department of Radioactive Materials)
Josefin Päiviö Jonsson (Head of unit for Disposal of Radioactive Waste)
Björn Dverstorp
Carina Wetzel
Karin Olofsson
Shulan Xu
Bo Strömberg
Jinsong Liu
Jan Linder
Georg Lindgren
Ernesto Fumero
Mikael Jensen
Anders Wiebert
Bengt Hedberg
Eva Simic
Pål Andersson
Maria Nordén

Appendix 2 Workshop programme

Day	Session	Time	Preliminary titles/activity	Speaker
30 Nov.	**Licensing review**	9:00	Welcome	Johan Anderberg
		9:10	Preparing for a Swedish licensing review	Björn Dverstorp
		9:30	Planning for and conducting a licensing review: Safety assessment aspects	Budhi Sagar
		10:15	*Coffee*	
		10:35	Planning for and conducting a licensing review: Natural barriers systems	Jude McMurry
		11:15	Planning for and conducting a licensing review: Engineered barriers systems	Hundal “Andy” Jung
		11:55	Reviewing alternate conceptual models for the geosphere	Joel Geier
		12:30	*Lunch*	
		13:30	Lessons learned from regulatory review of BNFL’s 2002 post-closure safety case for the LLWR near Drigg	Daniel Galson
		14:10	Checklist for review of scientific arguments	Yvonne Tsang
		14:40	*Coffee*	
		15:00	Approaches to Issue Resolution within the Context of Regulatory Reviews: Experience from the US Process	Mick Apted
	Working groups	15:30	Introduction to working groups	Björn Dverstorp
		15:40	Working groups	all
		17:30	*End*	
		19:00	*Dinner*	
1 Dec.	**Report from working groups**	08:30	Presentation by WG1	WG rapporteur
		8:55	Presentation by WG2	WG rapporteur
		9:20	Presentation by WG3	WG rapporteur
		9:45	Discussion	all
		10:00	*Coffee*	

	Safety assessment issues	10:20	Addressing the very-long term hazard potential of spent fuel in the regulatory review process	Neil Chapman
		11:00	Very long time scales in safety assessment	Claudio Pescatore
		11:40	Role of the biosphere – a measure of protection	Ryk Klos
		12:10	*Lunch*	
		13:10	Regulatory review of Onkalo: Integration of long-term safety requirements and construction practise	Jussi Heinonen
		13:50	Future human actions: their role in a safety case	Roger Wilmot
		14:30	*Coffee*	
	Summing-up	14:50	Plenary discussion	all
		16:00	*End of workshop*	

Appendix 3 Presentation summaries

Planning for and Conducting a Licensing Review: Safety Assessment Aspects

Budhi Sagar, USNRC

Introduction: The planning for the review of the license application started in 1987 when Yucca Mountain was selected as the only site for detailed characterization by an act of the U.S. Congress. The U.S. Nuclear Regulatory Commission (USNRC) has interacted with the USDOE on high level nuclear waste disposal as stipulated in the Nuclear Waste Policy Act of 1987 as amended. As a part of this interaction, the USNRC reviewed USDOE's site recommendation that was submitted to the Congress in 2002. The US NRC also commented on the draft environmental impact statement (EIS). When the license application was submitted by USDOE accompanied with the final EIS, the USNRC reviewed it with the objective of adopting it but found that parts of it would need updating.

Preparations for Licensing Review: In preparing for the licensing review, the NRC developed the regulations at 10 CFR Part 63 that are applicable to Yucca Mountain. In addition, it also developed a Yucca Mountain Review Plan (YMRP) that contained guidance on how a review will be conducted. Specifically, the YMRP indicated for each section of the regulation, the appropriate review method and acceptance criteria. Both the regulation and the YMRP were subjected to public review to get a buy-in from stakeholders. During the pre-licensing period starting in 1987 and culminating in 2008, NRC engaged USDOE in technical exchanges to discuss substantive technical matters and management meetings to discuss organizational/management issues. All pre-licensing meetings were open to the public. In addition, the USNRC conducted independent studies including laboratory research, model development, post-closure performance assessments, and pre-closure safety assessments. This work led to developing risk insights which were then used to conduct a risk-informed licensing review.

Licensing Review: The licensing review was conducted in two steps: (i) acceptance review in first 90 days after LA was received, and (ii) detailed technical review. In the first step, the application was found to be adequate and it was docketed for detailed review. Review teams consisting of The NRC and the CNWRA staff were created to conduct the review and develop each of the 50 chapters of the 5 volume Safety Evaluation Report (SER) using SharePoint that helped in sharing files and in configuration management. Draft SER text was developed with clearly marked gaps that required request for additional information to be sent to the USDOE. The challenge was to keep teams focused on risk significant issues and to have them write the SER text in a succinct manner. Even then the post-closure volume has about 700 pages.

Safety Assessment Portion of Licensing Review: Review of operational safety and post-closure performance consumed a large part of resources. Based on pre-licensing work, review teams had good idea where to focus. In the post-closure period, data support of abstracted models, screening out of FEPs, and handling of uncertainties were the main issues. In operational safety, screening out of event sequences, reliability of passive systems, level of design details became the focus.

Planning for and Conducting a Licensing Review: Natural Barrier System

Jude McMurry, USNRC

Introduction: In its license application, the U.S. Department of Energy (USDOE) proposed to construct a high-level radioactive waste repository at Yucca Mountain, Nevada, several hundred meters above the water table, in a thick sequence of unsaturated volcanic tuffs. The U.S. regulations for licensing a repository at Yucca Mountain (10 CFR Part 63) specify an annual dose limit to a reasonably maximally exposed individual of 0.15 mSv (15 mrem) over a compliance period of 10,000 years, and no greater than 1.0 mSv (100 mrem) beyond 10,000 years but within the period of geologic stability. USDOE's probabilistic performance assessment included a nominal scenario; disruptive events such as seismic activity, igneous intrusion, and volcanic eruption; and unexpected initial defects in engineered barriers.

Description of Natural Barriers: The regulations specify that the repository must have natural barriers as well as an engineered barrier system, and the barrier systems must work in combination to limit radiological exposures and radionuclide releases to the accessible environment. USDOE described an upper natural barrier system, located above the repository, and a lower natural barrier system, below the repository. An important upper natural barrier function is to limit the amount of water entering the repository, which in turn limits corrosion of engineered barriers and transport of radionuclides. The main function of the lower natural barrier, which includes the unsaturated zone below the repository and the groundwater flow paths below the water table, is to delay and attenuate radionuclide transport.

Review strategy: The postclosure review of the license application was assigned to teams of subject experts who examined the adequacy of USDOE's individual model abstractions; features, events, and processes (FEPs); multiple barriers; and performance assessment compliance with specified dose limits. Many individuals served on more than one review team, which promoted consistency and integration of the review. Each team worked with a technical coordinator familiar with multiple topics (e.g., water movement throughout the natural barriers) and a senior advisor who provided regulatory guidance. The reviews focused on development of a conceptual model, support for process-level models and their integration in the performance assessment, and data and uncertainty distributions for the models. Risk-important issues in the natural barriers system included seepage into repository tunnels; groundwater flow in fractured, unsaturated rocks; radionuclide sorption in rock matrix and alluvial sediments; colloid-associated transport of radionuclides; and the transition from fractured volcanic rock to alluvium in the saturated zone flow path. To help technical experts transition to new roles reviewing a license application, the U.S. Nuclear Regulatory Commission adapted a staff training course about how to conduct a risk-informed, performance-based regulatory review. Two factors that facilitated the model abstraction review were additional information requested from USDOE during the review period and risk insights obtained by integrating the multiple barriers analysis with single-realization results of performance assessment calculations to identify more clearly the link between particular natural system barriers and the effectiveness of particular processes in the applicant's model abstractions.

Planning for and Conducting a Licensing Review: Engineered Barrier System

Hundal "Andy" Jung, USNRC

Introduction: Functions of an engineered barrier system (EBS) in a repository at Yucca Mountain, Nevada are to prevent or significantly reduce the amount of water contacting nuclear wastes and control the radionuclide release rates from the wastes to the natural barrier. The EBS consists of emplacement drift (tunnel), titanium drip shield, Alloy 22 waste package outer barrier with stainless steel inner shell, waste package internals, waste forms, pallet, and invert (floor-level backfill). The drip shield and the waste package outer barrier are key components in preventing water from contacting wastes and mobilizing radionuclides. Applicable regulations at 10 CFR Part 63 do not specify quantitative performance criteria for EBS or EBS components except that the regulations require the system to be made up of multiple barriers which must contain at least one engineered and one natural barrier. The U.S. Nuclear Regulatory Commission (USNRC) and the Center for Nuclear Waste Regulatory Analyses (CNWRA) evaluated the EBS data and models used by the US Department of Energy (USDOE) in demonstrating safety of the overall repository system.

Technical areas and risk-significant issues in EBS: Technical areas reviewed in EBS included: (i) chemical degradation and mechanical disruption of engineered barriers, (ii) quantity and chemistry of water contacting engineered barriers and waste forms, and (iii) radionuclide release rates and solubility. Risk-significant issues for each area were identified and more extensively evaluated by focusing on the following aspects: adequacy of system description and model integration, sufficiency of data for model justification, characterization of data and model uncertainty and its inclusion in performance assessment, and supportability of model abstraction output. Inclusion or exclusion of features, events, and processes (FEPs) provided by USDOE that could significantly affect magnitude and timing of radionuclides release or dose were also reviewed. Additional necessary information to complete the evaluation report was requested from USDOE and the review was completed by evaluating the responses. An example of a request for additional information (RAI) will be included in the presentation.

Licensing Experience: The main challenges in reviewing long-term performance of EBS stemmed from a first time application of a risk-informed and performance-based approach derived from a solid understanding of multiple, complex repository subsystems. Other challenges included proper integration among review groups, tight schedules, and the need to write clearly and concisely. To be effective in reviewing license application in a timely manner, efforts were focused on initial intensive regulatory training, frequent consensus meetings among the technical groups, re-familiarization with model abstractions and supporting data for RAI development, simplified confirmatory analyses to check intermediate outputs from the process-level models, following guidelines on writing style and format , and overall good team work.

Review of Alternative Conceptual Models for the Geosphere

Joel Geier, Clearwater Hardrock Consulting

One foreseeable difficulty for license application review could arise if understanding of the site is strongly dependent on a single interpretative model, developed by the proponent. For a regulatory agency, a key question is whether plausible *alternative conceptual models* could lead to significantly different conclusions regarding safety.

An alternative model is a fully plausible alternative to the primary model, which is developed from an independent conceptual approach and ideally is calibrated for consistency with the available data. This differs from *model versions*, which are developed by successive refinement of the primary model. This also differs from *model variants* which are developed by variations of particular properties with respect to a base case of the primary model, often without calibration.

During site characterization for the candidate site at Forsmark, SSM's site investigation review teams identified multiple areas in which plausible alternatives to SKB's primary models might be of consequence for safety assessment. Some examples of alternative conceptual models for geosphere components will be presented to illustrate this issue, including models of (1) geometric configuration of large-scale deformation zones, (2) hydrologic connections within and among these deformation zones, and (3) relationship of smaller-scale fractures to deformation zones.

Three main situations can arise when reviewing alternative conceptual models for a given geosphere component:

1. Alternative models are not presented by the proponent;
2. Partially developed alternative models are presented; or
3. Fully developed alternative models are presented.

Case 1 requires an expert appraisal of whether plausible alternatives exist that could significantly affect the safety case. However, even in the other two cases, such an appraisal is desirable. Scoping calculations or independent modeling might be necessary for the reviewing agency to decide if the proponent should be required to address additional alternatives.

Case 2 arises when some alternatives are not developed to the same level as the primary model. The reviewing agency then needs to decide if the degree of development is adequate in relation to the importance for the safety case, or whether a request for additional information is warranted. Expert judgment and/or independent scoping calculations might be needed to justify such a request.

Case 3 is the most straightforward, as the same review procedures can be applied to the alternative models as for the primary model. However, reviewing multiple models requires additional resources, and where resources are limited, a system for prioritizing among alternatives.

A strategy for reviewing alternative conceptual models thus entails answering the following checklist of questions in the first stage of the license application review:

- Are there additional plausible alternatives that could affect the safety case?
- Have the alternatives been developed adequately to judge their importance for safety?
- Among the developed alternatives, which are most likely to impact the safety case?

In some cases, expert elicitation and/or scoping calculations may be needed to justify the answers and whether a request for additional information is motivated. Finally, the answers to the last question can help to guide allocation of resources for full review and, in some cases, independent modeling to check the alternative models.

Lessons from Regulatory Review of BNFL's 2002 Safety Case for the Low Level Waste Repository near Drigg

Dr. Daniel A. Galson, Galson Sciences Ltd

BNFL produced a safety case for the UK national LLW disposal facility near Drigg in September 2002. Galson Sciences Ltd co-ordinated a review of the safety case on behalf of the Environment Agency. Objectives of the review were to assess the safety case against UK regulatory guidance – the environmental regulators' Guidance on Requirements for Authorisation, and to make recommendations on authorisation of the facility. The presentation will summarise lessons learned from the review process that could assist SSM's preparation for review of SKB's SR-Site safety assessment documentation. Lessons for consideration by SSM concerning the regulatory review process are classified by whether they require consideration ahead of receiving documents from SKB, soon after receiving documents, or during the review process. Key issues for SSM include:

Before receipt of documents

- Indicate clearly how regulatory requirements apply to the facility – ambiguity in interpretation of national regulation and international guidance should be avoided – the applicant should understand regulatory expectations.
- Communicate the objectives and scope of a regulatory review at the outset, to ensure that developer submissions are well focused on regulatory needs.
- Understand how the findings of the assessment may be used to make decisions.
- Define the 'rules' governing communication and information exchange with the developer and with other stakeholders ahead of the review process commencing.
- Prepare review guidance to ensure comments are structured to address regulatory requirements, and are provided in a format that assists the regulatory process.

Soon after receipt of documents

- Consider a determination of safety case 'completeness' to ensure that the safety case submissions address required regulatory elements and provide sufficient information to enable full technical evaluation.
- Use risk-informed (as opposed to risk-based) approaches when deciding on issue significance and allocating review resources, and consider the use of regulatory assessment calculations to help identify key uncertainties.

As part of the review process

- Build confidence in the quality of regulatory judgements using formal review methods, a wide range of experts with independence from the developer, audits, and clear communication of findings using a variety of means and to a range of audiences.
- Use formal methods for recording review findings and evolving positions, to retain the long-term 'corporate memory' of dialogue with the developer and with others.

Checklist for Review of Scientific Arguments

Yvonne Tsang

The SSM regulations and guidelines that are applicable for the licensing review are general and high level. In the review of the scientific analysis within the safety assessment, it is helpful to have checklist questions developed to cast the high level, general, applicable regulations into more concrete and accessible language. These may be utilized by a reviewer to measure the license application against, in order to determine the credibility and validity of the safety case. As the license application SRSite will not be available until March 2011, development of checklist questions will be based on SKB's previous safety report SR-Can (SKB TR-06-09).

Central to a safety case for deep geological disposal of radioactive waste is the concepts of confidence and confidence building. Some elements that contribute to confidence in the assessment results are: (1) demonstration of detailed system understanding; (2) inclusion of "what if" scenarios to address situations or events which lie outside the range possibilities reasonably expected to occur according to the available scientific understanding; (3) traceability and transparency in documentation and document structure; and (4) treatment of uncertainties. The last item is of particular importance because a convincing case must be made to impart confidence in the safety assessment results, in the face of the inherent and inevitable uncertainties associated with a complex system such as a geological repository, and its evolution over such a long timeframe.

In this presentation one shall first look at the "proper/correct" way (as practiced within the risk analysis, applied statistics disciplines) of analyzing uncertainties. This includes the steps of identifying uncertainties, quantifying uncertainties, propagating uncertainties, and the state of the art uncertainty and sensitivity analysis approach. With this background, one can consider SKB's treatment of uncertainty in SR-Can. SKB's stated approach of uncertainty management in SR-Can identifies uncertainties; however, lacking in the approach is the tracking of uncertainties to the final dose results. If one is to have confidence in the safety assessment dose results, one must be convinced that the relevant uncertainties were properly analyzed and have been factored in. Since SR-CAN's approach does not convey a unified strategy for uncertainty propagation, it falls on the reviewer to ask questions in order to gain a sense of how reliable the final results of risk calculations are. Along the line of uncertainty propagation, checklist questions for scientific arguments have been developed in the areas of data, models, repository evolution, and radionuclide transport and consequence analysis. Checklist questions also pertain to elements listed above, other than uncertainty analysis, which contribute to confidence building.

Approaches to Issue Resolution within the Context of Regulatory Reviews: Experience from the US Process

Michael Apted, Intera, Inc., Denver, Colorado USA

The US Nuclear Regulatory Commission (USNRC) has been conducting independent safety evaluation (documented in a Safety Evaluation Report, SER) of the US Department of Energy's Safety Analysis Report (SAR) contained in the license application from the US Department of Energy for a high level waste repository at Yucca Mountain, Nevada. The first volume of the SER (General Information - NUREG-1949) has been published, and the third volume of the SER (Repository Safety After Permanent Closure) is nearing completion with possible publication in 2010.

NUREG-1949 states, "On the basis of its review and **specified DOE commitments**, the NRC staff concludes in this volume that DOE has **provided information that satisfies the requirements** of…the NRC's regulations. [**emphasis added**]" Perhaps the most important and relevant precedent with respect to SSM's own future licensing review is USNRC's approach to evaluation of the license application given the information that is reasonably available at this time. The approach has been to evaluate the information provided by the applicant, including the applicant's commitments for providing additional details that will be available later in the process. Additionally, the applicant will be collecting information throughout the lifetime of the operational phase of the repository through activities such as monitoring programs and the performance confirmation program. "**Performance confirmation**" is defined as a program for providing subsequent data to confirm that actual subsurface conditions encountered and changes in those conditions during construction and waste emplacement operations are within the limits assumed in the licensing review, and that natural and engineered systems and components required for repository operation function as intended and anticipated. Explicit commitments by the implementer in the license application on its plans for providing further information over the operational phase of the repository program progresses is an important factor in the regulators evaluation of the acceptability of the implementers license application, especially at early stages of repository development. However, it must be noted that the regulatory confidence on whether the implementer has complied with the regulatory requirements on any given issue may require more than commitments by the implementer. The regulator also uses license conditions to provide additional requirements that an implementer must meet as part of its licensed activities.

The second aspect of USNRC's regulatory review is application of a risk-informed approach in addressing issues. Stated succinctly, in a risk informed, performance-based approach "…risk insights, engineering analysis and judgment (e.g., defense in depth), and performance history are used to (1) focus attention on the most important activities, (2) establish objective criteria for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, (4) provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes, and (5) focus on the results as the primary basis for regulatory decision-making." (10 CFR Part 63, page

8643, Federal Registrar, Vol. 64, No. 34, February 22, 1999). Not all issues have significant impact on long-term safety, and sensitivity and prioritization of issues can be achieved by conducting system-level, risk-informed analyses. Examples of how different US stakeholders have applied risk-informed analysis on issues of relevance to repository safety are presented and reviewed.

Spent Nuclear Fuel – Time, Hazard Potential and Protection: Some Perspectives on Regulating Longer Term Hazard

Neil Chapman, Chapman & Co. Consulting, Switzerland

The objective of this presentation is to look at the hazard potential of geologically disposed spent nuclear fuel from a number of perspectives and, in particular, to consider the very long-term hazards beyond the period in which fully quantitative safety evaluations of disposal facilities are normally required.

I begin by defining 'hazard potential' qualitatively and look at two aspects: 'uptake hazard potential' and 'external hazard potential'. These will be used in the presentation as key indicators for the long-term.

At the outset, it is useful to go back to the ethical basis of certain safety principles (and thus standards) for disposal and see what these can tell us about long-term protection objectives. In particular, it is informative to look at the consistency of ethically based principles when we consider what we are trying to achieve with geological disposal at very long times into the future.

The presentation next looks at the quantitative hazard potential of SNF, considering first the isolation and containment measures taken to provide protection from uptake hazard potential. This is perhaps the most straightforward aspect of hazard potential to address. A key point here is confidence in ensuring high levels of protection during the first few thousand years when the spent fuel has the highest hazard potential.

Next, I look at the external hazard potential at distant times in the future. External hazard potential can only be realised by exposure, if the spent fuel is exhumed – either naturally, or by people. In tectonically stable regions, natural exhumation scenarios involve a combination of uplift and erosion. A close analogy is drawn with exposures from eroding uranium ore bodies at Earth's surface to help consider actual hazards and exposures.

How likely is exposure to external hazard potential from natural processes? I look briefly at different uplift and erosion mechanisms and rates of exhumation to draw the conclusion that, in Sweden, as in many countries, the likelihood is extremely low over a timescale of at least several millions of years.

Finally, I consider what level of very long-term protection is reasonable to strive for, based upon societal expectations for future generations and consider specifically how we might be expected to make best use of our resources by equating hazard potential to cost. The aim of the closing discussion is to help focus on if/when/how a regulator can accept that geological disposal can be considered to have 'done its job'.

Spent Fuel: A Management Issue With No Time Cut-off

Claudio Pescatore, OECD/NEA

Even if, after approximately 100,000 years, the radioactivity of spent fuel has decayed to a level similar to that which may be found in natural uranium minerals, it is still essential to consider the radiological risk that may be accrue to humans and the natural environment.

- High-grade uranium deposits are not benign. Because of the potential for radiation exposure both externally and internally, high-grade require remote mining.
- In a similar vein, even if the radioactivity of SF decreases significantly, it stabilizes at such levels and with certain characteristics that still maintain SF in the category of (at least) Intermediate Level Waste.

Additionally,

- Spent fuel contains stable elements that are chemo-toxic.
- Included in spent fuel are some radioactive materials such as U-238, which, per se, are more chemically-toxic than radiotoxic.

For the above reasons, spent fuel requires, in principle, continued confinement and isolation without time cut-offs.

The paper reviews the specificity of the evolution of spent fuel toxicity over time. It observes that much of the attention in discussions of long-term safety has focused on ingestion hazards over time scales of up to a million years and suggests that it would be worthwhile to take longer time scales into account as well as the potential for external exposures and for chemical impacts. In particular, in a very-long term contain-and-confine approach to protection, erosion and uplift are important exposure scenarios that may give rise to radiological exposures both externally and internally. They may also cause exposure to chemo-toxic substances.

The practically indefinite time-scales that are evoked for protection pose challenges of several kinds, both to the implementer, the regulator, and to the policy maker.

The Biosphere in Safety Assessment ~ A Measure of Protection

Ryk Kłos, Aleksandria Sciences

The role of the biosphere component of safety assessment is to provide a measure of protection on the human scale. It sets any release of radionuclides to the biosphere in the context of potential health risks to individuals who might be exposed to environmental radiation arising from the disposal of radioactive material.

The public has little feeling for the risks posed by waste disposal and are notoriously risk averse when considering radiation and radioactivity. The regulatory authorities define the acceptable safety standard: a risk of death of one in a million per year. The biosphere is used to convert a release (becquerel per year) from the repository, through the geosphere and into the biosphere, into first a radiation dose (millisievert per year) and thence to risk, using the ICRP's risk conversion factor of 7.3% per Sv (roughly equivalent to 15 µSv a^{-1}, compared to a public exposure from all sources of 3 to 4 mSv a^{-1}).

The safety case deals with containment: in the engineered barriers and, to a lesser extent, in the geosphere return paths through which contaminants might return to the biosphere. Containment and isolation reduce the quantity of radioactivity reaching the biosphere but cannot prevent all release. The nature of the delay is important to the estimation of future risks because the future system may not look like the present-day. Biosphere models cannot simulate reality as repository and geosphere models can.

One way of employing the biosphere has been to use a dose conversion factor (DCF) to scale the release to dose, since this is simple and robust. However, the more known about a site (cf SKB's site descriptive modelling) the more assessment specific the details of the biosphere model become. A simple DCF may not be appropriate.

Recognising that the aim is to evaluate risk/dose, there is a chain of underlying quantities that need to be represented: the exposure (intake/duration), radionuclide concentration in foodstuffs; concentration in the flora and fauna constituting the food web; and the concentration in environmental media, ultimately based on the input to the biosphere from the geosphere, across the geosphere-biosphere interface.

There are two model domains one describes transport and accumulation in the near surface environment (including the mixing of ground- and meteoric waters) and the other is the description of the lifestyle and habits of potentially exposed individuals. There is regulatory guidance on how exposed groups can be identified. This tends to be rather nation specific.

While a description of the system based on the "view from the window" is relatively straightforward the long timescales are a major complicating factor. Failure of containment may not occur until far into the future, potentially after several glaciations. The approach adopted by SKB is to describe the future of the system based on the history over a full glacial cycle. In Sweden a major programme-specific feature is isostatic land rise following deglaciation leading to rapid evolution of the surface system. Such details are used to determine a credible narrative. For example, a typical lake ecosystem might be expected to last for a few thousand years before transition to wetland. Human conversion of wetlands to agricultural land can take place over only a few years.

Differences of emphasis can give rise to conceptual uncertainties. SKB tend favour a more holistic description of the landscape. From a regulatory perspective a simpler, more cautious approach might be more useful. Documentation of the underlying modelling assumptions is of prime importance and for this reason an approach of *progressive realism* is advocated starting from strict and conservative assumptions which are systematically relaxed to evaluate the impact until a reasonably realistic estimate of risk is reached.

Regulatory Review of Onkalo: Construction Issues of Importance for Long-Term Safety

Jussi Heinonen, STUK

Licensing system

The Finnish disposal facility licensing has several steps that are similar to all nuclear facilities in Finland and are defined in Nuclear Energy Act (990/1987) and Degree (161/1988). These licensing steps are:

1. Decision in Principle is required for a nuclear facility having considerable general significance. This is essentially a political decision: the government decides if the construction project is in line with the overall good of society. The decision can applied for one or more sites, the host municipality has a, veto right and the parliament has the choice of ratifying or not ratifying the decision.
2. Construction License is granted by the Government and gives license to construct the facility. The actual construction is regulated by STUK and includes several review and approval steps, holdpoints and viewpoints.
3. Operational License is given by the Government and gives license to operate the facility for certain period. Operation license is needed before nuclear waste can be disposed.

During each licensing step STUK role is to review application documentation and give statement to Ministry of Employment and Economy (MEE) about the safety of the facility. In construction and operational license step the applicant is required to submit facility safety case for STUK's review. In construction license step STUK reviews and approves the following documents (similar "final" documentation is submitted with operational license application):

- the preliminary safety analysis report, which shall include the general design and safety principles of the nuclear facility, a detailed description of the site and the nuclear facility, a description of the operation of the facility, a description of the behavior of the facility during accidents, a detailed description of the effects that the operation of the facility has on the environment, and any other information considered necessary by the authorities;
- a probabilistic risk assessment of the design stage;
- a proposal for a classification document, which shows the classification of structures, systems and components important to the safety of the nuclear facility on the basis of their significance with respect to safety;
- a description of quality management during the construction of the nuclear facility, showing the systematic measures applied by the organizations that take part in the design and construction of the nuclear facility in their operations affecting quality;
- preliminary plans for the arrangements for security and emergencies;

- a plan for arranging the safeguards control that is necessary to prevent the proliferation of nuclear weapons; and

Disposal facility license applicant is also required to submit long-term safety case which in Posiva's case consists of document portfolio (Figure 1).

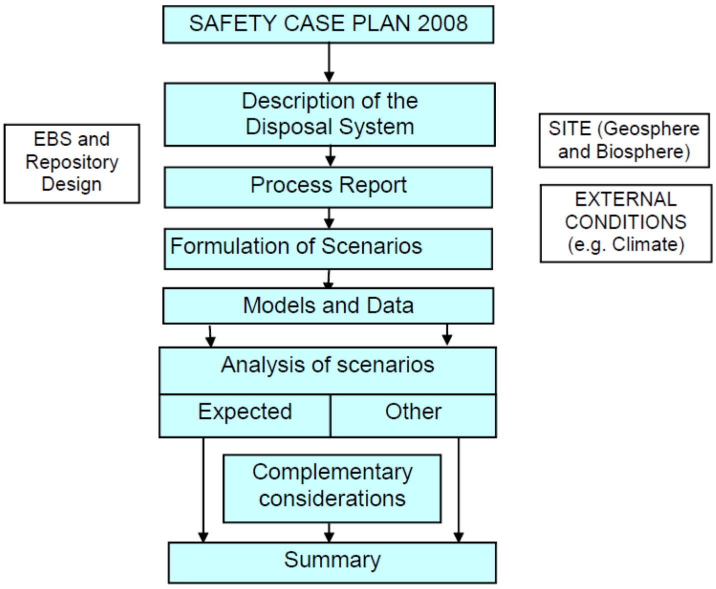

Figure 1. Posiva's main reports of the new safety case portfolio (in blue) and the main input from supporting technical and scientific activities (in white) (Posiva TKS-2009, Figure 6-3).

Onkalo

Posiva Oy has been constructing Underground rock characterization facility (URCF) in Olkiluoto island since 2004 and during year 2010 excavation reached the disposal depth (-420 m). Posiva plans that Onkalo will be a part of the disposal facility (Figure 2).

The Finnish regulation requires that the bedrock in disposal site shall be characterized from disposal depth before submitting the construction license application. This requirement is further developed in STUK guide YVL 8.4 which defines that characterization involves construction of research or characterization facility to the site. Onkalo URCF has been constructed prior to construction license based on Governments decision given in Decision in Principle. STUK has regulatory oversight on Onkalo construction like it would be an access ramp to nuclear facility. The Olkiluoto DiP, de facto, contains a limited pre-license for starting the facility construction.

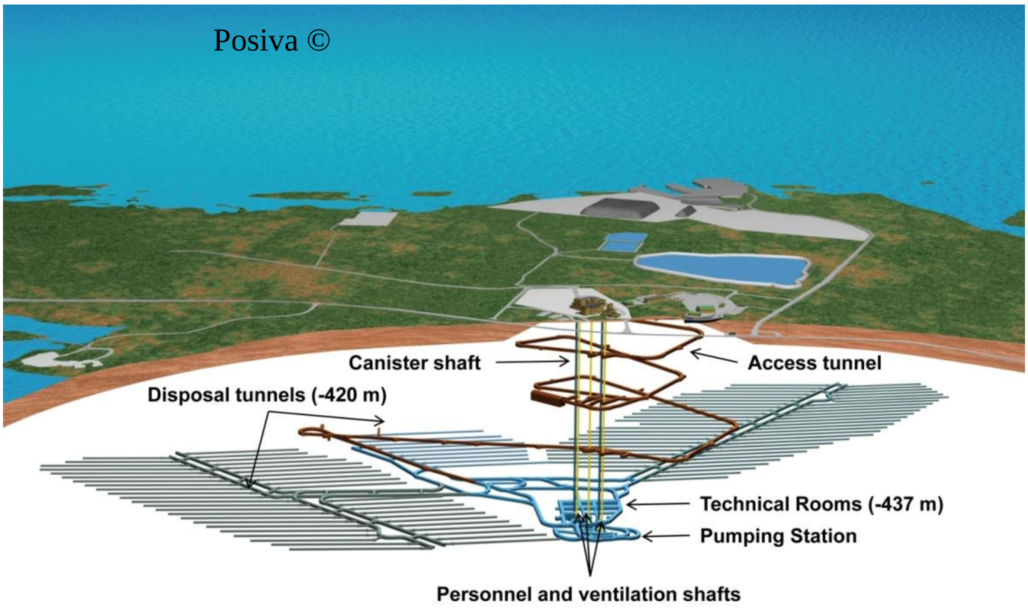

Figure 2. Posiva design for disposal facility. Onkalo URCF consist of access ramp, three safts and central auxiliary rooms.

Long-term safety constrains and construction

The Finnish regulatory framework has requirements that set the basic approach to bringing long-term safety requirements to facility design and construction practices.

- License applicant shall describe safety functions and performance targets for disposal system barriers. In case of bedrock these include isolation of waste and engineered barrier system from surface and retardation of radionuclides after canister has breached.
- License applicant shall developed rock classification system that will be used to classify for example rock structures and ground water conditions that can have an impact to long-term safety. Posiva is developing Rock Suitability Criteria (RSC) that takes into account requirements arising from long-term safety and which needs to be implemented when making decisions of rock suitability prior to excavation.
- The construction of disposal facility construction shall aim at maintaining favorable rock characteristics important to long-term safety as well as possible.
- Impacts of construction shall be measured with monitoring program that includes for example characterization and surveillance of changes in stress field, seismic activity, brittle deformation, hydrogeology and hydrogeochemistry.

In case of underground disposal facility operational and long-term safety sets requirements or constrains to constructions that differ from conventional construction. These requirements are related to characterization of rock prior to excavation, constrains on excavation work methods and monitoring of the excavation effect. In construction of underground nuclear facility the design needs to take into account long-term safety constrains, nuclear facility requirements (radiation, nuclear safety, etc), rock properties, rock construction standards and available construction methods. These requirements and constrains form so called safety envelope which defines borders for safe construction. The design of facility, selection of suitable tunnel locations and rock excavation practices has to be adapted to meet the safety envelope. This in taken to practice by developing decision methods for selecting tunnel locations (RSC), in design specifications and excavation plans and drawings and working procedures (Figure 3).

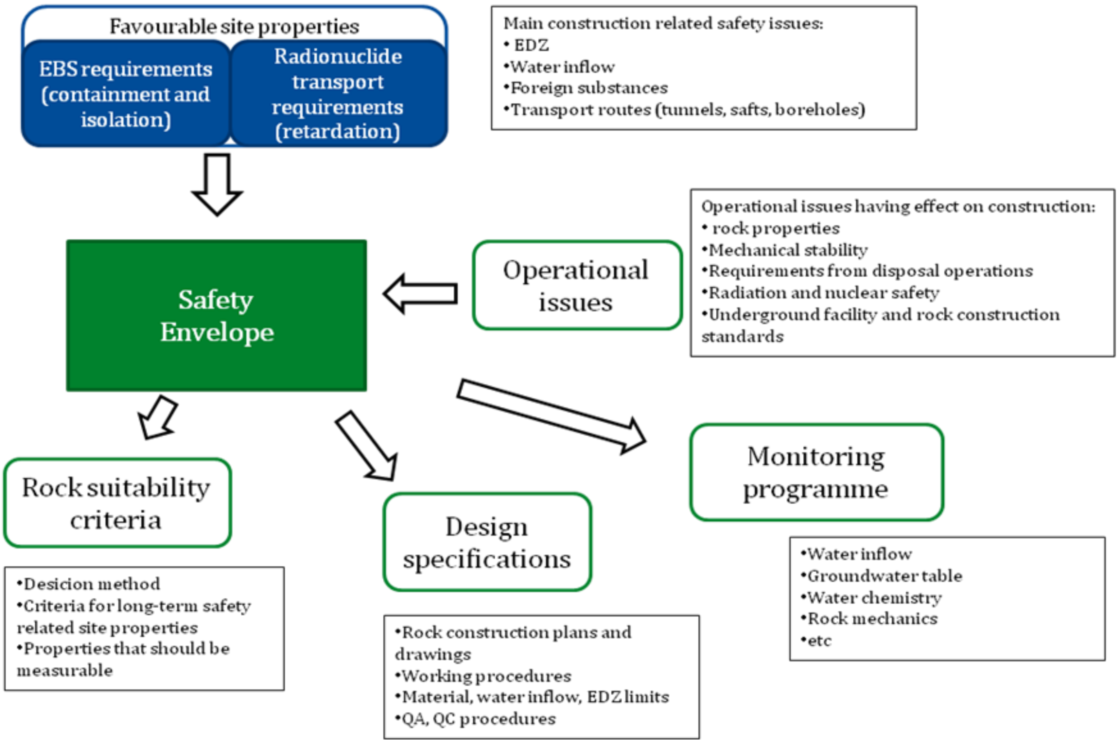

Figure 3. Illustration of bringing long-term safety requirements to actual rock construction practices.

Future human actions: their role in a safety case

Roger Wilmot, Galson Sciences Ltd

During the operational phase of a disposal facility, and for a period after closure, human activities in the vicinity of the site will be controlled and / or monitored to ensure that there are no adverse effects on disposal system performance. It cannot be assumed, however, that the period of control will last indefinitely and so there is a potential for future human actions to have an effect on disposal system performance. Future human actions must therefore be considered in any safety case.

The development of a safety case must be based on the applicable regulations and guidance and also on the particular concept, design and site being proposed. Differences in disposal concept and geological setting may therefore lead to different safety strategies and assessment approaches between different programmes. However, although there are differences in the surface environment and present-day human activities between sites, the approaches used to consider future human actions are generally similar between different programmes. This is in part because of international guidance on the assessment of future human actions and in part because the approach is generally stylised rather than realistic.

The presentation will summarise the principal aspects of how future human actions are considered, including reference to international guidance, exceptions where these illustrate key assumptions and the particular requirements of Swedish regulations and guidance.

There are a number of ways in which future human actions can affect disposal system performance and the doses calculated:

- Direct intrusion into the waste would lead to high doses to intruders.
- Intrusion that bypassed a safety barrier or degraded a safety function could affect disposal system performance.
- Future human actions that result in changes to the hydrogeological or geochemical regime or to the surface environment could affect calculated doses.

The uncertainties associated with all types of future human actions are different to those associated with the expected evolution of the disposal system. Whereas it may be possible to characterise uncertainties in the natural system, it is generally recognised that estimates of the probability of particular future human actions can only be conjectural, even with an assumption that technology and society remain as they are at present.

Regulatory criteria and guidance on how future human actions should be treated in a safety case need to acknowledge these differences in uncertainties, and must also recognise that the consequences of direct intrusion may be very high. Criteria for doses arising from intrusion may therefore be set at intervention levels rather than protection levels, and the consequences of direct intrusion may be excluded from regulatory requirements. Guidance should ensure that the safety case describes how the potential for future human actions has been considered in the siting and design of the repository, and what measures have been taken to reduce the probability of intrusion.

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The Swedish Radiation Safety Authority has a comprehensive responsibility to ensure that society is safe from the effects of radiation. The Authority works to achieve radiation safety in a number of areas: nuclear power, medical care as well as commercial products and services. The Authority also works to achieve protection from natural radiation and to increase the level of radiation safety internationally.

The Swedish Radiation Safety Authority works proactively and preventively to protect people and the environment from the harmful effects of radiation, now and in the future. The Authority issues regulations and supervises compliance, while also supporting research, providing training and information, and issuing advice. Often, activities involving radiation require licences issued by the Authority. The Swedish Radiation Safety Authority maintains emergency preparedness around the clock with the aim of limiting the aftermath of radiation accidents and the unintentional spreading of radioactive substances. The Authority participates in international co-operation in order to promote radiation safety and finances projects aiming to raise the level of radiation safety in certain Eastern European countries.

The Authority reports to the Ministry of the Environment and has around 270 employees with competencies in the fields of engineering, natural and behavioural sciences, law, economics and communications. We have received quality, environmental and working environment certification.

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