Radioactive Waste Management
Gestion des déchets radioactifs

Regulatory Reviews of Assessments of Deep Geologic Repositories

Lessons Learnt

Évaluation des dépôts géologiques profonds dans un contexte réglementaire

Enseignements tirés

NUCLEAR ENERGY AGENCY
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
AGENCE POUR L'ÉNERGIE NUCLÉAIRE
ORGANISATION DE COOPÉRATION ET DE DÉVELOPPEMENT ÉCONOMIQUES

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Pursuant to Article 1 of the Convention signed in Paris on 14th December 1960, and which came into force on 30th September 1961, the Organisation for Economic Co-operation and Development (OECD) shall promote policies designed:

- to achieve the highest sustainable economic growth and employment and a rising standard of living in Member countries, while maintaining financial stability, and thus to contribute to the development of the world economy;
- to contribute to sound economic expansion in Member as well as non-member countries in the process of economic development; and
- to contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations.

The original Member countries of the OECD are Austria, Belgium, Canada, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The following countries became Members subsequently through accession at the dates indicated hereafter: Japan (28th April 1964), Finland (28th January 1969), Australia (7th June 1971), New Zealand (29th May 1973), Mexico (18th May 1994), the Czech Republic (21st December 1995), Hungary (7th May 1996), Poland (22nd November 1996) and the Republic of Korea (12th December 1996). The Commission of the European Communities takes part in the work of the OECD (Article 13 of the OECD Convention).

NUCLEAR ENERGY AGENCY

The OECD Nuclear Energy Agency (NEA) was established on 1st February 1958 under the name of the OEEC European Nuclear Energy Agency. It received its present designation on 20th April 1972, when Japan became its first non-European full Member. NEA membership today consists of 27 OECD Member countries: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, Norway, Portugal, Republic of Korea, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The Commission of the European Communities also takes part in the work of the Agency.

The mission of the NEA is:

- *to assist its Member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purposes, as well as*
- *to provide authoritative assessments and to forge common understandings on key issues, as input to government decisions on nuclear energy policy and to broader OECD policy analyses in areas such as energy and sustainable development.*

Specific areas of competence of the NEA include safety and regulation of nuclear activities, radioactive waste management, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information. The NEA Data Bank provides nuclear data and computer program services for participating countries.

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

AVANT-PROPOS

Le Groupe consultatif de l'AEN sur l'évaluation des performances des systèmes d'évacuation des déchets radioactifs (PAAG) a établi en 1994 un Groupe de travail sur les évaluations intégrées des performances des dépôts géologiques profonds (IPAG). La mission générale de l'IPAG est d'offrir un cadre privilégié pour mener des discussions éclairées sur l'évaluation des performances, et de procéder à un examen de l'état d'avancement général des études d'évaluation des performances et des problèmes spécifiques cernés par le Groupe de travail, le PAAG et d'autres groupes de l'AEN. Ces travaux sont exécutés en plusieurs phases, la composition et les tâches du Groupe devant normalement changer d'une phase à une autre.

Au cours de la Phase 1 (IPAG-1), l'objectif a été d'examiner les études d'évaluation des performances exécutée récemment. Il s'agissait d'avoir un ensemble concret d'éléments d'appréciation susceptibles de refléter l'état actuel de l'évaluation des performances et de signaler ce qui peut et devrait être fait lors d'études futures. Les travaux ont été menés essentiellement de juin 1995 à avril 1996 et ont été décrits dans un rapport de l'AEN/OCDE.

Au cours de la Phase 2 (IPAG-2), l'objectif visé était de faire le point sur l'expérience des examens par des pairs des évaluations intégrées des performances et plus particulièrement des examens exécutés à l'appui de l'évaluation réglementaire, du point de vue tant des autorités de sûreté que des exploitants. Les travaux, menés principalement de mai 1997 à octobre 1998, sont décrits dans le présent rapport.

Une nouvelle phase de travaux est en préparation, consacrée aux arguments utilisés pour asseoir la confiance dans les résultats des études d'évaluation intégrée des performances.

REMERCIEMENTS

La Division de la gestion des déchets radioactifs de l'AEN remercie chaleureusement le *Statens Kärnkraftinspektion-SKI* (Service national d'inspection de l'énergie nucléaire de la Suède) et l'*UK Environment Agency* (Agence de l'environnement du Royaume-Uni) pour leur soutien financier.

FOREWORD

The NEA Performance Assessment Advisory Group (PAAG) set up the Working Group on Integrated Performance Assessments of Deep Repositories (IPAG) in 1994. The overall aim of the IPAG is to provide a forum for informed discussion on performance assessment (PA), to examine the overall status of PA studies and specific issues identified by the group, by the PAAG, and by other NEA groups. The work is carried out in several phases where the membership and tasks of the group are expected to change between phases.

In Phase 1, IPAG-1, the goal was to examine recently completed PA studies as a practical body of evidence that would indicate the current status of PA and could shed light on what can and should be done in future studies. The work was carried out mainly between June 1995 and April 1996, and was documented in an OECD/NEA report.

In Phase 2, IPAG-2, the goal was to examine the experience of peer reviews of integrated PAs, and especially reviews performed in support of regulatory assessment, from both the implementer and regulator points of view. The work, carried out mainly between May 1997 and October 1998 is documented in this report.

A further phase of work is in preparation dealing with arguments to support confidence in the results of integrated performance assessment studies.

ACKNOWLEDGEMENTS

The NEA Division of Radioactive Waste Management acknowledges the kind support of the Swedish Nuclear Power Inspectorate and the UK Environment Agency which provided funding for this project.

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EXECUTIVE SUMMARY

The NEA Performance Assessment Advisory Group (PAAG) set up the Working Group on Integrated Performance Assessments of Deep Repositories (IPAG) in 1994. The overall aim of the IPAG is to provide a forum for informed discussion on performance assessment (PA), to examine the overall status of PA studies and specific issues identified by the group and by the PAAG, and by other NEA groups. The work will be carried out in several phases where the membership and tasks of the group are expected to change between phases.

In the first phase, IPAG-1, the goal was to examine recently completed PA studies as a practical body of evidence that would indicate the current status of PA and could shed light on what can and should be done in future studies. Ten organisations participated in this phase, where each submitted their most recent integrated PA study for examination and as a basis for discussion within the group. The work, carried out mainly between June 1995 and April 1996, focused on the production, refinement and answering of a questionnaire on the submitted PAs, and examination and discussion of the answers. The exercise was reported to PAAG and also documented in an OECD/NEA report [NEA 1997].

In the second phase, IPAG-2, the goal was to examine the experience of peer reviews of integrated PAs, and especially reviews performed in support of regulatory assessment, from both the implementer and regulator points of view. Seventeen national organisations have participated in this phase, where each has either carried out or reviewed a recent integrated PA study. The work, carried out mainly between May 1997 and October 1998, was focused by means of a questionnaire on the PAs and review process, and examination and discussion of the answers. The exercise has been reported and discussed within the NEA, and is documented in this report. The main text describes the findings of IPAG-2, and presents some final considerations including comments on the IPAG-2 experience, comparison of the findings of IPAG-1 and IPAG-2, and suggestions for a new phase of IPAG.

Summary observations and recommendations of IPAG-2 are presented below. Where recommendations are made, these are addressed primarily to organisations carrying out or reviewing integrated PAs.

Conduct of review

Dialogue between the implementer and regulator

Dialogue is important and to the benefit of both implementers and regulators at all phases of the PA preparation and review process. IPAG-2 recommends that implementers and regulators discuss approaches for maintaining dialogue that benefit the IPA preparation and regulatory review process and, at the same time, preserve the independence of the regulator and the implementer. Making the written records and documentation from the dialogue available to the public could enhance the public perception and overall credibility of the process.

IPA and reviews within a stepwise process of repository development

A stepwise process is necessary to develop a repository concept and to prepare a convincing case showing long-term safety and compliance with regulatory requirements. This is consistent with the legal and regulatory frameworks since, a safety case, supported by an integrated PA, is required as a basis for decision making at a number of points within the repository development process in most countries. IPAG-2 suggests that the implementer and regulator should establish a structured framework for PAs and reviews early in a repository programme.

Integrating PA and repository safety

There are two broad aspects to making a safety case for a repository. The first is the selection of a site and development of a design that possesses "intrinsic or inherent quality" with respect to safety, e.g. the site displays long-term geological stability and the engineered barriers use materials with well-understood properties. The second is provided by the PA itself, which involves the acquisition of information relevant to the repository site and design, and the development and application of methods and models to assess this information. While the PA provides a vehicle that illustrates why a particular site and design should function so as to provide the required level of safety, it is the quality of the selected site and design that provides that safety.

IPAG-2 observes that a safety case should clearly and convincingly document the factors that give confidence in the intrinsic quality of the selected site and design, as well as the technical demonstration of safety provided by quantitative PA analyses.

Independent assessment or calculations by regulators

IPAG-2 observes that it is the responsibility of the implementer to produce a complete analysis of repository safety, but that independent calculations by the regulator, at various levels of detail, can benefit both the regulator and the review process. Such calculations help the regulator to prepare for a critical review by enhancing their own understanding of the disposal system and its performance, and may also be used to check or extend the scope of analyses presented by the implementer. Thus, the review is more likely to be focused on factors most relevant to safety. Some regulators are of the view that the possession and use of an independent PA capability is important to establish the technical credentials of the regulator to the public and other stakeholders.

Aspects of the safety case

Technical issues and concerns

Although many technical issues are site or design specific, responses to the IPAG-2 questionnaire revealed some concerns that are more generic and are also cited in several reviews of integrated PAs. Important examples are insufficient integration of site investigation and integrated PA programmes and results, the adoption of potentially non-conservative assumptions in modelling, and an insufficient depth of scenario and/or uncertainty analysis. That these complaints were common to several reviews, indicates that PA methods, themselves, may still be improved in these areas.

Multiple lines of reasoning

All IPAG-2 participants consider that multiple lines of reasoning are valuable in building confidence in the results of a PA, although there are different opinions on their importance in developing the overall safety case. Some regard the main technical analysis as the essential central plank of a demonstration of regulatory compliance, with other lines of evidence providing only ancillary support. Others believe that alternative lines of reasoning should take a more central role, especially in view of the need to provide convincing demonstrations of safety to a range of audiences. IPAG-2 observes that few existing integrated PAs have made use of multiple safety indicators, but this may be a fruitful area for continued international work to identify and assess the applications of potential safety indicators.

Variety of assessment techniques

While differences in opinion remain on the relative values of various modelling and calculation techniques and approaches in integrated PAs, IPAG-2 confirms a conclusion of IPAG-1, that there is a role for a variety of techniques and approaches in PA, and that these can be used in a complementary manner. All PAs use a variety of techniques, and practitioners of PA appreciate the relative merits of, for example, probabilistic versus deterministic calculations and conservative versus more realistic assessment models. Some PAs may focus on particular techniques for pragmatic reasons but, in general, the intent has not been to exclude other approaches.

Qualitative and quantitative information

IPAG-2 observes that scientists and engineers sometimes view qualitative, or “soft”, information as of less value than “hard”, quantitative information. Qualitative information is, however, essential in long-term safety assessments, and thus IPAG-2 considers that it would be useful to explore ways to better use qualitative information. Rather than viewing qualitative information as being inferior to quantitative information, they should be considered as different types of information that can be used for different purposes in PA. IPAG-2 suggests that consideration be given both to presenting qualitative arguments and information, and to increasing their value in the decision-making process.

Meaning of the multi-barrier system

The multi-barrier concept is one of the key bases for long-term safety of deep geological disposal systems, and it is considered important to overall confidence building. However, non-technical stakeholders may consider that the realisation of the multi-barrier concept in practical repository systems falls short of their expectations if they start from the reactor, defence-in-depth, premise that barriers can and should be completely redundant and independent. IPAG-2 has given some preliminary consideration to this topic, but suggests that further work is necessary develop a definition for the multi-barrier concept that describes the concept in the context of what is achievable and necessary in a deep geological disposal system.

Stylised and standardised approaches

Stylised approaches are typically used for situations where there is inherent and irreducible uncertainty, to illustrate system performance and to aid communication. Stylised approaches that are accepted internationally can be termed “standardised” approaches. IPAG-1 recommended that PAAG should explore whether there is an interest in co-operation to produce stylised presentations for use in performance assessment. Responses to the IPAG-2 questionnaire indicate that it is not feasible to develop standardised scenarios that would be acceptable in all programmes. However, discussions at the PAAG consistently show that there is continued interest in efforts to develop standardised approaches to help treat aspects and components of the safety case.

Traceability and transparency

Both the IPAG-1 report and this report discuss the challenges and aspects of building traceability into integrated PAs, and making PAs transparent. All IPAG-2 respondents agree that integrated PAs prepared for licensing purposes need to be traceable, reproducible and publicly available.

Achieving the level of traceability and transparency desired by regulators

Regulators and their technical reviewers are the primary audiences for most IPAs. However, many regulators continue to have difficulties tracing the results and logic in PAs, even though implementers have placed increased efforts on building traceability into their PAs. To resolve this problem it is necessary to recognise that both implementers and regulators have a difficult task to do. Certainly, it is easy to acknowledge that implementers face a difficult challenge to produce comprehensive documentation of the complex process of obtaining, processing and synthesising data and models in sufficient detail and clarity. It should also be recognised that the regulator, initially, also faces the difficulty of understanding the structure and formalisms used by the implementer. Thus, at least one aspect of developing traceability, and understanding between the implementer and regulator, is stability of methods and documentation structure and style, and iterative reviews.

Implications on traceability and transparency to other stakeholders

Other, non-technical stakeholders also review integrated PAs, and have different needs with regard to traceability and transparency. These stakeholders generally approach PAs from different viewpoints and make judgements using different value systems. IPAG-2 observes that interactions with these stakeholders are becoming increasingly more important as potential repository sites are selected, and regulatory decisions are made for those sites. IPAG-2 suggests that the NEA should explore in greater detail approaches and techniques for addressing the needs of the public and other non-technical stakeholders in PAs.

Regulatory guidance

Regulatory guidance should clearly state the requirements and expectations for demonstrating compliance with regulatory criteria. This will help define the task to be undertaken by the implementer as well as enhancing the transparency and public credibility of the review process. Regulatory guidance may be developed in a stepwise manner, consistent with the stepwise development of national repository programmes, and should be reviewed at strategic points to ensure its continuing applicability.

International consistency is desirable in regulatory guidance, and organisations such as the IAEA, ICRP and NEA contribute significantly to such harmonisation. The importance of national factors should not be overlooked, however, and it is important that regulatory guidance should reflect the concerns of stakeholders.

Suggestions for a new phase of IPAG

The IPAG could pursue topics that have been recognised as critical areas for developing confidence in integrated PAs. These could all fit under the general heading of:

"Supporting arguments used to build confidence in integrated PAs".

At the fourteenth meeting of PAAG, in October 1998, consensus was reached to set-up an *ad hoc* working group to further develop this general topic in 1999. The new IPAG phase would therefore identify, discuss and document supporting arguments and approaches, and explore how and why they are used.

GENERAL OVERVIEW

1. INTRODUCTION

Implementing and regulatory organisations in many of the OECD Member countries are involved in the investigation and resolution of issues associated with the long-term safety of underground repositories for radioactive waste. Safety must be demonstrated to the satisfaction of the implementing organisations, the regulatory bodies, the wider scientific and technical community, political decision makers and the general public. In particular, convincing arguments are required that instil in these groups confidence in the safety of the proposed repositories, taking into account the uncertainties that inevitably exist in forecasting the behaviour of complex natural and engineered systems for long times into the future.

In recent years it has been increasingly recognised that the development and licensing of repository systems should be undertaken in a stepwise manner. At important milestones, a decision is needed by the regulatory authorities and other decision makers whether to proceed to the next development stage. The decision to proceed with the next stage of repository development involves commitments on the part of the implementing organisation and society at large, and these commitments must be weighed against the uncertainties that exist at that stage. To support that decision an integrated performance assessment (IPA) is normally carried out by the implementing organisation and reviewed by the regulatory authorities.

Several implementing and regulatory organisations are now approaching a period in which they may be called on to make and explain licensing decisions, and the actions of both implementing and regulatory organisations are likely to be subject to detailed public and political scrutiny. The NEA Radioactive Waste Management Committee (RWMC) and its Performance Assessment Advisory Group (PAAG) found it timely to evaluate, within an international context, the experience accumulated so far of peer review – and especially regulatory review – of IPAs. This task was assigned to the Working Group on Integrated Performance Assessments of Deep Repositories (IPAG) that works under the mandate:

- To learn what has been produced.
- To shed light on what can and should be done in the future.
- To report the lessons to the PAAG and other NEA groups.
- To produce information for use in NEA reports.

Phase 1 of IPAG (IPAG-1) produced a report emphasising the lessons learnt from the conduct of ten IPAs [NEA, 1997]. This document reports on the findings of Phase 2 of IPAG (IPAG-2), which focuses on the experience of regulatory review of IPAs. IPAG-2 was carried out between May 1997 and October 1998 under the Chairmanship of D. Metcalfe (AECB, Canada) and proceeded as follows:

- Participation was elicited of regulators and implementers who had experience of reviewing IPAs or producing IPAs that were reviewed.

- Information of the experience of the reviews was collected through the use of a questionnaire distributed to all waste management organisations represented within PAAG. The questionnaire had been previously tested amongst a core group of organisations. The final questionnaire requested information on the approaches to reviewing IPAs, the ways IPA reviews are presented and interpreted, and opinions on future directions and changes needed for regulatory decision making.
- Seventeen organisations responded to the questionnaire addressing the experience of reviewing 10 IPAs, see Table 1. For 7 studies, it was possible to take account of the views of both the regulator and implementer.
- The questionnaire answers were analysed to understand the experiences of both regulators and implementers in the review process. The answers to the questionnaire were rationalised into a document hereafter referred to as "the compilation".
- Commonalties and differences of view were identified and discussed at a plenary meeting of IPAG-2 in May 1998. At the meeting key issues were identified and discussed and a skeleton structure of the present document was produced. Individual IPAG-2 members prepared text for each identified area, and the texts were assembled into a draft report in August 1998. The draft was then distributed to the PAAG and the SEDE (NEA Site Evaluation and Design of Experiments Co-ordinating Group) members for their comments.
- A topical session was held at the fourteenth PAAG meeting in October 1998 on the perspectives from regulatory reviews of IPAs. The results of discussions at the topical session were used to further clarify and refine the main observations of the study.

In this report, the main text describes the findings of IPAG-2, organised as follows:

- Conduct of the review (Section 2.1).
- Aspects of the safety case (Section 2.2).
- Traceability and transparency (Section 2.3).
- Regulatory guidance (Section 2.4).

and presents some final considerations including comments on:

- The IPAG-2 experience (Section 3.1).
- Comparison of the findings of IPAG-1 and IPAG-2 (Section 3.2).
- Suggestions for a new phase of IPAG (Section 3.3).

This is supported by the following appendices:

- Appendix A: the compilation of the questionnaire answers.
- Appendix B: a summary of regulatory endpoints that are used in the IPAs and reviews.
- Appendix C: the IPAG-2 questionnaire.
- Appendix D: a list of the participants in IPAG-2.

Table 1: **Organisations providing answers to the questionnaire; IPAs reviewed; and purpose of IPA and reviews**
(The Annex to Appendix A contains full references to the IPAs and reviews concerned)

Implementer	Reviewer	IPA	Purpose of IPA and review
VTT (on behalf of Posiva the Finnish implementer), Finland	STUK, Finland	TVO-92 and TILA-96 on spent fuel disposal in crystalline rock.	Background for selection of sites for more detailed investigation. Feedback to R&D.
SKB, Sweden	SKI, Sweden	SFR repository for operational waste (LLW and ILW).	To permit full scale operation. (Operational license had stipulations).
Nagra (on behalf of GNW), Switzerland	HSK, Switzerland	Repository for LLW and ILW at Wellenberg.	Application for General license (site selection and general outline of project) and Cantonal concession for the use of the underground.
NRI, Czech republic		EIA documentation.	Feedback to R&D at an early stage of development.
Ontario Hydro, Canada (IPA was pre-pared by AECL)	AECB, Canada	AECL EIS on the concept for disposal of Canada's nuclear fuel waste.	Safety and acceptability of AECL's concept for disposal. A federal review panel made recommendations on the future steps to be taken with respect to the management of nuclear fuel waste in Canada.
DOE/YM, USA	USNRC, USA	TSPA-95 evaluation of the potential Yucca Mountain repository.	Aid regulator and applicant to prepare for licensing. TSPA-1995 focused on components determined by previous analyses to be most significant.
DOE/WIPP, USA	US EP (did not participate in IPAG-2)	Compliance Certification Application (CCA) for the WIPP repository for TRU-waste.	The IPA served as the basis in the CCA for demonstrating compliance with the quantitative requirements of the EPA's regulations, 40 CFR 191 and 194.
BfS, Germany	GRS, Germany	Konrad repository for LLW and ILW.	Part of license application of the repository.
UK Nirex, UK	UKEA, UK	NR 337, a preliminary assessment of the post-closure performance of a potential deep waste repository at Sellafield.	HMIP (now UKEA) undertook a review of the Nirex documents to test and develop its regulatory assessment capabilities.
PNC, Japan (Implementer will be decided after 2000)	ACRWM of AEC, Japan (did not participate in IPAG-2)	H3, updated knowledge on Japan's geological environment, the technology of geological disposal and the performance assessment of the multi-barrier system.	A basis for the further research and development with the objective of confirming scientific and technical feasibility of the geological disposal concept in Japan.

2. FINDINGS OF IPAG-2

2.1 Conduct of a review

Dialogue before, during and after review

The implementer-regulator dialogue is viewed as essential in the responses to the IPAG-2 questionnaire. Dialogue consists of all forms of written and verbal communication, including telephone conversations, meetings, minutes from meetings, and written correspondence by mail and other media. For reasons of transparency and to maintain independence, regulatory agencies emphasise that all information obtained from the dialogue that is to be considered in, or contributes to, regulatory decisions needs to be properly documented. Making the written records and documentation from the dialogue available to the public could enhance the public perception and overall credibility of the process.

Dialogue is needed during the preparation of the IPA, during the IPA review, and after the IPA review has been completed. *It is recommended that implementers and regulators discuss approaches for maintaining a dialogue that benefit the IPA preparation and regulatory review process, and at the same time preserve the independence of regulator and implementer*.

Dialogue is required during the preparation of the IPA to ensure a common understanding of regulatory expectations, and to provide an opportunity for early regulatory input. For example, early dialogue could allow implementers and regulators to discuss possible PA approaches and the benefits of various modelling techniques and approaches for demonstrating compliance with regulatory requirements.

Regulators note that they appreciate openness on the part of the implementer in identifying issues of concern in the IPA and safety case. It is recommended that implementers discuss in the IPA areas of uncertainty and aspects that require improvement. In particular, it would be useful for implementers to discuss the time frame and steps required for resolution of the remaining issues. If the implementer provides a “road map” showing how compliance with the applicable regulations will eventually be achieved, then regulators may be better able to accept identified limitations in the IPAs produced at any given stage of the licensing process.

There is agreement amongst implementers that a dialogue during the review process is essential to the good development of the review. Dialogue can help to clarify any misunderstandings on the technical details of the IPA, or the basis for assumptions made regarding data, models and scenarios used in the IPA. Dialogue can also provide the implementer with early notice of any needs for further analysis or information to support the IPA and its subsequent iterations.

There is a need for continued dialogue after the IPA review is completed. Answers to the IPAG-2 questionnaire indicate that the key messages identified by implementers and regulators for the same IPA review were generally not in conflict. In some cases, however, the key technical issues listed by the implementer and regulator did differ. The comparison of regulators' and implementers' responses also showed that implementers and regulators had different interpretations on the priorities and expectations for improving the IPA for the next iteration. *This indicates that after the IPA review is completed, the implementer and regulator should meet to discuss the review and ensure that there is a common understanding of the messages and future expectations implied in the IPA review*.

Integrating the development of a PA and its review within the stepwise process of repository development

In most countries, the need for a stepwise approach is reflected in the legal and regulatory framework within which repository programmes operate. In general, an IPA may be required at a number of pre-defined points within the repository-development process. For example, IPAs may be required in support of license applications for detailed site investigations, for repository construction, to begin disposal operations and at repository closure. In addition, an implementing organisation may choose to establish its own stages or milestones between any legally-defined points. Before any license application is made, for example, the implementer may wish to assess the feasibility of a repository located at a particular site. It is therefore possible to distinguish development stages that are controlled by decisions of the regulator and of legislative bodies from those that are controlled by project decisions within an implementing organisation. In the case of project decisions, the number of stages (and hence the level of commitment at any particular stage) may, to some extent, be adapted according to the confidence in safety that an IPA can provide at any given stage.

IPAG-2 has considered IPAs and reviews that have been conducted at different stages in the stepwise process of repository development. These stages vary from seeking feedback on research and development at the beginning of repository development to seeking a permit for operation of a repository. The adoption of a stepwise approach is common to most programmes and reflects the demanding nature of the task of developing a repository concept, and an understanding of relevant phenomena, that together provide a convincing case for long-term safety. Rather than attempting to assemble a safety case in a single step, the repository concept and the understanding of relevant phenomena are progressively refined and enhanced over a number of stages. IPAs provide the means of assessing a concept, based on the level of understanding that is available at a given stage. The findings of the IPA, and the review of these findings, provide:

- a basis for the decision as to whether the concept and understanding are adequate in order to proceed to the next development stage; and,
- guidance for refinement and enhancement during subsequent stages.

The "level of ambition" of an IPA may vary according to the implications or resource commitments involved in proceeding to the next development stage. If these implications are far-reaching, then the IPA must seek to demonstrate, with a high degree of confidence, that safety can be achieved, irrespective of the uncertainties that exist at this stage. This is generally a requirement of an IPA that supports a license application. For other decisions, such as those to implement minor design modifications, the "level of ambition" of the supporting assessment may be lower, corresponding to the level of commitments involved.

The establishment of clearly defined stages within the process of repository development provides a structured framework within which repository development can take place. The existence of a structured framework, which involves interaction between the implementer and regulator, aids the development of a common understanding between the two organisations on issues that need to be resolved to demonstrate safety. In particular, each stage should involve an assessment of the relevance to repository feasibility and safety, of key issues that have been identified by the implementer, the regulator, or by other reviewers, and the identification of a strategy to deal with these issues in the course of future stages. *It is therefore advantageous to establish a structured framework early in a repository programme.* Formal interaction between implementer and regulator will take place at those stages corresponding to license applications. In addition, the programme will benefit if the regulator is continually familiarised with the implementer's planned programme of work and progress towards making the overall case for safety, as the programme develops. Such regular exchange of views promotes mutual understanding between the organisations, allowing:

- prompt identification and resolution of any misunderstandings;
- identification of the issues that are perceived to be most important to safety, and agreement on priorities, so that efforts can be properly focused;
- the regulator to have access to the information that is required, for example, for independent assessments; and
- the implementer to benefit from feedback from the regulator.

In the interest of public confidence in the repository development programme, it is, however, important that interaction between the implementer and the regulator does not compromise (or is not perceived as compromising) the independence of the regulator. Formal publication of the regular exchanges, or inviting other stakeholders to participate as observers, could be considered and would help to dispel the image of agreements having been reached "behind closed doors".

Integrating performance assessment and repository safety

Within the stepwise process of repository development, the description of a site and design is initially made at a conceptual level. For example, the positions of geological features that may eventually constrain the repository layout are, in general, initially unknown. After verification that at least part of the applicable requirements are fulfilled, the aim of the implementer is generally to show, that there exists sufficient confidence to justify continuation of the project, i.e. that construction appears to be feasible and long-term safety is expected. As development progresses towards licensing stages, and more information and understanding is acquired, the concept can be refined and optimised. By identifying those aspects of a site and design that are key to the provision of safety, integrated performance assessments (IPAs), and their reviews, can provide guidance in the process of refinement and optimisation. For example, it may be possible to use the results of the IPA to assess where changes in the dimensions and properties of particular barriers, the provision of additional barriers, or the removal of others, will have the greatest impact on safety.

There are two broad aspects to the making of a case for the safety of a repository. The first is the selection of a site and development of a design that possesses "intrinsic or inherent quality" with respect to safety. This involves, for example, the selection of a site that displays long-term geological stability and a design of engineered barriers that incorporates materials with well-understood properties. It also involves the selection of a site and design that are favourable to analysis in IPAs and favours confidence in its findings (e.g. the use of multiple barriers and the selection of a site that can be adequately characterised). The second is the IPA itself, which involves the acquisition of information relevant to the repository site and design and the development and application of methods and models to assess this information. It must be appreciated that, while an IPA provides a vehicle that demonstrates to decision makers (e.g. the regulator) why a particular site and design should function in such a way as to provide the required level of safety, it is the quality of the selected site and design that provides that safety. The quality of methods and models, and the completeness of the data that are acquired, though important, do not compensate for intrinsic deficiencies in the site and design. There is an increasing emphasis in repository programmes on qualitative arguments that support the "intrinsic quality" of a site and design with respect to safety, and build confidence in the findings of IPAs, as a complement to quantitative modelling. The quantification of safety provided by the IPA remains important, however, so that, in practice, the site selection, design and IPA must progress together.

The IPA should clearly and convincingly present the safety case for the repository, including both quantitative analyses and qualitative arguments, and demonstrate that issues most important to safety have been adequately identified and addressed. Regulators are then in a position to conduct effective reviews, as they can focus the review on fundamental performance issues, and address issues in their review documents in relation to their importance to safety.

Independent assessment or calculations by regulators

All regulators participating in IPAG-2 carried out their own calculations as a part of the review work, but with a varying degree of sophistication. The scope of the calculations ranged from simple estimates to check the order of magnitude of the implementer's assessment results to the development and application of an independent IPA capability. Regulators with their own IPA capability generally used their calculations to focus on aspects that are potentially most important to safety, and to review or explore issues not covered in the implementer's IPA, as opposed to trying to duplicate the implementer's IPA. Regulators also performed calculations to assess the importance of different sets of parameter values to those used by the implementer, and the implications of alternative conceptual models. All IPAG participants agreed, however, that it is the responsibility of the implementer to produce a full, quality-assured IPA. The assessment calculations performed by the regulator were usually published, either separately or in connection with their review report.

In summary, regulators give three main reasons for conducting their own analyses:

- to prepare for the review, by enhancing their own understanding of issues and parameters that are potentially most important to safety;
- to test the reproducibility of the implementer's results; and,
- to extend the analyses performed by the implementer using other sets of parameter values, and exploring the implications of alternative conceptual models.

Some regulators are of the view that they require an independent performance assessment capability to demonstrate to the public their ability to make a professional judgement on the IPA reviewed. Those regulators also expect to be able to reduce the requests for supplementary calculations by the implementer, in that their own, internal calculations will resolve some issues. Dialogue is required when differences emerge between the assessment results of the implementer and regulator, to resolve the differences or understand the underlying reasons for the differences. It is the responsibility of implementer and regulator together to explain to the public the context in which differences are identified, in particular, that differences are to be expected and that an iterative process of an independent review should lead to greater, not less, overall confidence.

Additional observations

Regarding the *conduct of reviews,* the following points are also observed from the compilation of questionnaire answers:

- Most of the IPAs reviewed will be updated. All IPA updates will also be reviewed.
- In addition to the review conducted by the regulator, most of the IPAs were reviewed by other organisations and groups.
- Most regulators, but not all, considered and were expected to consider, other sources of information, over and above that contained in the implementer's IPA.
- Most regulators used consultants to assist in the review work but also recognised that the regulator needs to take ownership of the final IPA review comments.
- In most countries the review documents are published and/or placed on public records.

2.2 Aspects of the safety case

Technical issues and concerns

Although many technical issues and concerns are specific to a given site or design, the answers to the IPAG-2 questionnaire identify several concerns that are more generic and also common to the findings of several IPA reviews. Important examples are:

- Insufficient integration of site investigation and IPA programmes and their results.
- The adoption of potentially non-conservative assumptions in modelling.
- An insufficient depth of scenario and/or uncertainty analysis.

Regarding the apparent lack of integration of PA and site characterisation efforts, it is observed that this lack of integration leads to problems in two directions. New site information is not always integrated into models in a timely fashion, and new system calculations are not always used to redirect and focus site characterisation toward obtaining the most important data. It is clear that in early phases, the IPA calculations may have to use assumed or derived data because site characterisation activities have not yet provided the necessary data. IPA arguments and calculations should, however, be designed in such a way that their data requirements can, in principle, be met by the planned site characterisation studies. Equally, site characterisation studies should focus on obtaining the information that is needed in PA. As PA and site characterisation progress, it is inevitable that there may be some discrepancy between the information incorporated into PA models and the very latest information that is available from the site. This problem can be controlled by using staged data releases so that it is clear which data release a given set of PA calculations is based on. Similar integration issues may exist between PA and engineered system design activities, but were not as frequently noted in IPA reviews.

General comments on the use of conservative versus realistic approaches are given in Section 2.2. A specific concern of IPAG-2 respondents, however, was the use of simplifying assumptions that although apparently conservative in the expected conditions and for the considered scenario might be non-conservative in other circumstances. It has been observed, for example, that it is difficult to anticipate conditions that can arise during radionuclide migration in a complex path, especially for radionuclide chains, and assumptions that are conservative for simple systems are not necessarily conservative in more complex systems, e.g. low sorption values are generally conservative, but high sorption values of ^{226}Ra in near-surface rocks can increase calculated doses.

Regarding the criticism of insufficient depth of scenario and uncertainty analysis, this is motivated by a feeling that IPAs often deal in great depth and rigour with certain selected scenarios but pay insufficient attention to fully exploring the range of scenarios that might occur. Thus, reviewers are not able to judge the extent to which the analysed scenarios are representative of possible futures. IPAG-2 participants agree, however, that considerable progress is being made in the development of systematic scenario development methods, and these are seen as the basis on which a more balanced analysis of scenarios may be made in future.

Multiple lines of reasoning

The responses to the IPAG-2 questionnaire recognise that the use of a variety of different lines of reasoning and modelling techniques and approaches are important for confidence building and, in some cases, are required to demonstrate long-term safety. Examples of PA approaches and techniques that can be used to develop multiple lines of reasoning for demonstrating compliance and safety include:

- Simple and direct approaches to demonstrating safety.
- A variety of indicators.
- Natural analogues.
- Site paleohydrogeology.
- Expert judgement.
- International consensus.

There are, however, different opinions on the extent to which multiple lines of reasoning should contribute to the overall safety case. Some regulators and implementers feel the main focus needs to remain on the detailed, rigorous assessment of long-term performance, as they believe this is the only type of assessment that can give the technical assurance necessary in judging regulatory compliance. For these respondents, multiple lines of reasoning can be used to fill in gaps not addressed by the detailed analyses, provide supporting arguments, illustrate the level of conservatism built into the system, and help to build public confidence. Other respondents see a more central role for multiple lines of reasoning in safety assessments. They argue that given the complexity of natural systems and the long time frames involved, it is unlikely that any one analysis will be able to provide sufficient confidence in the long-term safety of a radioactive waste disposal facility. As a result, the safety case for a radioactive waste disposal facility should be based on a set of complementary analyses that can be used to provide multiple lines of reasoning that the facility will be safe. Two regulators have stated in their guidance documentation that multiple lines of reasoning should be part of safety assessments.

A safety case for a disposal facility needs to focus on the intrinsic safety of the disposal system, and not only on the detailed calculations used to demonstrate long-term safety (see Section 2.1). A number of IPAG-2 participants noted that the use of multiple lines of reasoning can help to focus the safety case on disposal system safety. For example, approaches such as natural analogues and paleohydrogeology highlight the intrinsic safety of disposal systems, and complement the detailed performance measures yielded by assessment calculations.

IPAG-2 participants noted that few existing IPAs made use of other safety indicators, and a number of participants suggested that it would be useful for the PAAG to identify and assess the applications of other potential safety indicators.

Variety of assessment techniques

There are a variety of techniques available for assessing the performance and safety of radioactive waste disposal systems. *While differences in opinion remain on the relative values of the various modelling techniques and approaches to conducting assessments, most IPAG-2 respondents see a role for a variety of techniques and approaches in performance assessment*.

Most methods employ a conceptual and mathematical model for the disposal system and develop the associated computer software and database to carry out the analysis. Both deterministic and probabilistic methods are used. Probabilistic calculations can provide a systematic analysis of the effects of parameter uncertainty in a direct and comprehensive manner. It is generally agreed, however, that deterministic calculations can be more transparent and are more easily explained. There are limits on the extent to which conceptual model uncertainty can be evaluated within probabilistic calculations. Instead, different models of the disposal system should be developed and assessed in a separate fashion. In many cases, the choice of assessment technique depends on the regulatory requirements in each country. Nevertheless, both deterministic and probabilistic methods can contribute to the safety case for geologic disposal of radioactive waste, and are viewed as complementary approaches.

Modelling of a disposal system varies from simple and conservative to complex and more realistic. Most respondents found that both modelling approaches were necessary in an IPA. More detailed modelling may be complex and hard to justify in terms of the available data; conservative simplifications may therefore be necessary in order to make more robust estimates of performance. However, in order to identify and remove overly conservative approximations or assumptions, more realistic modelling is needed. More realistic modelling may also be required to optimise, or select between, repository design options.

There was some discussion on the meaning of “conservative” in IPA. Some respondents prefer to use the word “pessimistic” and also noted that the meaning can vary from one country to another. Consequently, it would be useful to define these terms, and others such as “realistic” and “best estimate”, in the IPA documentation in order to reduce the ambiguity.

The choice of input parameter values was also discussed by the group. Some respondents use “conservative”, “realistic” or “best estimate” values in their deterministic calculations whereas others rely on the probabilistic approach to randomly sample over a defined input probability distribution. Some feel that it is difficult, if not impossible, to determine and justify the “conservative” value for every input parameter in a complex disposal system (see also Section 2.2).

While differences in opinion remain on the relative values of various modelling and calculation techniques and approaches in integrated PAs, IPAG-2 confirms a conclusion of IPAG-1, that *there is a role for a variety of techniques and approaches in PA, and that these can be used in a complementary manner.* All PAs use a variety of techniques, and practitioners of PA appreciate the relative merits of, for example, probabilistic versus deterministic calculations and conservative versus more realistic assessment models. Some PAs may focus on particular techniques for pragmatic reasons but, in general, the intent has not been to exclude other approaches.

Qualitative and quantitative information

IPAG-2 participants agreed that qualitative information is needed as a complement to quantitative information, as invariably there are gaps in the “hard” information available for analyses. This is the case for both probabilistic and deterministic calculations as well as in setting up conservative or realistic calculations. Also, qualitative information and arguments typically form the basis for some of the supporting arguments for long-term safety.

Qualitative information is defined as any information that cannot be directly observed, or that cannot be calculated directly from measured data. Qualitative information involves more judgement than quantified model parameters, such as permeability, and often is developed from a synthesis of measured data and system observations. Judgement is also often required in obtaining numerical values for quantitative model parameters. For example, interpretative tools are required to estimate permeability values from borehole test data. It was suggested that implementers describe the extent to which the data and information used in the safety case are based on qualitative information, and explain the process used for making judgements.

Scientists and engineers sometimes view qualitative information as “soft”, and of less value than “hard”, quantitative information. Since qualitative information is essential in long-term safety assessments, IPAG-2 suggests that it would be useful to explore ways to better use qualitative information. Rather than viewing qualitative information as being inferior to quantitative information, it should be considered a different type of information that can be used for different purposes in PA. *IPAG-2 recommends that a subsequent phase of IPAG could consider ways for both presenting and assessing qualitative arguments and information to increase their value in the decision-making process.*

Meaning of the multiple barrier principle

All IPAG-2 participants emphasise the need for a multi-barrier concept or passive barrier system with multiple safety functions. Furthermore, multiple barriers are usually required by the regulations, and are viewed as an important concept for confidence building in most national radioactive waste disposal programs. The International Atomic Energy Agency (IAEA) Radioactive Waste Management Glossary [IAEA, 1993] defines a barrier as follows:

> “A physical obstruction that prevents or delays the movement (e.g. migration) of radionuclides or other material between components in a system, e.g. a waste repository. In general a barrier can be an engineered barrier which is constructed or a natural barrier which is inherent to the environment of the repository.”

This definition should be extended to include chemical phenomena, such as solubility limits, that prevent or delay the movement of radionuclides. The multi-barrier concept is defined, for example by the Swiss Federal Nuclear Safety Inspectorate [HSK, 1993], as:

> “A series of different engineered and natural barriers which will prevent and delay the movement of radionuclides contained in the waste, in order to ensure the safety of a repository”.

The concept requires that each of several barriers (e.g. waste form, canister, buffer, geologic media) will contribute to safety and the various safety functions provide a certain degree of redundancy with respect to isolation and/or retention of radionuclides. Multiple safety functions are intended to compensate for uncertainties in the future behaviour of the individual engineered barriers and the natural system. IPAG-2 observes, however, that repository barriers cannot be totally independent and redundant, as a deep geologic disposal facility consists of passive components which act together in a complementary manner. For example, the performance of the engineered barriers may depend on the properties of the surrounding geology, and natural and engineered barriers will interact chemically and mechanically both in the short term and also long term following repository closure. Nevertheless, a useful design objective is to maximise the extent to which the barriers functions are independent and also to achieve some redundancy for key safety functions.

IPAG-2 participants noted that the existing definitions of the multi-barrier concept leave room for misinterpretation amongst specialists and by non-technical stakeholders. The difficulty in interpretation arises when the multi-barrier concept is confused with the "defence-in-depth" principle used in reactor safety. The defence-in-depth principle requires that multiple barriers should be completely independent and that there should be redundant barriers. This is possible in a reactor system, as reactors are actively controlled, and redundant and independent barriers can be engineered for the reactor environment. It is not possible in a repository system where evolution of the barriers over thousands of years needs to be considered.

The multi-barrier concept is one of the key bases for long-term safety of deep geological disposal systems, and it is considered important to overall confidence building. However, non-technical stakeholders may consider that the realisation of the multi-barrier concept in practical repository systems falls short of their expectations if they start from the reactor, defence-in-depth, premise that barriers can and should be completely redundant and independent. *IPAG-2 recommends that a definition for the multi-barrier concept should be developed that clearly states that full independence and redundancy are not necessary or possible* and describes the concept in the context of what is achievable and necessary in a deep geological disposal system. *IPAG-2 also recommends that implementers clearly define their interpretation of the multi-barrier concept in IPAs.*

IPAG-2 participants made the following observations about the multi-barrier concept, which can contribute to a definition:

- Application of the multi-barrier principle should imply that moderate damage to a single barrier does not significantly affect the overall safety of the disposal system or the performance of the other barriers. Such moderate damage may be due to a predictable alteration or an initial defect in a barrier. A significant feature is that the barriers will respond differently to the various processes or events that may threaten the required performance of the repository.
- A certain degree of redundancy is inherent to passive multi-barrier systems, as several independent phenomena within a single barrier may be effective in retaining radionuclides. For instance, radionuclides may be retained by both slow transport (e.g. due to diffusion with sorption) and partial immobilisation (e.g. due to solubility limits) within a buffer material. Barriers can also have several functions. For example, the buffer around waste canisters is typically designed to both protect the canister and retain radionuclides.
- Multiple barriers in nuclear waste repositories are not meant to entirely offset catastrophic failures (of low probability) of other barriers. It is the total repository performance that matters even after such failures.

Stylised and standardised approaches

All PA modelling and calculations involve some degree of abstraction of reality and thus are "stylised" in the general sense of the word. In the IPAG-1 report [NEA, 1997] stylised is attributed the following, more specific meaning:

> "A stylised presentation refers to a situation where a part of the disposal system is treated in performance assessment in a standardised or simplified way. The need for stylised presentations occurs if there is a general lack of experimental evidence such that decisions on treatment and parameter values put into performance assessment is highly judgmental."

IPAG-2 concludes that it is useful to preserve this special meaning, and agrees with the above definition and further statements concerning stylised presentations in the IPAG-1 report. For example, the IPAG-1 report states that "the acceptability of stylised presentations cannot be decided by the performance assessment community alone". Some additional clarification can be offered, however.

In general, stylised calculations illustrate how the disposed system might function under prescribed, and possibly hypothetical, conditions.

Stylised approaches are motivated by the presence of uncertainty which is, by agreement, considered as either not relevant to, or should not unduly affect the decision-making process. An example is the adoption of International Commission on Radiological Protection (ICRP) standard man and dosimetric factors which neglect uncertainty (and variability) in metabolism. In this case, the approach is also "standardised" because it is a common and accepted approach internationally.

Another case is the adoption of a fixed set of assumptions to provide an illustrative calculation of human intrusion. In this case, there is large and irreducible uncertainty concerning future human actions but a single, or few, stylised calculation(s) may be carried out to illustrate specific cases. Approaches to human intrusion are standardised to the extent that there is consensus that only current or past human technology should be considered in assessments. The stylisation of human intrusion calculations is, however, likely to be concept or site specific.

IPAG-1 recommended that the PAAG should explore whether there is an interest in co-operation to produce stylised presentations for use in performance assessment. Responses to the IPAG-2 questionnaire indicate that it is not feasible to develop, *standardised* scenarios for deep geological disposal that would be acceptable in all programmes. *Discussions at the fourteenth PAAG meeting showed that there is continued interest in efforts to develop standardised approaches to help treat aspects and components of the safety case.* For example, the PAAG strongly supports the efforts of the BIOMASS project in the development of reference biospheres which include the adoption of standard assumptions.

Additional observations

Regarding *handling of uncertainty and other technical matters* in the safety case, the following is also observed from the compilation of answers:

1. There are still some differences in vocabulary concerning the meaning of scenario uncertainty; some definitions stress time evolution, whereas others focus on the

identification of features, events and processes (FEPs). It does not, however, appear fruitful to strive for more convergence in vocabulary, since national programmes address both comprehensiveness of FEPs and uncertainty in time evolution in IPAs. Some organisations, out of policy, consider that it is up to the implementer to develop the approach for handling uncertainty, and thus to define the terminology they use.

2. It was suggested that the concept of system uncertainty be introduced to cover the issue of completeness of the system description. There was little support for this, however, as most organisations consider that this issue is already covered by the definitions of conceptual model uncertainty and scenario uncertainty.
3. The favoured means of developing and selecting scenarios is generally a structured and transparent approach for identifying FEPs and their combination into scenarios. Additional techniques have also been applied. There are varying opinions on the needs and possibilities of estimating scenario probabilities and on the appropriateness of aggregating such estimates in a probabilistic framework.
4. Conceptual model uncertainty is generally handled by applying a diverse range of models or by making conservative assumptions. The difficulties lie in demonstrating that the analysis of variants is comprehensive, or that assumptions made are conservative.
5. High consequence, low probability scenarios are usually evaluated in a disaggregated manner.
6. None of the IPAG-2 respondents advocated application of failure mode analysis for disposal systems, but some suggested that failure mode analysis techniques can be used to verify the comprehensiveness of the scenarios and FEPs identified. A few were more directly negative to the application of failure mode analysis to a geologic repository because it is difficult to conceive how barriers such as the host geology might “fail”.
7. Some respondents see little direct use of natural analogues as a first line argument in the safety case, while others see a more direct use.

2.3 Traceability and transparency

All IPAG-2 respondents agreed that IPAs prepared for licensing purposes need to be traceable, reproducible and, preferably, publicly available. Regulators and other stakeholders should be able to reproduce the IPA, in whole or in part, from published or publicly available information. Regulators continue to have difficulties tracing the results and logic in IPAs, however, even though implementers have placed increased efforts on building traceability into IPAs. Regulators expect to be able to follow and understand the data trail and decision making process for aspects of the IPA back to the raw data and the rationale for the fundamental assessment assumptions and decisions. Thus, implementers must build in a high degree of traceability throughout the IPA. Implementers must also ensure that the extensive “book-keeping” required for full traceability does not obscure the transparency of the IPA to the regulator and to other stakeholders.

Challenges in achieving the level of traceability desired by regulators

Regulators, and the technical reviewers that support decision makers, are the primary audiences for IPAs. For this audience, it is important that arguments are complete and technically defensible, and that analyses can be understood in their conception, execution, analysis, and interpretation. Alternative conceptual interpretations of data, and an exploration of reasonable possibilities, e.g. illustration of low-probability events, are part of the full exploration of the system and its behaviour into the distant future.

Achieving this level of traceability is difficult in a comprehensive IPA. The future evolution of the system must be assessed, and justification is required for the parameter values and distributions selected, the processes and events considered over time, and the couplings or lack of couplings of the processes and events in the analyses. The portrayal and interpretation of results is a challenge, as there is a need to describe both the limitations of the analyses and the strengths and meaning of the analyses in terms that relate to public health and safety, environmental impacts and potential risk.

The regulatory decision-making process is scrutinised by the public and other stakeholders. The credibility of the process is enhanced if stakeholders perceive that regulatory decisions are based on a careful and comprehensive examination of potential risks. The IPA documentation should therefore be clear and comprehensible also to a wide range of stakeholders, particularly regarding issues of safety.

The implementer has a difficult task. Comprehensive documentation must be produced of the process of obtaining and manipulating data, such as to allow an independent expert to reconstruct the work done and follow the interpretations and assumptions made. This includes documenting how data interpretation, subsystem and total system models were arrived at, e.g. the abstraction and simplification of models, and model testing. Model testing may include running several alternate models to show that the selected approach is appropriate to the problem. Models may also be calibrated against other, more detailed models, or against different data sets.

How to achieve the required traceability

Well-defined and documented methods should be used in identifying features and processes, designing and instrumenting tests and experiments, interpreting test results, constructing conceptual models, and analysing and evaluating the models. If there are deviations, the nature, extent and reasons for the deviations must be recorded. This is typically part of a quality assurance programme.

Completeness, which affects both transparency and traceability, can be improved by using peer reviews. The reviewers must be qualified to perform the review, but should not have been associated with any significant part of the work being reviewed.

References to project documents or other literature must be accurate. This should include page or section numbers if appropriate.

Implications on transparency to regulators and other stakeholders

As stated above, IPA documents are primarily written for the regulators and technical reviewers. These reviewers are expected to be well informed on the subject and should be capable of understanding the information given in the IPA documents. However, technical complexity or poor presentation can make it difficult to follow the arguments and discussions in the IPA, even for these reviewers. In particular, the requirement for exhaustive traceability may obscure key arguments and results, and, thus, transparency.

Other stakeholders can include members of the general public, concerned groups, politicians and highly qualified experts. They are thus a rather heterogeneous group. These stakeholders approach the IPA from very different viewpoints and may make judgements using different value systems. Communicating the results of the IPA, including post-closure risk estimates and their bases, to non-technical stakeholders requires communicators to understand how such stakeholders receive and process technical information, so that appropriate means of presentation can be developed and applied. Through interaction with sample non-technical stakeholders, it may be possible to understand how the public responds to IPA information, including the factors that influence those responses. Through such efforts it may be possible to develop the types of information that will facilitate the communication of the IPA and its results to the wider public audience.

Special writing skills are required to prepare summary IPA documents in such a way that non-technical stakeholders can understand the concepts being presented, assess the proposed disposal facility in the context of other risks and decisions made by society, and allow them to form independent, objective opinions on the issues. It has been suggested that trained technical writers and journalists with experience of writing for popular science magazines should be involved in the preparation of IPA documentation for non-technical stakeholders. In preparing the documents, there is typically tension between, on the one hand, being easily understandable and, on the other hand, giving full information. To ensure that the key messages remain clear, a certain degree of loss of detail and nuance has to be accepted.

It is recognised that documentation is just one part of dialogue with the public, and that the subject of dialogue with the public and other non-technical stakeholders is outside the scope of IPAG-2. IPAG-2 observes, however, that interactions with these stakeholders are becoming increasingly more important as potential repository sites are selected, and regulatory decisions are made for those sites. *IPAG-2 recommends that the PAAG/RWMC explore in greater detail approaches and techniques for addressing the needs of the public and other non-technical stakeholders in IPAs.*

Additional observations

Regarding *documentation* of IPAs and reviews of IPAs, the following is also observed from the compilation of answers:

1. The use of a hierarchical structure is generally regarded as positive.
2. Many hold the view that the IPA document structure could probably be the same in different stages of repository development, although some parts of the report will be more detailed in later stages. Others suggest that, at early stages, the IPA focuses on issues and future directions of research and development, whereas at a licensing stage a structure focused on the regulatory requirements might be expected.
3. Respondents agree that the list of IPA contents proposed by IPAG-1 [NEA, 1997] is still valid and it does not need revision.

2.4 Regulatory guidance

Both regulators and implementers identified a number of purposes for, and benefits from, regulatory guidance.

Nature of guidance needed

Regulatory guidance should be developed in a stepwise manner, starting from very general principles and ending with guidance applicable to a licensing review. Submission of draft guidance to a formal consultation process with interested parties, including the implementer, other regulators and the public, should help to ensure that the guidance is workable and commands the necessary acceptance. This may also enhance public credibility of the subsequent regulatory review process.

Regulatory guidance must clearly state the requirements, expectations and options for demonstrating compliance with regulatory principles and criteria. It forms a basis for the dialogue between regulator and implementer that should take place during the repository development process.

Guidance should not be overly prescriptive. The burden of proof rests with the implementer and, therefore, the implementer should not be unduly restricted in the types of approaches and techniques used to demonstrate long-term safety. Guidance can, however, present and discuss the regulator's general views and preferences for PA and development of a safety case. Flexibility is desirable to make allowances for advancements in technology and possible changes to the disposal concept. Flexible guidance will require less frequent revisions, which may also enhance public credibility.

The regulatory endpoints, such as dose constraints or risk targets, are normally defined in mandatory regulations. Regulatory guidance is needed to elaborate on and clarify regulatory requirements, and describe acceptable approaches for demonstrating compliance with the endpoints. It should also give advice on meeting more qualitative requirements, e.g. related to site selection, development of repository design and fulfilment of multi-barrier requirements.

Guidance may give preferred approaches or techniques for conducting IPA, or provide advice on specific topics such as scenario analysis, the treatment of uncertainties, or the definition of critical groups and reference biospheres. In particular, implementers expressed a desire for guidance on handling "abstract" issues and issues with high, irreducible uncertainty, such as human intrusion. The recommended content for IPAs could also be outlined in regulatory guidance, especially at the stage of formal compliance demonstration.

International consistency in regulatory guidance is desirable. International organisations, notably the IAEA, ICRP and NEA, have contributed significantly to such harmonisation. The nature and content of guidance is, however, affected by national factors, such as regulatory practice, disposal concept and stage of repository development. The apparent differences between guidance in different countries can be largely explained by these factors.

Additional observations

Regarding development of *regulatory guidance* the following is also observed:

1. IPAG-2 respondents agree that it is the task of the regulator to develop guidance and that the implementer and other stakeholders should be allowed to comment on the proposals before the guidance is finalised. The process for developing regulatory guidance is often stipulated in government legislation. In some countries the implementer has a special status in the process as one of the most affected stakeholders. In other countries the implementer status is only a reflection of their specific expertise in radioactive waste disposal matters.
2. All agree that regulators have the right to update or change regulatory guidance. In general, the same procedures apply for updating regulations as for issuing them initially. The formality of these procedures varies from country to country. Implementers stress the need for open procedures for revising regulatory guidance. Some regulators consider regulatory guidance and other statements made prior to a licensing decision to be non-binding on the regulator.

3. FINAL CONSIDERATIONS

3.1 The IPAG-2 experience

The working group approach applied in IPAG-2 provides an excellent forum for compiling, discussing and analysing information, and drawing conclusions and recommendations, this was also a conclusion in the earlier IPAG-1 report [NEA, 1997]. In particular, the working group approach provided participants an opportunity to become aware of the practices and views of a number of implementer and regulator organisations on the development of IPAs and their review, and to gain first-hand knowledge of the experiences of those organisations from their IPA review processes. The value of IPAG-2 was reflected in the number of organisations that participated, the quality and thoroughness of the questionnaire answers submitted, and timely inputs to the preparation of this report.

The time period between the first IPAG-2 ad-hoc working group meeting (May 1997) and the PAAG topical session summarising the group's findings (October 1998) was approximately one year less than the corresponding time period for IPAG-1 (February 1994 to October 1996). The increased efficiency can be attributed to the lessons learned from conducting IPAG-1. In particular, time was saved in IPAG-2 by having a core group develop and test the questionnaire before involving the other IPAG-2 participants.

The observations and recommendations from the IPAG-2 exercise are, perhaps, not as focused and precise as those coming from the IPAG-1 exercise, c.f. [NEA 1997]. This reflects the more subjective and subtle nature of the IPA review process compared to the technical activity of actually performing IPAs in which a greater experience has been amassed. It may also reflect more diverse approaches to IPA review and experiences among the different national organisations that participated in IPAG-2.

3.2 Comparison of the findings of IPAG-1 and IPAG-2

The only direct question in the IPAG-2 questionnaire concerning the adequacy of the IPAG-1 observations and recommendations concerned the recommended contents of an IPA. Most IPAG-2 participants agreed with the general list of contents proposed by IPAG-1, and few saw a need to revise the list. Suggested updates mainly concerned the inclusion of information on the operational phase and closure of the repository. Country-specific regulatory requirements will also affect the structure of an IPA. Some regulators do not intend to issue any guidance on IPA structure or contents, as they believe the implementer should be allowed to tailor the structure and list of contents to best present the safety case.

There were several issues concerning the traceability and transparency and handling of uncertainty that were evaluated both in IPAG-1 and IPAG-2. The lessons learned and recommendations made in IPAG-2 concerning the handling of uncertainty confirm the statements made in IPAG-1. However, IPAG-2 further elaborates and makes recommendations on a number of topics, including multiple lines of reasoning, the use of the multiple-barrier principle, the use of stylised and standardised approaches, and the relative weight given to the technical IPA and the "intrinsic or inherent" safety of a repository.

The discussion on traceability and transparency in this report builds on the definitions made and conclusions reached within IPAG-1. It was, however, possible to further develop lessons and observations using the insights and views of the regulators (stressing the need for traceability), recent experiences in balancing traceability with transparency in IPAs, and communicating the contents of IPAs to the public and other non-technical stakeholders.

3.3 Suggestions for a new phase of IPAG

The IPAG-2 participants discussed possible activities that could usefully continue within the framework of IPAG and developed a number of suggestions which were then discussed at the 14th PAAG meeting in October 1998.

The possibility of repeating an IPAG Phase-1 style examination of new IPAs was considered. It was decided that this is not appropriate at this time, but could be reconsidered in the Autumn of 2000, by which time a greater body of new IPAs would be available.

Phase 1 considered the execution of IPAs, and Phase 2 considered the peer review of IPAs, especially in support of regulatory review. A logical extension for Phase 3 might, therefore, be to consider the needs of the public and other stakeholders in IPA. This might cover such questions as:

- how should other stakeholders be involved in IPA and the decision-making process?
- what information do other stakeholders need?
- how can the results and conclusion of IPA be presented to other stakeholders?

It was concluded that proper execution of this activity would require the involvement of a wider range of expertise and organisations than are represented in PAAG. Moreover, the exercise tends in the direction of work which the RWMC is considering. The PAAG, therefore, considers it most appropriate that RWMC should consider the possibilities for work in this direction. PAAG will give the necessary technical support.

The discussions during the IPAG-2 topical session at the 14th PAAG meeting showed that there was considerable interest among PAAG members in continuing the IPAG working group, but that the group should confine itself to technical matters. In particular, the IPAG could pursue topics that had been recognised in IPAG-2 as critical areas for developing confidence in IPA. These included:

- demonstrating the intrinsic safety and quality of site and design – what are the strategies for demonstrating intrinsic safety and quality and how should IPA be focused to make this demonstration?
- presenting and assessing qualitative data and arguments – consider approaches for presenting and assessing qualitative data and arguments to enhance their value in IPAs and regulatory decision making;
- alternative lines of reasoning – to study approaches and techniques used by implementers, regulators and other reviewers to provide alternative lines of reasoning that disposal systems will be safe over the long term. This could include scoping and

bounding calculations, other safety indicators, paleohydrogeology, natural analogues, simplified arguments prepared for non-technical stakeholders, the use of qualitative information, information on the intrinsic and inherent safety of a disposal concept, and existing environmental data;
- develop examples to illustrate the framework proposed in the NEA document on technical aspects of confidence in the long-term safety of deep geological repositories [NEA, 1999].

These could all fit under the general heading of:

“Supporting arguments used to build confidence in IPAs”.

A consensus was reached to set-up an ad-hoc working group to further develop this general topic in 1999, and to report back to the PAAG at its Autumn 1999 meeting. The new IPAG phase would therefore document and categorise supporting arguments and approaches, and explore how and why they were used. The resultant benefits should be documented, along with the associated limitations.

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EXPOSÉ DE SYNTHÈSE

Le Groupe consultatif de l'AEN sur l'évaluation des performances des systèmes d'évacuation des déchets radioactifs (PAAG) a établi en 1994 un Groupe de travail sur les évaluations intégrées des performances des dépôts profonds (IPAG), ayant pour mission générale d'offrir un cadre privilégié pour mener des discussions éclairées sur l'évaluation des performances, de procéder à un examen de l'état d'avancement général des études d'évaluation des performances et des problèmes spécifiques cernés par le Groupe de travail, le PAAG et d'autres groupes de l'AEN. Ces travaux sont exécutés en plusieurs phases, la composition et les tâches du groupe devant normalement changer d'une phase à une autre.

Au cours de la Phase 1, (IPAG-1), l'objectif a été d'examiner les études d'évaluation des performances exécutées récemment, s'agissant d'un ensemble concret d'éléments d'appréciation susceptibles de fournir une indication de l'état actuel de l'évaluation des performances et permettant de se faire une idée sur ce qui peut et devrait être fait lors d'études futures. Dix organisations ont pris part à cette phase, au cours de laquelle chacune a soumis son étude la plus récente d'évaluation intégrée des performances pour examen et comme base d'échanges de vues au sein du Groupe. Les travaux menés principalement de juin 1995 à avril 1996, ont surtout consisté à élaborer et affiner un questionnaire sur les évaluations des performances, qui ont été soumises, et à y répondre, puis à dépouiller et à examiner les réponses. Cette activité a fait l'objet d'un compte rendu au PAAG et a également été décrite dans un rapport de l'AEN/OCDE [NEA 1997].

Au cours de la Phase 2 (IPAG-2), l'objectif visé était d'examiner l'expérience des examens par des pairs des évaluations intégrées des performances (EIP), et plus particulièrement des examens exécutés à l'appui de l'évaluation réglementaire, du point de vue tant des autorités de sûreté que des exploitants. Cette phase a bénéficié de la participation de 17 organisations nationales, chacune d'entre elle ayant procédé soit à l'exécution soit à l'examen d'une étude récente d'évaluation intégrée des performances. Les travaux, menés principalement de mai 1997 à octobre 1998, ont été axés par l'intermédiaire d'un questionnaire, sur les évaluations des performances et le processus d'examen, ainsi que sur le dépouillement et l'examen des réponses. Cette activité a fait l'objet d'un compte rendu et de débats au sein de l'AEN et est décrite dans le présent rapport. Le corps du document expose les conclusions de l'IPAG-2 et présente quelques considérations finales, notamment des commentaires sur l'expérience de l'IPAG-2, une comparaison des résultats de l'IPAG-1 et de l'IPAG-2, et des suggestions relatives à une nouvelle phase de l'IPAG.

On trouvera ci-après un résumé des observations et des recommandations de l'IPAG-2. Lorsque des recommandations sont formulées, elles s'adressent au premier chef aux organisations procédant à l'exécution ou à l'examen d'évaluations intégrées des performances.

Conduite de l’examen

Dialogue entre les exploitants et les autorités de sûreté

L’existence d’un dialogue revêt de l’importance et présente des avantages tant pour les exploitants que pour les autorités de sûreté à toutes les phases du processus de préparation et d’examen de l’évaluation des performances. L’IPAG-2 recommande que les exploitants et les autorités de sûreté examinent des méthodes permettant de maintenir un dialogue qui soit profitable au processus de préparation et d’examen des EIP dans un contexte réglementaire, tout en permettant de préserver l’indépendance des autorités de sûreté et des exploitants. Le fait de mettre à la disposition du public les enregistrements écrits et la documentation issus de ce dialogue, pourrait améliorer la perception que le public a du processus et sa crédibilité générale.

L’évaluation intégrée des performances et les examens dans le cadre d’un processus par étapes d’aménagement des dépôts

Il faut un processus par étapes pour mettre au point une formule de dépôt et préparer un dossier convaincant démontrant la sûreté à long terme et le respect des prescriptions réglementaires. Cela est conforme aux cadres juridiques et réglementaires car, dans la plupart des pays, un dossier de sûreté, appuyé par une évaluation intégrée des performances, est nécessaire pour servir de base à la prise de décision à un certain nombre de stades du processus d’aménagement d’un dépôt. De l’avis de l’IPAG-2, les exploitants et les autorités de sûreté devraient établir un cadre structuré pour des évaluations des performances et des examens à un stade précoce d’un programme d’aménagement de dépôts.

L’intégration de l’évaluation des performances et de la sûreté d’un dépôt

La démonstration du bien fondé d’un dépôt du point de vue de la sûreté présente deux grands aspects. Le premier concerne le choix d’un site et la mise au point d’un projet possédant une « qualité intrinsèque ou inhérente » en ce qui concerne la sûreté, par exemple un site présentant une stabilité géologique à long terme et des barrières ouvragées faisant appel à des matériaux dotés de caractéristiques bien connues. Le second est constitué par l’évaluation des performances proprement dite, qui implique l’acquisition d’informations ayant trait au site et à la conception du dépôt, ainsi que la mise au point et l’application de méthodes et de modèles permettant d’évaluer ces informations. Alors que l’évaluation des performances offre un instrument qui montre pourquoi un site et une conception déterminés devraient fonctionner de manière à assurer le niveau requis de sûreté, c’est la qualité du site et de la conception choisis qui garantit cette sûreté.

L’IPAG-2 observe qu’un dossier de sûreté devrait documenter de façon claire et convaincante les facteurs qui donnent confiance dans la qualité intrinsèque du site et de la conception choisis, de même que la démonstration technique de la sûreté fournie par des analyses quantitatives des évaluations des performances.

Évaluation ou calculs indépendants effectués par les autorités de sûreté

L'IPAG-2 observe qu'il incombe aux exploitants d'établir une analyse complète de la sûreté d'un dépôt, mais que des calculs indépendants effectués par les autorités de sûreté, à divers niveaux de détail, peuvent être profitables tant pour les autorités de sûreté que pour le processus d'examen. De tels calculs aident les autorités de sûreté à préparer un examen critique en leur permettant de mieux comprendre le système d'évacuation et ses performances, et peuvent également servir à vérifier ou à élargir la portée des analyses présentées par les exploitants. Ainsi, l'examen est davantage susceptible de s'attacher aux facteurs intéressant particulièrement la sûreté. Certains autorités de sûreté estiment que la possession et l'utilisation d'une capacité indépendante d'évaluation des performances revêtent de l'importance pour asseoir la réputation technique de ces autorités aux yeux du public et des autres parties prenantes.

Aspects du dossier de sûreté

Problèmes et préoccupations techniques

Bien que de nombreuses questions techniques soient propres au site ou au projet considéré, les réponses au questionnaire de l'IPAG-2 ont mis en lumière certaines préoccupations qui sont de nature plus générique et sont également mentionnées dans plusieurs examens d'évaluations intégrées des performances. Parmi les principales d'entre elles, on peut citer une intégration insuffisante de l'étude du site et des programmes et résultats de l'évaluation intégrée des performances, l'adoption d'hypothèses éventuellement peu empreintes de conservatisme dans la modélisation, et une analyse de scénario et/ou d'incertitude insuffisamment approfondie. Le fait que ces critiques se retrouvent dans plusieurs examens, indique que les méthodes d'évaluation des performances elles-mêmes peuvent encore être améliorées dans ces domaines.

Argumentation à lignes de force multiples

Tous les participants à l'IPAG-2 estiment qu'une argumentation à lignes de force multiples est utile pour gagner la confiance dans les résultats d'une évaluation des performances, bien que les opinions diffèrent quant à l'importance de ces lignes de force dans la mise au point de l'ensemble du dossier de sûreté. Certains considèrent l'analyse technique principale comme étant l'élément central d'une démonstration de conformité aux prescriptions réglementaires, les autres types de preuve ne constituant qu'un renfort subsidiaire. D'autres sont persuadés qu'une argumentation selon d'autres lignes de force devrait jouer un rôle plus central, étant donné, en particulier, la nécessité d'apporter des démonstrations convaincantes de la sûreté à toute une gamme de publics. L'IPAG-2 observe que parmi les évaluations intégrées des performances existantes, peu nombreuses sont celles qui ont recours à des indicateurs multiples de sûreté, mais cela peut constituer un domaine dans lequel il serait productif de poursuivre des travaux au plan international en vue de cerner et d'évaluer les applications d'indicateurs potentiels de sûreté.

Variété des techniques d'évaluation

Alors qu'il subsiste des différences d'opinion quant à la valeur relative de diverses techniques et méthodes de modélisation et de calcul dans les évaluations intégrées des performances, l'IPAG-2 confirme une conclusion de l'IPAG-1, à savoir qu'il y a place pour une variété de techniques et de méthodes dans l'évaluation des performances, et que celles-ci peuvent être utilisées de manière complémentaire. Toutes les évaluations des performances ont recours à une variété de techniques et les spécialistes de l'évaluation des performances apprécient les avantages relatifs, par exemple, des calculs probabilistes par rapport aux calculs déterministes, et des modèles d'évaluation empreints de conservatisme par rapport à ceux qui sont plus réalistes. Certaines évaluations des performances peuvent privilégier des techniques particulières pour des raisons pragmatiques mais, en général, l'intention n'était pas d'exclure d'autres méthodes.

Information qualitative et quantitative

L'IPAG-2 observe que les scientifiques et les ingénieurs considèrent parfois l'information qualitative, autrement dit « incertaine » comme étant d'une valeur moindre que l'information quantitative dite « fiable ». L'information qualitative est toutefois essentielle dans les évaluations de la sûreté à long terme, aussi l'IPAG-2 considère-t-elle qu'il serait utile d'étudier des moyens permettant de mieux utiliser l'information qualitative. Plutôt que de la considérer comme étant inférieure à l'information quantitative, il y aurait lieu d'y voir des types différents d'information qui peuvent être utilisés à des fins différentes dans l'évaluation des performances. L'IPAG-2 suggère d'examiner la possibilité à la fois de présenter des informations et des arguments qualitatifs, et de leur conférer davantage de valeur dans le processus de décision.

Définition du système à barrières multiples

Le concept de barrières multiples constitue l'une des bases essentielles de la sûreté à long terme des systèmes d'évacuation à grande profondeur dans les formations géologiques et il est considéré comme revêtant de l'importance pour l'ensemble des efforts en vue de susciter la confiance. Toutefois, les parties prenantes de non-spécialistes peuvent considérer que la mise en œuvre du concept des barrières multiples dans des systèmes d'évacuation concrets ne répond pas à leurs attentes, si elles partent du principe de la défense en profondeur du réacteur, selon lequel les barrières peuvent et doivent être entièrement redondantes et indépendantes. L'IPAG-2 a procédé dans une certaine mesure à un examen préliminaire de ce sujet, mais il est nécessaire, à son avis, de poursuivre les travaux afin de mettre au point une définition du concept de barrières multiples qui décrive ce concept dans le contexte de ce qui est réalisable et nécessaire dans un système d'évacuation dans des formations géologiques profondes.

Méthodes « stylisées » et « standardisées »

On utilise d'ordinaire des méthodes « stylisées » dans des situations où il existe une incertitude inhérente et irréductible, afin de donner un aperçu des performances du système et de faciliter la communication. Des méthodes stylisées, qui sont admises au plan international, peuvent être qualifiées de méthodes « standardisées ». L'IPAG-1 a recommandé que le PAAG détermine s'il y a intérêt à coopérer en vue d'établir des présentations stylisées destinées à être utilisées dans l'évaluation des performances. Les réponses au questionnaire de l'IPAG-2 indiquent qu'il n'est pas matériellement possible de mettre au point des scénarios standardisés qui soient acceptables dans tous les programmes. Toutefois, les débats au sein du PAAG font apparaître régulièrement que les efforts en vue de mettre au point des méthodes standardisées afin de faciliter le traitement de certains aspects et composants du dossier de sûreté continuent de susciter de l'intérêt.

Traçabilité et transparence

Tant le rapport de l'IPAG-1 que le présent rapport contiennent un examen des aspects que présente le fait d'assurer la traçabilité dans les évaluations intégrées des performances et de conférer de la transparence à ces évaluations, ainsi que des défis que cela représente. Tous les auteurs de réponses à l'IPAG-2 conviennent que les évaluations intégrées des performances établies à des fins d'autorisation doivent être traçables, reproductibles et à la disposition du public.

Parvenir au niveau de traçabilité et de transparence souhaité par les autorités de sûreté

Les autorités de sûreté et leurs agents chargés des examens techniques sont les principaux destinataires de la plupart des EIP. Cependant, nombreux sont parmi eux ceux qui continuent d'éprouver des difficultés à retrouver les résultats et la logique dans les évaluations des performances, même si les exploitants se sont davantage efforcés d'assurer la traçabilité de leurs évaluations des performances. Afin de résoudre ce problème, il est nécessaire de reconnaître que tant les exploitants que les autorités de sûreté doivent s'acquitter d'une tâche complexe. Il n'est pas aisé assurément de reconnaître que les exploitants se trouvent confrontés à la tâche ardue d'avoir à établir la documentation exhaustive du processus complexe consistant à obtenir, traiter et faire la synthèse de données et de modèles avec suffisamment de détail et de clarté. Il convient aussi de reconnaître que les autorités de sûreté ont aussi à faire face initialement à la difficulté de comprendre la structure et les formalismes utilisés par les exploitants. Ainsi, un aspect au moins de la réalisation de la traçabilité et de la compréhension entre les exploitants et les autorités de sûreté, est la stabilité des méthodes ainsi que de la structure et du mode de présentation de la documentation, de même que des examens itératifs.

Répercussions en matière de traçabilité et de transparence dans le cas des autres parties prenantes

D'autres parties prenantes de non-spécialistes procèdent aussi à des examens d'évaluations intégrées des performances, et ont des besoins différents en matière de traçabilité et de transparence. Ces parties prenantes abordent en général les évaluations des performances sous des angles différents et formulent des jugements à l'aide de systèmes de valeurs différents. L'IPAG-2 observe que les interactions entre ces parties prenantes deviennent de plus en plus importantes à mesure que des sites potentiels de dépôts sont sélectionnés et que des décisions réglementaires sont prises à propos de ces sites. L'IPAG-2 estime que l'AEN devrait étudier plus en détail des méthodes et des techniques permettant de répondre aux besoins du public et d'autres parties prenantes de non-spécialistes dans les évaluations des performances.

Orientations d'ordre réglementaire

Des orientations d'ordre réglementaire devraient indiquer clairement les exigences et les attentes s'agissant d'apporter la démonstration du respect des critères réglementaires. Cela permettra de définir plus aisément la tâche à entreprendre par les exploitants de même que d'améliorer la transparence et la crédibilité aux yeux du public du processus d'examen. Des orientations réglementaires peuvent être mises au point par étapes, parallèlement à la mise en place par étapes des programmes nationaux d'aménagement de dépôts, et devraient être examinées à des stades stratégiques afin de s'assurer qu'elles conservent leur validité.

Il est souhaitable que les orientations réglementaires soient cohérentes au plan international et des organisations telle que l'AIEA, la CIPR et l'AEN contribuent notablement à une telle harmonisation. L'importance des facteurs nationaux ne doit toutefois pas être méconnue et il importe que les orientations réglementaires reflètent les préoccupations des parties prenantes.

Suggestions relatives à une nouvelle phase de l'IPAG

L'IPAG pourrait poursuivre l'étude de sujets qui ont été reconnus comme des aspects critiques si l'on veut asseoir la confiance dans les évaluations intégrées des performances. Tous ces aspects pourraient s'inscrire sous une rubrique générale intitulée :

« Arguments utilisés pour asseoir la confiance dans les évaluations intégrées des performances ».

Lors de sa quatorzième réunion tenue en octobre 1998, le PAAG est convenu d'un commun accord d'établir un groupe de travail ad hoc chargé d'approfondir cette question générale en 1999. La nouvelle phase de l'IPAG consisterait donc à inventorier, examiner et documenter les méthodes et arguments justificatifs, et à rechercher comment et pourquoi ils sont utilisés.

APERÇU

1. INTRODUCTION

Dans de nombreux pays Membres de l'OCDE, les agences des déchets et les autorités de sûreté prennent part à l'étude et à la solution des problèmes liés à la sûreté à long terme des dépôts souterrains destinés aux déchets radioactifs. La sûreté doit être démontrée de manière à convaincre les agences des déchets, les autorités réglementaires, la communauté scientifique et technique plus large, les décideurs au plan politique et le grand public. En particulier, il faut des arguments convaincants capables de susciter au sein de ces groupes la confiance dans la sûreté des dépôts proposés, compte tenu des incertitudes qui entachent inévitablement la prévision du comportement de systèmes naturels et artificiels complexes pendant de longues durées à l'avenir.

Ces dernières années, on s'est de plus en plus accordé à reconnaître que la mise au point et l'autorisation de systèmes d'évacuation devaient être menées par étapes. Aux stades importants, il faut une décision des autorités réglementaires ou d'autres décideurs sur le point de savoir s'il convient de passer à la phase suivante de développement. La décision de le faire, dans le cas de l'aménagement d'un dépôt, implique des engagements de la part de l'agence des déchets et de la société dans son ensemble, et ces engagements doivent être évalués en fonction des incertitudes qui existent à ce stade. Pour étayer cette décision, l'agence des déchets procède normalement à une évaluation intégrée des performances (EIP) qui est examinée par les autorités réglementaires.

Plusieurs agences des déchets et autorités réglementaires se rapprochent maintenant d'une période où elles peuvent être appelées à prendre et à expliquer des décisions en matière d'autorisation, et les actions tant des agences des déchets que des autorités réglementaires sont susceptibles de faire l'objet d'un examen public et politique minutieux et détaillé. Le Comité de la gestion des déchets radioactifs (RWMC) de l'AEN et son Groupe consultatif sur l'évaluation des performances des systèmes d'évacuation des déchets radioactifs (PAAG) ont estimé que le moment était venu d'évaluer, dans un contexte international, l'expérience acquise jusqu'à présent par suite de l'examen par des pairs – notamment du point de vue réglementaire – des évaluations intégrées des performances. Cette tâche a été assignée au Groupe de travail sur les analyses intégrées de performance des dépôts profonds (IPAG) qui a reçu pour mission :

- de tirer les enseignements de ce qui a été réalisé ;
- de mettre en lumière ce qui peut et devrait être fait à l'avenir ;
- de rendre compte des enseignements tirés au PAAG et à d'autres groupes de l'AEN ; et
- de fournir des informations destinées à être utilisées dans des rapports de l'AEN.

La phase 1 de l'IPAG (IPAG 1) a permis d'établir un rapport axé sur les enseignements tirés de l'exécution de dix évaluations intégrées des performances [AEN, 1997]. Le présent document rend compte des résultants de la phase 2 de l'IPAG (IPAG-2) qui a été centrée sur l'expérience de l'examen dans un contexte réglementaire de l'évaluation intégrée des performances. L'IPAG-2 a été menée entre mai 1997 et octobre 1998 sous la présidence de D. Metcalfe (CCEA, Canada) et on a procédé de la façon suivante :

- On a sollicité la participation d’autorités de sûreté et d’exploitants, qui possédaient une expérience de l’examen des évaluations intégrées des performances ou de l’établissement de telles évaluations ayant fait l’objet d’examens.
- On a recueilli des informations sur l’expérience de ces examens à l’aide d’un questionnaire diffusé à toutes les agences de gestion des déchets représentées au sein du PAAG. Ce questionnaire avait été testé auparavant sur un groupe restreint d’agences. Dans la version finale du questionnaire, on a demandé des informations sur les façons d’aborder l’examen des EIP, les manières dont ces examens sont présentés et interprétés, et les opinions relatives aux orientations et modifications qu’il faut apporter à l’avenir au processus de décision au plan réglementaire.
- Dix-sept organisations ont répondu au questionnaire portant sur l’expérience acquise à l’occasion de l’examen de dix EIP (voir Tableau 1). Dans le cas de sept études, il a été possible de pendre en compte les avis tant des autorités de sûreté que des exploitants.
- Les réponses au questionnaire ont été analysées afin d’appréhender l’expérience tant des autorités de sûreté que des exploitants au cours du processus d’examen. On a structuré les réponses au questionnaire dans un document appelé ci-après « la compilation ».
- Les convergences et les divergences d’opinions ont été cernées et examinées lors d’une réunion plénière de l’IPAG-2 tenue en mai 1998. Au cours de cette réunion, les questions clés ont été inventoriées et débattues et le plan schématique du présent document a été établi. Des membres individuels de l’IPAG-2 ont rédigé des textes relatifs à chacun des aspects ainsi définis, et ces textes ont été assemblés dans un projet de rapport en août 1998. Ce projet a ensuite été diffusé pour commentaires aux membres du PAAG et du SEDE (Groupe de coordination sur l'évaluation des sites et la conception des expériences pour l'évacuation des déchets radioactifs).
- Lors de la 14ème réunion du PAAG tenue en octobre 1998, une séance thématique a été consacrée aux perspectives s’offrant aux examens des EIP dans un contexte réglementaire. Les résultats des débats lors de la séance thématique ont servir à clarifier et à affiner davantage les principales observations de l’étude.

Dans le présent rapport, le corps du document décrit les conclusions de l’IPAG-2, articulées comme suit :

- Conduite de l’examen (Section 2.1) ;
- Aspects du dossier de sûreté (Section 2.2) ;
- Traçabilité et transparence (Section 2.3) ;
- Orientations d’ordre réglementaire (Section 2.4) ;

et présente certaines considérations finales, notamment des commentaires sur :

- L’expérience de l’IPAG-2 (Section 3.1) ;
- La comparaison des résultats de l’IPAG-1 et de l’IPAG-2 (Section 3.2) ;
- Des suggestions relatives à une nouvelle phase de l’IPAG (Section 3.3).

Le rapport est étayé par les Appendices suivants :

- Appendice A : compilation des réponses au questionnaire ;
- Appendice B : récapitulatif des grandeurs de référence réglementaires qui sont utilisées dans les EIP et les examens ;
- Appendice C : questionnaire de l’IPAG-2 ;
- Appendice D : liste des participants à l’IPAG-2.

Tableau 1 : **Organisations ayant répondu au questionnaire ; évaluations intégrées des performances (EIP) ayant fait l'objet d'un examen ; et finalités des EIP et des examens.**
(*On trouvera à l'Appendice A les références complètes des EIP et des examens en question*)

Exploitant	Examinateur	EIP	Objet de l'EIP et de l'examen
VTT (pour le compte de Posiva), Finlande	STUK, Finlande	TVO-92 et TILA-96 concernant l'évacuation du combustible irradié dans des roches cristallines.	Éléments d'appréciation en vue de la sélec-tion de sites devant faire l'objet d'études plus détaillées. Retour d'informations pour la R-D.
SKB, Suède	SKI, Suède	Dépôt SFR destiné aux déchets issus de l'exploitation (déchets de faible et de moyenne activité).	Permettre une exploitation à l'échelle industrielle. (L'autorisation d'exploitation comportait certaines dispositions).
CEDRA (pour le compte de la GNW), Suisse	DSN, Suisse	Dépôt de déchets de faible et de moyenne activité à Wellenberg.	Demande d'autorisation générale (choix du site et plan général du projet) et de concession cantonale relative à l'utilisation du sous-sol.
NRI, République tchèque		Documentation destinée à l'évaluation des incidences sur l'environnement.	Retour d'informations pour la R-D à un stade précoce de mise au point.
Ontario Hydro, Canada (l'EIP a été établie par l'EACL)	CCEA, Canada	EIE de l'EACL visant le système d'évacuation des déchets de combustible nucléaire du Canada.	Sûreté et acceptabilité du système d'évacuation de l'EACL. Un groupe fédéral d'examen a formulé des recommandations sur les futures mesures à prendre concernant la gestion des déchets de combustible nucléaire au Canada.
DOE/YM, États-Unis	USNRC, États-Unis	Évaluation TSPA-95 des possibilités offertes par le dépôt de Yucca Mountain.	Aider les autorités de sûreté et le demandeur à se préparer pour la délivrance de l'autorisation. La TSPA-95 s'est axée sur les éléments revêtant une grande importance d'après les analyses précédentes.
DOE/WIPP, États-Unis	USEPA, (n'a pas participé à l'IPAG-2), États-Unis	Demande de certificat de conformité concernant le dépôt WIPP pour déchets transuraniens.	L'EIP a servi de base à la demande de certificat de conformité afin de démontrer le respect des prescriptions quantitatives de la réglementation de l'EPA, 40 CFR 191 et 194.
BfS, Allemagne	GRS, Allemagne	Dépôt de Konrad pour déchets de faible et de moyenne activité.	Partie de la demande d'autorisation du dépôt.
UK Nirex, Royaume-Uni	UKEA, Royaume-Uni	NR 337, évaluation préliminaire des performances après fermeture d'un éventuel dépôt de déchets à grande profondeur à Sellafield.	L'HMIP (devenue l'UKEA) a procédé à un examen des documents de la Nirex afin de tester et d'améliorer ses capacités d'évaluation du point de vue réglementaire.
PNC, Japon (l'exploitant sera déterminé après 2000)	Le Comité consultatif de la gestion des déchets radioactifs de la Commission de l'énergie atomique du Japon (n'a pas participé à l'IPAG-2)	H3, mise à jour des connaissances sur le contexte géologique du Japon, la technologie du stockage géologique et l'évaluation des performances du système à barrières multiples.	Base pour la poursuite des travaux de R-D avec pour objectif de confirmer la faisabilité scientifique et technique du mode d'évacuation dans les formations géologiques au Japon.

2. CONCLUSIONS DE L'IPAG-2

2.1 Conduite d'un examen

Dialogue avant, pendant et après l'examen

Le dialogue entre les exploitants et les autorités de sûreté est considéré comme essentiel dans les réponses au questionnaire de l'IPAG-2. Ce dialogue revêt toutes les formes de la communication écrite et orale, y compris les conversations téléphoniques, les réunions, les comptes rendu de réunions, et la correspondance écrite par courrier et sur d'autres supports. Pour des raisons de transparence et pour maintenir l'indépendance, les autorités réglementaires soulignent que toutes les informations tirées du dialogue, qui doivent être prises en considération dans les décisions réglementaires ou y contribuer, ont besoin d'être convenablement étayées. Le fait de mettre à la disposition du public les enregistrements et la documentation par écrit résultant du dialogue pourrait améliorer la perception du processus par le public et sa crédibilité générale.

Le dialogue est nécessaire pendant la préparation de l'EIP, au cours de son examen et après que ce dernier a été achevé. *Il est recommandé que les exploitants et les autorités de sûreté examinent des méthodes permettant de préserver un dialogue qui soit profitable au processus de préparation et d'examen réglementaire des EIP, tout en sauvegardant l'indépendance des autorités de sûreté et des exploitants.*

Il faut un dialogue pendant la préparation de l'EIP pour s'assurer d'une compréhension commune des attentes réglementaires, et pour permettre une contribution précoce au plan réglementaire. Par exemple, grâce à l'instauration à bref délai d'un dialogue, les exploitants et les autorités de sûreté auraient la possibilité d'examiner les méthodes à envisager pour l'évaluation des performances ainsi que les avantages des diverses techniques et méthodes de modélisation permettant de démonter la conformité aux prescriptions réglementaires.

Les autorités de sûreté observent qu'elles apprécient la franchise de la part des exploitants, s'agissant de cerner les sujets de préoccupation dans l'EIP et le dossier de sûreté. Il est recommandé aux exploitants d'examiner dans l'EIP les domaines d'incertitude et les aspects qui appellent une amélioration. En particulier, il serait utile que les exploitants réfléchissent sur le calendrier et les mesures nécessaires pour trouver une solution aux questions en suspens. Lorsque les exploitants fournissent un plan de marche montrant comment la conformité aux règlements en vigueur sera finalement obtenue, les autorités de sûreté peuvent être mieux à même d'accepter des certaines lacunes précises dans les EIP établies à un stade donné du processus d'autorisation.

Les exploitants s'accordent à reconnaître qu'un dialogue au cours du processus d'examen est essentiel au bon déroulement de l'examen. Le dialogue peut aider à clarifier tout malentendu concernant les détails techniques de l'EIP ou la base des hypothèses admises concernant les données, les modèles et les scénarios utilisés dans l'EIP. Le dialogue peut aussi alerter rapidement les exploitants à propos des éventuels besoins d'analyses ou d'informations complémentaires afin d'étayer l'EIP et ses itérations ultérieures.

Il est nécessaire que le dialogue se poursuive une fois l'EIP achevée. Il ressort des réponses au questionnaire de l'IPAG-2, que les enseignements clés relevés par les exploitants et les autorités de sûreté dans le cas de l'examen d'une même EIP, ne sont généralement pas incompatibles. Dans certains cas, toutefois, les problèmes techniques essentiels respectivement mentionnés par les exploitants et les autorités de sûreté ont effectivement fait apparaître des différences. La comparaison des réponses des autorités de sûreté et des exploitants a aussi montré que les exploitants et les autorités de sûreté ont des interprétations différentes quant aux priorités et aux améliorations attendues de l'EIP dans le cas de la prochaine itération. *Cela indique qu'une fois achevé l'examen de l'EIP, les exploitants et les autorités de sûreté devraient se rencontrer afin de débattre de l'examen et de s'assurer qu'il existe une concordance de vues sur les enseignements et les attentes futures contenues implicitement dans l'examen de l'EIP.*

Intégrer l'élaboration d'une évaluation des performances et son examen dans le processus par étapes d'aménagement d'un dépôt

Dans la plupart des pays, la nécessité d'une démarche par étapes est inscrite dans le cadre juridique et réglementaire dans lequel fonctionnent les programmes de dépôts. En général, une EIP peut être exigée en un certain nombre de stages prédéfinis du processus d'aménagement d'un dépôt. Par exemple, des EIP peuvent être requises à l'appui des demandes d'autorisation relatives aux études détaillées de site, à la construction du dépôt, au démarrage des opérations d'évacuation et à la fermeture du dépôt. En outre, une agence des déchets peut choisir de définir ses propres étapes ou grandes phases entre les éventuels stades définis sur le plan juridique. Avant de soumettre toute demande d'autorisation, par exemple, les exploitants souhaiteront peut-être déterminer la faisabilité d'un dépôt implanté sur un site particulier. Il est donc possible d'établir une distinction entre les stades de l'aménagement qui dépendent de décisions des autorités de sûreté ou des organismes législatifs et ceux qui sont régis par des décisions relatives au projet prises au sein d'une agence des déchets. Dans le cas de ces dernières décisions, le nombre des étapes (et en conséquence le niveau d'engagement à chaque stade particulier) peut, dans une certaine mesure, être adapté en fonction de la confiance dans la sûreté qu'une EIP peut apporter à tout stade donné.

L'IPAG-2 s'est penché sur des EIP et des examens qui ont été exécuté à différents stades du processus par étapes d'aménagement d'un dépôt. Ces stades vont de la recherche d'un retour d'information sur les travaux de R-D menés au début de l'aménagement d'un dépôt à la demande de permis d'exploitation d'un dépôt. L'adoption d'une démarche par étapes est commune à la plupart des programmes et reflète la nature exigeante de la tâche consistant à mettre au point un modèle de dépôt, et à acquérir une connaissance des phénomènes pertinents, qui conjointement permettent d'avoir un dossier convaincant visant la sûreté à long terme. Au lieu de chercher à constituer un dossier de sûreté en une seule étape, le modèle de dépôt et la connaissance des phénomènes pertinents sont progressivement affinés et améliorés au cours d'un certain nombre de stades. Les EIP offrent les moyens d'évaluer un modèle, sur la base du niveau de connaissance dont on dispose à un stade donné. Les résultats de l'EIP, et l'examen de ces résultats offrent :

- une base permettant de décider si le modèle et les connaissances sont suffisants pour passer au stade suivant de l'aménagement ; et
- des indications visant les précisions et les améliorations à apporter aux cours des stades suivants.

Le « niveau d'ambition » d'une EIP peut varier selon les répercussions ou les engagements de ressources qu'implique le passage au stade suivant de l'aménagement. Si ces répercussions sont d'une grande portée, l'EIP doit alors chercher à démontrer, avec un degré élevé de confiance, que la sûreté peut être obtenue, quelles que soient les incertitudes existant à ce stade. C'est en général ce qui est exigé d'une EIP qui étaye une demande d'autorisation. Pour d'autres décisions, par exemple celles visant la mise en œuvre de modifications techniques mineures, le « niveau d'ambition » de l'évaluation justificative peut être moindre, correspondant au niveau des engagements en jeu.

L'établissement de stades clairement définis à l'intérieur du processus d'aménagement d'un dépôt fournit un cadre structuré dans lequel l'aménagement du dépôt peut s'effectuer. L'existence d'un cadre structuré, qui implique une interaction entre les exploitants et les autorités de sûreté, facilite le développement d'une compréhension mutuelle entre les deux organisations concernant les questions qui doivent être résolues afin de démontrer la sûreté. En particulier, chaque stade devrait comporter une détermination de la pertinence, eu égard à la faisabilité et à la sûreté du dépôt, des questions clés qui ont été cernées par les exploitants, les autorités de sûreté ou d'autres examinateurs, et la définition d'une stratégie en vue de régler ces questions au cours de stades futurs. *Il est donc avantageux d'établir un cadre structuré à un stade précoce d'un programme d'aménagement d'un dépôt.* L'interaction officielle entre les exploitants et les autorités de sûreté aura lieu aux stades correspondant aux demandes d'autorisations. En outre, il est dans l'intérêt du programme que les autorités de sûreté aient en permanence une bonne connaissance du programme de travail prévu des exploitants et de l'état d'avancement de la réalisation de l'ensemble du dossier de sûreté, au fur et à mesure du déroulement du programme. De tels échanges de vues réguliers favorisent la compréhension mutuelle entre les organisations, en permettant :

- de cerner rapidement et de lever tout malentendu ;
- de recenser les questions qui sont jugées très importantes pour la sûreté, de se mettre d'accord sur les priorités, de manière à ce que les efforts soient convenablement ciblés ;
- aux autorités de sûreté d'avoir accès aux informations qui sont nécessaires, par exemple à des évaluations indépendantes ; et
- aux exploitants de bénéficier d'un retour d'information des autorités de sûreté.

Dans l'intérêt de la confiance du public dans le programme d'aménagement d'un dépôt, il importe toutefois que l'interaction entre les exploitants et les autorités de sûreté ne porte pas (ou ne soit pas perçue comme portant) atteinte à l'indépendance de ces derniers. La publication officielle des échanges réguliers ou l'invitation d'autres parties prenantes à participer en qualité d'observateurs, pourraient être envisagées et contribueraient à redresser l'image d'accords réalisés « à huis clos ».

Intégrer l'évaluation des performances et la sûreté des dépôts

Dans le cadre du processus par étapes d'aménagement des dépôts, la description d'un site et d'un projet s'effectue d'abord à un niveau conceptuel. Par exemple, la localisation des particularités géologiques qui peuvent le moment venu peser sur la configuration du dépôt est, en général, inconnue à l'origine. Après vérification du fait qu'au moins une partie des prescriptions en vigueur est respectée, les exploitants ont généralement pour objectif de montrer qu'il existe une confiance suffisante pour justifier la poursuite du projet, autrement dit que la construction paraît faisable et que l'on escompte une sûreté à long terme. À mesure que l'aménagement s'achemine vers les stades d'autorisation, et que l'on acquiert davantage d'informations et de connaissances, le modèle peut être perfectionné et optimisé. En cernant les aspects d'un site et d'une conception qui sont déterminants pour assurer la sûreté, les évaluations intégrées des performances (EIP) et leurs examens peuvent fournir des orientations pour ce processus de perfectionnement et d'optimisation. Par exemple, les résultats des EIP peuvent être utilisés pour déterminer à quels endroits des modifications apportées aux dimensions et aux caractéristiques de certaines barrières, la mise en place de barrières supplémentaires ou la suppression d'autres, auront la plus forte incidence sur la sûreté.

L'établissement d'un dossier visant la sûreté d'un dépôt revêt deux grands aspects. Le premier est le choix d'un site et la mise au point d'un projet doté d'une « qualité intrinsèque ou inhérente » eu égard à la sûreté. Il s'agit, par exemple, de choisir un site qui présente une stabilité géologique à long terme et une conception des barrières ouvragées qui utilise des matériaux ayant des propriétés bien connues. Il s'agit aussi de choisir un site et une conception qui se prêtent à l'analyse dans le cadre d'EIP, et de pouvoir avoir confiance dans leurs conclusions (par exemple, utilisation de barrières multiples et choix d'un site susceptible d'être convenablement caractérisé). Le second est l'EIP proprement dite, qui implique l'acquisition d'informations ayant trait au site et à la conception du dépôt ainsi que la mise au point et l'application de méthodes et de modèles permettant d'évaluer ces informations. Il faut savoir que si l'EIP fournit un instrument qui démontre aux décideurs (autorités de sûreté, par exemple) pourquoi un site et un projet particulier devraient fonctionner de manière à assurer le niveau requis de sûreté, c'est la qualité du site et du projet retenus qui assurent cette sûreté. La qualité des méthodes et modèles, et l'exhaustivité des données qui sont obtenues, sont certes importantes, mais elles ne compensent pas les imperfections intrinsèques du site et du projet. Il existe une tendance croissante dans les programmes d'aménagement de dépôts à privilégier les arguments qualitatifs qui justifient la « qualité intrinsèque » d'un site et d'un projet eu égard à la sûreté, et suscitent la confiance dans les conclusions des EIP, en complément à la modélisation quantitative. La quantification de la sûreté obtenue grâce à l'EIP, demeure toutefois importante, de sorte que dans la pratique, le choix du site, la conception et l'EIP doivent progresser ensemble.

L'EIP devrait présenter de façon claire et convaincante le dossier de sûreté du dépôt, incluant à la fois des analyses quantitatives et des arguments qualitatifs, et démontrer que les questions revêtant une grande importance pour la sûreté ont été convenablement cernées et traitées. Les autorités de sûreté sont alors à même de mener des examens efficaces, car elles peuvent les axer sur les questions fondamentales en matière de performances et traiter les questions dans leurs documents d'examen par rapport à leur importance pour la sûreté.

Évaluation ou calculs indépendants effectués par les autorités de sûreté

Toutes les autorités de sûreté participant à l'IPAG-2 ont effectué leurs propres calculs dans le cadre des travaux d'examen, mais avec un degré variable raffinement. La portée de ces calculs allait de simples estimations afin de vérifier l'ordre de grandeur des résultats figurant dans l'évaluation des exploitants à la mise au point et à l'application d'une capacité indépendante d'EIP. Les autorités de sûreté disposant de leur propre capacité d'EIP ont généralement eu recours à leurs calculs pour se focaliser sur des aspects qui revêtent en puissance une grande importance pour la sûreté, et pour examiner ou rechercher des questions non traitées dans l'EIP des exploitants, au lieu de s'efforcer de reproduire l'EIP des exploitants. Les autorités de sûreté ont aussi exécuté des calculs pour déterminer l'importance d'ensembles de valeurs de paramètres différents de ceux utilisés par les exploitants, et les conséquences pouvant découler d'autres modèles conceptuels. Tous les participants à l'IPAG-2 se sont toutefois accordés à reconnaître qu'il appartient aux exploitants d'établir une EIP complète à qualité contrôlée. Les calculs d'évaluation exécutés par les autorités de sûreté sont habituellement publiés, soit séparément, soit en liaison avec leur rapport d'examen.

En résumé, les autorités de sûreté avancent trois raisons principales pour justifier l'exécution de leurs propres analyses :

- se préparer en vue de l'examen, en améliorant leur propre connaissance des questions et des paramètres qui revêtent en puissance une grande importance pour la sûreté ;
- tester la reproductibilité des résultats des exploitants ; et
- élargir les analyses effectuées par les exploitants en utilisant d'autres ensembles de valeurs des paramètres, et en étudiant les conséquences possibles d'autres modèles conceptuels.

Certaines autorités de sûreté sont d'avis qu'elles ont besoin de disposer d'une capacité indépendante d'évaluation des performances afin de démontrer au public leur aptitude à formuler un jugement de spécialiste sur l'EIP examinée. Ces autorités de sûreté escomptent aussi être à même de réduire les demandes de calculs supplémentaires à effectuer par les exploitants, du fait que leurs propres calculs internes permettront de résoudre certaines questions. Un dialogue est nécessaire lorsque des différences apparaissent entre les résultats des évaluations des exploitants et des autorités de sûreté, afin d'aplanir ces différences ou de comprendre les raisons qui les sous-tendent. Il incombe aux exploitants et aux autorités de sûreté d'expliquer ensemble au public le contexte dans lequel des différences sont constatées, en particulier, qu'il faut s'attendre à des différences et qu'un processus itératif d'examen indépendant devrait conduire à une confiance générale non pas moindre, mais plus grande.

Observations supplémentaires

En ce qui concerne la *conduite des examens*, les points suivants sont aussi relevés à partir de la compilation des réponses au questionnaire :

- La plupart des EIP examinées seront actualisées. Toutes les mises à jour d'EIP seront également examinées.
- En plus de l'examen mené par les autorités de sûreté, la plupart des EIP ont été examinées par d'autres organisations et groupements.
- La plupart des autorités de sûreté, mais non la totalité d'entre elles, ont pris et étaient censés prendre en considération d'autres sources d'informations, en plus de celles contenues dans l'EIP des exploitants.
- La plupart des autorités de sûreté ont eu recours à des consultants pour les aider dans le travail d'examen, mais ont aussi reconnu que les autorités de sûreté ont besoin de prendre possession des commentaires formulés à l'issue de l'examen de l'EIP.
- Dans la plupart des pays, les documents d'examen sont publiés et/ou versés aux archives nationales.

2.2 Aspects du dossier de sûreté

Questions et préoccupations techniques

Bien que de nombreuses questions et préoccupations techniques soient propres à un site ou un projet donné, les réponses au questionnaire de l'IPAG-2 relèvent plusieurs préoccupations qui revêtent un caractère plus générique et se retrouvent aussi dans les conclusions de plusieurs examens d'EIP. Parmi les plus importantes, on peut citer :

- une intégration insuffisante des programmes de recherches relatives au site et d'EIP ainsi que de leurs résultats ;
- l'adoption d'hypothèses susceptibles de manquer de conservatisme dans la modélisation ; et
- un scénario et/ou une analyse des incertitudes insuffisamment approfondis.

En ce qui concerne le défaut apparent d'intégration des efforts d'évaluation des performances et de caractérisation du site, il est observé que ce défaut d'intégration conduit à des problèmes dans deux voies. De nouvelles informations relatives au site ne sont pas toujours intégrées en temps voulu dans les modèles, et de nouveaux calculs systémiques ne sont pas toujours utilisés pour réorienter et cibler la caractérisation du site en vue d'obtenir les données les plus importantes. Il est manifeste que dans les premières phases, les calculs destinés à l'EIP peuvent devoir utiliser des données hypothétiques ou dérivées, parce que les activités de caractérisation du site n'ont pas encore fourni les données nécessaires. Les arguments et les calculs de l'EIP devraient toutefois être conçus de telle manière que leurs besoins en données puissent en principe être satisfaits par les études projetées de caractérisation du site. On peut venir à bout de ce problème en ayant recours à une communication par étape des données de manière à ce qu'on sache clairement sur quelle communication de données repose un ensemble déterminé de calculs utilisé dans l'EIP. Des problèmes analogues d'intégration peuvent se poser entre l'évaluation des performances et les activités de conception des systèmes ouvragés, mais ils n'ont pas été aussi fréquemment signalés dans les examens d'EIP.

On trouvera dans la Section 2.2, des commentaires généraux sur l'utilisation de méthodes empreintes de conservatisme par opposition à des méthodes réalistes. Une préoccupation particulière des auteurs des réponses au questionnaire de l'IPAG-2 a toutefois visé l'utilisation d'hypothèses simplificatrices qui, bien que paraissant empreintes de conservatisme dans les conditions escomptées et pour le scénario considéré, pourraient ne pas l'être dans d'autres circonstances. On a observé, par exemple, qu'il est difficile d'anticiper des conditions susceptibles de survenir au cours de la migration des radionucléides suivant un cheminement complexe, en particulier dans le cas de chaînes de radionucléides, et des hypothèses, qui sont empreintes de conservatisme pour des systèmes simples, ne le sont pas nécessairement pour des systèmes plus complexes, par exemple de faibles valeurs de la sorption sont généralement empreintes de conservatisme, mais des valeurs élevées de la sorption de ^{226}Ra dans des roches proches de la surface peuvent majorer les doses calculées.

En ce qui concerne les critiques visant le caractère insuffisamment approfondi du scénario et de l'analyse des incertitudes, elles sont motivées par le sentiment que les EIP traitent souvent de façon très approfondie et avec beaucoup de rigueur certains scénarios choisis, mais n'accordent pas suffisamment d'attention à l'étude exhaustive de l'éventail des scénarios qui pourraient se produire. Ainsi les responsables des examens ne sont pas à même de juger de la mesure dans laquelle les scénarios analysés sont représentatifs des devenirs possibles. Les participants à l'IPAG-2 se sont toutefois accordés à reconnaître que des progrès considérables sont actuellement réalisés dans la mise au point de méthodes systématiques d'élaboration de scénarios et ces dernières sont considérées comme constituant la base sur laquelle il sera possible à l'avenir de procéder une analyse plus équilibrée des scénarios.

Argumentation à lignes de force multiples

Les auteurs des réponses au questionnaire de l'IPAG-2 reconnaissent que le recours à une variété d'axes différents d'argumentation ainsi que de techniques et méthodes de modélisation revêt de l'importance si l'on veut susciter la confiance et, dans certains cas est requis pour démonter la sûreté à long terme. Parmi les méthodes et techniques d'évaluation des performances qui peuvent être utilisées pour élaborer une argumentation à lignes de force multiples afin de démontrer la conformité et la sûreté, on peut citer :

- des façons simples et directes d'aborder la démonstration de la sûreté ;
- une variété d'indicateurs ;
- les analogues naturels ;
- la paléohydrologie du site ;
- l'opinion d'experts ; et
- le consensus international.

Les opinions diffèrent toutefois quant à la mesure dans laquelle une argumentation à lignes de force multiples devrait contribuer à l'ensemble du dossier de sûreté. Certaines autorités de sûreté et certains exploitants estiment que le principal centre d'intérêt doit demeurer l'évaluation rigoureuse et détaillée des performances à long terme, car ils sont persuadés qu'il s'agit du seul type d'évaluation capable de fournir l'assurance technique requise pour juger de la conformité réglementaire. Pour ceux qui ont ainsi répondu, une argumentation à lignes de forces multiples peut être utilisée pour combler les lacunes non traitées par les analyses détaillées, fournir des arguments à l'appui, illustrer le degré de conservatisme dont le système est empreint, et aider à gagner la confiance du public. D'autres auteurs de réponses considèrent que l'argumentation à lignes de force multiples doit jouer un rôle plus crucial dans les évaluations de sûreté. Ils font valoir qu'étant donné la complexité des systèmes naturels et les horizons temporels éloignés en jeu, il est peu probable qu'à elle seule une quelconque analyse sera capable de susciter une confiance suffisante dans la sûreté à long terme d'une installation d'évacuation des déchets radioactifs. Il s'ensuit que le dossier de sûreté d'une installation d'évacuation des déchets radioactifs devrait se fonder sur un ensemble d'analyses complémentaires qui peuvent servir à démonter par une argumentation à lignes de force multiples que l'installation sera sûre. Deux autorités de sûreté ont déclaré dans leur documentation d'orientation qu'une argumentation à lignes de force multiples devrait faire partie des évaluations de sûreté.

Un dossier de sûreté relatif à une installation d'évacuation doit être axé sur la sûreté intrinsèque du système d'évacuation, et non pas uniquement sur les calculs détaillés utilisés pour démontrer la sûreté à long terme (voir Section 2.1). Un certain nombre de participants à l'IPAG-2 ont observé que le recours à une argumentation à lignes de force multiples peut aider à focaliser le dossier de sûreté sur la sûreté du système d'évacuation. Par exemple, des méthodes comme celles faisant appel aux analogues naturels et à la paléohydrologie mettent en exergue la sûreté intrinsèque des systèmes d'évacuation et sont complémentaires aux mesures détaillées des performances obtenues à l'aide des calculs d'évaluation.

Les participants à l'IPAG-2 ont relevé que, parmi les EIP existantes, peu nombreuses sont celles qui ont recours à d'autres indicateurs de sûreté, et un certain nombre de participants ont suggéré qu'il serait utile que le PAAG détermine et évalue les applications d'autres indicateurs potentiels de sûreté.

Variété des techniques d'évaluation

On dispose d'une variété de techniques pour évaluer les performances et la sûreté des systèmes d'évacuation des déchets radioactifs. *Alors qu'il subsiste des divergences d'opinions quant à la valeur relative des diverses techniques et méthodes de modélisation pour l'exécution d'évaluations, la plupart de ceux qui ont répondu au questionnaire de l'IPAG-2 estiment qu'une variété de techniques et de méthodes a sa place dans l'évaluation des performances.*

La plupart des méthodes ont recours à un modèle conceptuel et mathématique du système d'évacuation et comportent la mise au point du logiciel informatique et de la base de données connexes requis pour procéder à l'analyse. Des méthodes tant déterministes que probabilistes sont employées. Les calculs probabilistes peuvent fournir une analyse systématique des effets de l'incertitude entachant les paramètres de manière directe et exhaustive. On s'accorde en général à considérer toutefois que les calculs déterministes peuvent être plus transparents et sont plus faciles à expliquer. La mesure dans laquelle l'incertitude entachant un modèle conceptuel peut être évaluée dans le cadre de calculs probabilistes, présente des limites. Il convient plutôt de mettre au point et d'évaluer de façon séparée différents modèles du système d'évacuation. Dans de nombreux cas, le choix de la technique d'évaluation dépend des prescriptions réglementaires de chaque pays. Néanmoins, des méthodes tant déterministes que probabilistes peuvent concourir à la réalisation du dossier de sûreté relatif à l'évacuation de déchets radioactifs dans des formations géologique, et sont considérées comme des démarches complémentaires.

La modélisation d'un système d'évacuation varie du simple et empreint de conservatisme au complexe et réaliste. La plupart des auteurs de réponses ont constaté que ces deux façons d'aborder la modélisation étaient nécessaires dans une EIP. Une modélisation plus détaillée peut être complexe et difficile à justifier eu égard aux données disponibles ; des simplifications empreintes de conservatisme peuvent par conséquent s'avérer nécessaires afin de rendre plus solides les estimations des performances. Toutefois, afin de repérer les approximations ou hypothèses par trop empreintes de conservatisme, on a besoin d'une modélisation plus réaliste. Une telle modélisation peut aussi être requise pour optimiser des options en matière de conception du dépôt ou choisir entre elles.

Ce que l'on entend par « empreint de conservatisme » dans une EIP, a donné lieu à certaines controverses. Quelques auteurs de réponses préfèrent l'emploi du terme « pessimiste » et ont aussi relevé que la signification de l'expression peut varier d'un pays à un autre. En conséquence, afin de réduire l'ambiguïté, il serait utile de définir ces termes, ainsi que d'autres tels que « réaliste » et « estimé au mieux », dans la documentation d'une EIP.

Le choix des valeurs des paramètres d'entrée a aussi été examiné par le groupe. Certains auteurs de réponses utilisent des valeurs « empreintes de conservatisme », « réalistes » ou « estimées au mieux » dans leurs calculs déterministes, alors que d'autres comptent sur la démarche probabiliste afin d'obtenir un échantillon aléatoire sur une distribution de probabilité d'entrée déterminée. Certains estiment qu'il est difficile, voire impossible, de déterminer et de justifier la valeur « empreinte de conservatisme » pour chaque paramètre d'entrée dans un système d'évacuation complexe (voir aussi la Section 2.2).

Alors qu'il subsiste des différences d'opinion quant aux valeurs relatives des diverses techniques et méthodes de modélisation et de calcul dans les EIP, l'IPAG-2 a confirmé une conclusion de l'IPAG-1, à savoir qu'*il y a place pour une variété de techniques et de méthodes dans l'évaluation des performances, et que celles-ci peuvent être utilisées de manière complémentaire.* Toutes les évaluations des performances font appel à une variété de techniques et les spécialistes de ces évaluations apprécient à leur juste valeur les avantages relatifs, par exemple, de calculs probabilistes par comparaison à des calculs déterministes, et de modèles d'évaluation empreint de conservatisme par rapport à des modèles plus réalistes. Certaines évaluations des performances peuvent privilégier des techniques particulières pour des raisons pragmatiques mais, en général, l'intention n'a pas été d'exclure les autres méthodes.

Informations qualitatives et quantitatives

Les participants à l'IPAG-2 se sont accordés à reconnaître que des informations qualitatives sont nécessaires pour compléter les informations quantitatives, car il existe inévitablement des lacunes dans les informations « fiables » dont on dispose pour les analyses. C'est le cas pour les calculs aussi bien probabilistes que déterministes, de même que dans la mise sur pied de calculs empreints de conservatisme ou réalistes. Les informations et l'argumentation qualitatives constituent également d'ordinaire la base de certains des arguments invoqués à l'appui de la sûreté à long terme.

Par information qualitative, on entend toute information qui ne peut pas être observée directement ou qui ne peut pas être calculée directement à partir de données mesurées. L'information qualitative implique une part de jugement plus importante que les paramètres quantifiés d'un modèle, tels que la perméabilité, et est souvent établie à partir d'une synthèse de données mesurées et d'observations relatives au système. Il faut aussi souvent faire appel au jugement pour obtenir des valeurs numériques pour les paramètres quantitatifs d'un modèle. Par exemple, des outils interprétatifs sont requis pour estimer des valeurs de la perméabilité à partir de données d'essai de sondage. Il a été suggéré que les exploitants décrivent la mesure dans laquelle les données et les informations utilisées dans le dossier de sûreté se fondent sur des informations qualitatives, et expliquent le processus employé pour formuler des jugements.

Les scientifiques et les ingénieurs considèrent parfois l'information qualitative comme « incertaine », et d'une valeur moindre que l'information quantitative « fiable ». Étant donné que l'information qualitative est essentielle dans les évaluations de la sûreté à long terme, l'IPAG-2 a indiqué qu'il serait utile de rechercher des moyens permettant de mieux utiliser l'information qualitative. Plutôt que de considérer l'information qualitative comme étant inférieure à l'information quantitative, il convient d'y voir un type différent d'information qui peut servir à des fins différentes dans l'évaluation des performances. *L'IPAG-2 recommande que, dans une phase ultérieure, l'IPAG examine des moyens permettant à la fois de présenter et d'évaluer des arguments et des informations de caractère qualitatif afin d'en accroître la valeur dans le processus de prise de décision.*

Signification du principe des barrières multiples

Tous les participants à l'IPAG-2 ont souligné la nécessité d'un modèle à barrières multiples ou d'un système à barrière passive ayant des fonctions multiples en matière de sûreté. En outre, la réglementation exige habituellement des barrières multiples qui sont considérées comme un facteur important pour susciter la confiance dans la plupart des programmes nationaux d'évacuation des déchets radioactifs. Le Glossaire de la gestion des déchets radioactifs de l'Agence internationale de l'énergie atomique (AIEA) [AIEA, 1993] donne d'une barrière la définition suivante :

> « Un obstacle matériel qui empêche ou retarde le mouvement (par exemple, la migration) des radionucléides ou d'autres matières entre les composants d'un système, un dépôt de déchets, par exemple. En général, il peut s'agir d'une barrière ouvragée, qui est construite ou d'une barrière naturelle qui est inhérente à l'environnement du dépôt. »

Cette définition doit être étendue de manière à inclure des phénomènes chimiques, tels que les limites de solubilité qui empêchent ou retardent le mouvement des radionucléides. Le concept des barrières multiples est, par exemple, défini comme suit par la Division principale de la sécurité des installations nucléaires de la Suisse [DSN, 1993] :

> « Étayage de la sécurité d'un dépôt final par des barrières, tant ouvragées que naturelles, diverses par leur nature et qui, échelonnées, contribuent au confinement et à la rétention des radionucléides contenus dans les déchets. »

Ce concept exige que chacune des diverses barrières (par exemple, la forme des déchets, le conteneur, le matériau tampon, les milieux géologiques) contribue à la sûreté et que les diverses fonctions de sûreté présentent un certain degré de redondance eu égard au confinement et/ou à la rétention des radionucléides. De multiples fonctions en matière de sûreté sont conçues pour compenser les incertitudes entachant le comportement futur des diverses barrières ouvragées et du système naturel. L'IPAG-2 observe cependant que les barrières d'un dépôt ne peuvent pas être entièrement indépendantes et redondantes, car une installation d'évacuation à grande profondeur dans les formations géologiques est constituée par des composants passifs qui interviennent ensemble de manière complémentaire. Par exemple, les performances des barrières ouvragées peuvent dépendre des caractéristiques du milieu géologique alentour, et des barrières ouvragées et naturelles auront des interactions chimiques et mécaniques, tant à court terme qu'également à long terme après la fermeture du dépôt. Néanmoins, un objectif utile de la conception consiste à maximiser la mesure dans laquelle les fonctions des barrières sont indépendantes, et également de parvenir à une certaine redondance dans le cas des fonctions essentielles pour la sûreté.

Les participants à l'IPAG-2 ont relevé que les définitions existantes du concept de barrières multiples laissent subsister la possibilité d'erreurs d'interprétation entre spécialistes et parties prenantes de non-spécialistes. La difficulté lors de l'interprétation se présente lorsqu'il a confusion entre le concept de barrières multiples et le principe de la « défense en profondeur » utilisé dans la sûreté des réacteurs. Le principe de la défense en profondeur exige que les barrières multiples soient entièrement indépendantes et qu'il existe des barrières redondantes. C'est possible dans le cas d'un système de réacteur, car les réacteurs sont activement contrôlés et des barrières redondantes et indépendantes peuvent être conçues pour l'environnement d'un réacteur. Ce n'est pas possible dans un système de dépôt où l'évolution des barrières sur des milliers d'années doit être considérée.

Le concept de barrières multiples est l'un des fondements essentiels de la sûreté à long terme des systèmes d'évacuation à grande profondeur dans les formations géologiques et il est considéré comme important lorsqu'il s'agit de gagner la confiance dans l'ensemble. Toutefois, des parties prenantes de non-spécialistes peuvent considérer que la réalisation du concept de barrières multiples dans des systèmes réels d'évacuation n'est pas à la hauteur de leurs attentes, s'ils partent du principe de la défense en profondeur tel qu'il s'applique aux réacteurs, selon lequel les barrières peuvent et doivent être entièrement redondantes et indépendantes. *L'IPAG-2 recommande de mettre au point une définition du concept de barrières multiples qui énonce clairement qu'une indépendance et une redondance complètes ne sont ni nécessaires ni possibles* et qui décrive le concept dans le contexte de ce qui est réalisable et nécessaire dans un système d'évacuation dans des formations géologiques profondes. *L'IPAG-2 recommande également que les exploitants donnent dans les EIP une définition claire de leur interprétation du concept de barrières multiples.*

Les participants à l'IPG-2 ont formulé les observations suivantes concernant le concept de barrières multiples, qui peuvent contribuer à l'établissement d'une définition :

- L’application du principe de barrières multiples devait impliquer que des dommages modérés causés à une seule d’entre elles n’affectent pas notablement la sûreté globale du système d’évacuation ni les performances des autres barrières. De tels dommages modérés peuvent être imputables à une altération prévisible ou à un défaut initial d’une barrière. Le fait que les barrières réagiront différemment aux divers processus ou événements, qui peuvent menacer les performances requises du dépôt, constitue une caractéristique importante.
- Un certain degré de redondance est inhérent aux systèmes passifs à barrières multiples, car plusieurs phénomènes indépendants à l’intérieur d’une seule et même barrière peuvent avoir pour effet de retenir les radionucléides. Par exemple, les radionucléides peuvent être retenus à la fois par un transport lent (dû, par exemple, à une diffusion accompagnée d’une sorption) et par une immobilisation partielle (due, par exemple, aux limites de solubilité) à l’intérieur d’un matériau tampon. Les barrières peuvent aussi avoir plusieurs fonctions. par exemple, le matériau tampon autour des conteneurs de déchets est d’ordinaire conçu à la fois pour protéger le conteneur et pour retenir les radionucléides.
- Les barrières multiples dans les dépôts de déchets nucléaires ne sont pas censées compenser entièrement des défaillances catastrophiques (de faible probabilité) d’autres barrières. Ce sont les performances totales du dépôt qui comptent même après de telles défaillances.

Méthodes « stylisées » et « standardisées »

Tous les travaux de modélisation et de calcul relatifs à l’évaluation des performances impliquent un certain degré d’abstraction par rapport à la réalité et sont de ce fait « stylisés » au sens général du terme. Dans le rapport de l’IPAG-1[AEN, 1997] la signification plus spécifique suivante est donnée à ce terme :

> « Par présentation stylisée, on désigne une situation où une partie du système d’évacuation est traitée dans l’évaluation des performances de façon standardisée ou simplifiée. Il est nécessaire de recourir à des présentations stylisées lorsqu’il existe un manque général de preuves expérimentales tel que les décisions sur le traitement et les valeurs des paramètres introduits dans l’évaluation des performances revêtent un caractère hautement subjectif. »

L’IPAG-2 conclut qu’il est utile de conserver cette signification particulière, et souscrit à la définition ci-dessus ainsi qu’aux autres déclarations relatives aux présentations stylisées figurant dans le rapport de l’IPAG-1. Par exemple, le rapport de l’IPAG-1 stipule que « l’acceptabilité des présentations stylisées ne peut pas être décidée par la seule communauté des spécialistes de l’évaluation des performances ». Certaines précisions supplémentaires peuvent toutefois être apportées.

D’une façon générale, des calculs stylisés donnent un aperçu de la manière dont le système d’évacuation pourrait fonctionner dans les conditions prescrites, éventuellement hypothétiques.

Le recours à des méthodes stylisées est motivé par l’existence d’une incertitude qui, d’un commun accord, est considérée soit comme n’étant pas pertinente pour le processus de décision, soit comme ne devant pas l’affecter outre mesure. A titre d’exemple, on peut citer l’adoption de l’homme standard et des facteurs dosimétriques de la Commission Internationale de Protection Radiologique

(CIPR) qui négligent l'incertitude (et la variabilité) entachant le métabolisme. Dans ce cas, la méthode est également « standardisée », car il s'agit d'une méthode commune admise au plan international.

L'adoption d'un ensemble déterminé d'hypothèses en vue d'obtenir à titre d'exemple un calcul de l'intrusion humaine, constitue un autre exemple. Il existe en l'occurrence une incertitude importante et irréductible concernant les actions humaines futures, mais un ou plusieurs calculs stylisés peuvent être effectués afin d'illustrer des cas spécifiques. Les façons d'aborder l'intrusion humaine sont standardisées dans la mesure où l'on s'accorde à reconnaître que seules les technologies humaines actuelles ou passées doivent être prises en considération dans les évaluations. La stylisation des calculs relatifs aux intrusions humaines est toutefois susceptible d'être propre à un concept ou un site particulier.

L'IPAG-1 a recommandé que le PAAG cherche à savoir si une coopération en vue d'établir des présentations stylisées destinées à servir à l'évaluation des performances, suscite de l'intérêt. Les réponses au questionnaire de l'IPAG-2 montrent qu'il n'est pas possible, dans la pratique, de mettre au point des scénarios *standardisés* pour l'évacuation dans des formations géologiques profondes qui soient acceptables dans tous les programmes. *Les échanges de vues au cours de la quatorzième réunion du PAAG ont montré que les efforts en vue de mettre au point des méthodes standardisées afin de faciliter le traitement de certains aspects et composants du dossier de sûreté continuent de susciter de l'intérêt*. Par exemple, le PAAG appuie fortement les efforts du projet BIOMASS visant à mettre au point des biosphères de référence qui impliquent l'adoption d'hypothèses standard.

Observations complémentaires

En ce qui concerne le *traitement des incertitudes et autres aspects techniques* dans le dossier de sûreté, les observations suivantes se dégagent de la compilation des réponses :

1. Il subsiste certaines différences de vocabulaire concernant la signification des incertitudes entachant les scénarios ; certaines définitions insistent sur l'évolution dans le temps, alors que d'autres privilégient la détermination des caractéristiques, événements et processus (CEP). Il ne semble cependant pas productif de s'efforcer de parvenir à davantage de convergence dans le vocabulaire, étant donné que les programmes nationaux prennent en compte dans les EIP à la fois l'exhaustivité des CEP et l'incertitude entachant l'évolution dans le temps. Certaines organisations considèrent par principe qu'il incombe aux exploitants de mettre au point la méthode permettant de traiter l'incertitude, et donc de définir la terminologie qu'ils emploient.
2. Il a été suggéré d'introduire la notion d'incertitude systémique afin de couvrir la question de l'exhaustivité de la description du système. Cette idée n'a guère suscité d'adhésion car la plupart des organisations considèrent que la question est déjà couverte par les définitions de l'incertitude entachant les modèles conceptuels et de celle relative aux scénarios.
3. Le moyen préconisé pour mettre au point et choisir des scénarios consiste en général en une méthode structurée et transparente de détermination des CEP et de leurs combinaisons dans des scénarios. Des techniques supplémentaires ont aussi été appliquées. Les opinions diffèrent quant aux besoins et possibilités d'estimer les probabilités des scénarios et l'opportunité de regrouper de telles estimations dans un cadre probabiliste.
4. L'incertitude entachant le modèle conceptuel est généralement traitée grâce au recours à un éventail varié de modèles ou à la formulation d'hypothèses empreintes de

conservatisme. Les difficultés tiennent à la démonstration du fait que l'analyse des variantes est exhaustive ou que les hypothèses formulées sont empreintes de conservatisme.

5. Les scénarios ayant de fortes conséquences et une faible probabilité sont habituellement évalués de manière détaillée.
6. Dans aucune des réponses au questionnaire de l'IPAG-2, on n'a préconisé l'application de l'analyse des modes de défaillance aux systèmes d'évacuation, mais il a été suggéré dans certaines que les techniques d'analyse des modes de défaillance peuvent être utilisées pour vérifier l'exhaustivité des scénarios et des CEP recensés. Quelques-unes ont été plus directement défavorables à l'application de l'analyse des modes de défaillance à un dépôt dans les formations géologiques, parce qu'il est difficile de concevoir de quelle manière des barrières telles que la formation géologique réceptrice pourrait « devenir défectueuse ».
7. Les auteurs de certaines réponses ne voient guère d'application directe pour les analogues naturels en tant qu'argument de première ligne dans le dossier de sûreté, alors que d'autres considèrent qu'ils sont d'un intérêt plus direct.

2.3 Traçabilité et transparence

Tous les auteurs de réponses au questionnaire de l'IPAG-2 s'accordent à considérer que les EIP établies à des fins d'autorisation doivent être traçables, reproductibles et de préférence à la disposition du public. Les autorités de sûreté et d'autres parties prenantes devraient être à même de reproduire l'EIP, en totalité ou en partie, à partir des informations publiées ou à la disposition du public. Les autorités de sûreté continuent cependant à éprouver des difficultés à retrouver les résultats et la logique dans les EIP, même si les exploitants ont redoublé d'efforts en vue de conférer de la traçabilité aux EIP. Les autorités de sûreté comptent bien être à même de suivre à la trace et de comprendre les données et le processus de décision afin de rattacher les aspects de l'EIP aux données brutes et à la démarche logique utilisées pour les hypothèses et les décisions à la base de l'évaluation. Ainsi, les exploitants doivent conférer un haut degré de traçabilité à l'ensemble de l'EIP. Ils doivent également veiller à ce que la « comptabilité » complète requise pour une traçabilité intégrale ne vienne pas obscurcir la transparence de l'EIP pour les autorités de sûreté et d'autres parties prenantes.

Difficultés pour atteindre le niveau de traçabilité souhaité par les autorités de sûreté

Les autorités de sûreté et les examinateurs techniques, qui prêtent leur concours aux décideurs, constituent les tous premiers destinataires des EIP. Pour ce public, il importe que les arguments soient complets et techniquement défendables, et que les analyses puissent être comprises dans leur conception, leur exécution, leur bilan et leur interprétation. D'autres interprétations conceptuelles possibles des données, et une investigation des possibilités raisonnables, par exemple l'explication d'événements à faible probabilité, font partie de l'étude complète du système et de son comportement dans un avenir lointain.

Il est difficile de parvenir à ce niveau de traçabilité dans une EIP exhaustive. L'évolution future du système doit être évaluée, et il faut une justification pour les valeurs et les distributions des paramètres qui sont retenues, les processus et les événements pris en considération dans le temps, ainsi que les couplages ou l'absence de couplages de ces processus et événements dans les analyses. La présentation et l'interprétation des résultats constituent une tâche délicate, car il est nécessaire de décrire tant les limitations des analyses que leurs points forts et leur importance dans des termes qui ont trait à la santé et à la sécurité du public, aux incidences sur l'environnement et au risque potentiel.

Le processus de décision au plan réglementaire est passé au crible par le public et les autres parties prenantes. Le processus gagne en crédibilité si les parties prenantes ont le sentiment que les décisions réglementaires sont fondées sur un examen méthodique et très complet des risques potentiels. La documentation de l'EIP devrait donc être claire et compréhensible également pour un large éventail de parties prenantes, s'agissant en particulier des questions de sûreté.

Les exploitants ont une tâche difficile. Le processus d'obtention et de manipulation des données doit donner lieu à l'établissement d'une documentation détaillée, de manière à permettre à un expert indépendant de reconstruire le travail effectué et de suivre les interprétations et les hypothèses formulées. Il s'agit notamment de documenter la manière dont on est parvenu à l'interprétation des données, aux modèles des sous-systèmes et de l'ensemble du système, par exemple à l'abstraction et la simplification des modèles, ainsi qu'à l'expérimentation de ces derniers. L'expérimentation des modèles peut impliquer l'essai de plusieurs autres modèle afin de démontrer que la méthode choisie convient au problème. Les modèles peuvent également être étalonnés par rapport à d'autres modèles plus détaillés ou par rapport à des ensembles de données différents.

Moyens de parvenir à la traçabilité requise

Il convient d'utiliser des méthodes bien définies et documentées pour cerner les caractéristiques et les processus, concevoir et instrumenter des essais et des expériences, interpréter les résultats d'essais, construire des modèles conceptuels, ainsi qu'analyser et évaluer ces modèles. S'il existe des écarts, la nature, l'étendue et les raisons doivent en être enregistrés. Cela fait d'ordinaire partie d'un programme d'assurance de la qualité.

L'exhaustivité, qui influe tant sur la transparence que sur la traçabilité, peut être améliorée grâce aux examens par des pairs. Ces examinateurs doivent posséder les qualifications requises pour procéder aux examens, mais ne devraient pas être associés à une quelconque partie importante des travaux examinés.

Les références aux documents relatifs au projet ou à d'autres publications doivent être exactes. Elles devraient inclure le numéro de la page ou de la section, le cas échéant.

Incidences sur la transparence pour les autorités de sûreté et d'autres parties prenantes

Comme cela est indiqué plus haut, les documents relatifs à l'EIP sont avant tout rédigés à l'intention des autorités de sûreté et des examinateurs techniques. Ces examinateurs devraient normalement être bien informés du sujet et être capables de comprendre les informations présentées dans les documents relatifs à l'EIP. Toutefois, la complexité technique ou une piètre présentation peuvent rendre difficile de suivre l'argumentation et les exposés dans l'EIP, même pour ces examinateurs. En particulier, l'exigence d'une traçabilité complète peut obscurcir des arguments et résultats essentiels, et donc nuire à la transparence.

Parmi les autres parties prenantes peuvent figurer des personnes du public, des groupements intéressés, des politiciens et des experts hautement qualifiés. Il s'agit donc d'un groupe assez hétérogène. Ces parties prenantes abordent l'EIP de points de vue très différents et peuvent formuler des jugements en utilisant des systèmes de valeur différents. Pour communiquer les résultats de l'EIP, notamment les estimations des risques après fermeture et leurs bases, à des parties prenantes de non-spécialistes, il faut que ceux qui sont chargés de le faire, comprennent la manière dont ces parties prenantes recevront et traiteront les informations techniques, afin de faire en sorte que des modes de présentation appropriés puissent être élaborés et mis en œuvre. Par l'intermédiaire d'une interaction avec un groupe représentatif de ces parties prenantes de non-spécialistes, il peut être possible de comprendre comment le public réagit aux informations de l'EIP, notamment les facteurs qui influent sur ces réactions. Des efforts de cette sorte sont susceptibles de permettre d'élaborer les types d'information qui faciliteront la communication de l'EIP et de ses résultats au grand public.

Des capacités rédactionnelles particulières sont requises pour établir les documents de synthèse des EIP de telle manière que des parties prenantes de non-spécialistes puissent comprendre les notions présentées, évaluer l'installation d'évacuation proposée dans le contexte d'autres risques et décisions pris par la société, et leur permettre de se forger des opinions objectives et indépendantes sur les problèmes. Il a été suggéré que des rédacteurs techniques qualifiés et des journalistes possédant l'expérience de la rédaction pour des revues scientifiques connues devraient être associés à la préparation de la documentation relative à l'EIP à l'intention des parties prenantes de non-spécialistes. Lors de la préparation de ces documents, il est d'ordinaire difficile de concilier les exigences qu'implique le fait, d'une part, d'être aisément intelligible et, d'autre part, de fournir des informations complètes. Pour faire en sorte que les messages essentiels demeurent clairs, il faut accepter de perdre un certain degré de détail et de nuance.

On s'accorde à reconnaître que la documentation n'est qu'un élément du dialogue avec le public, et que la question du dialogue avec le public et d'autres parties prenantes de non-spécialistes sort du cadre des attributions de l'IPAG-2. L'IPAG-2 observe toutefois que les interactions avec ces parties prenantes prennent une importance croissante à mesure que des sites potentiels de dépôt sont choisis et que des décisions réglementaires sont prises concernant ces sites. *L'IPAG-2 recommande que le PAAG et/ou le RWMC étudient plus en détail des méthodes et des techniques permettant de se pencher sur les besoins du public et des autres parties prenantes de non-spécialistes dans les EIP.*

Observations complémentaires

En ce qui concerne la *documentation* relative aux EIP et aux examens des EIP, les observations suivantes se dégagent de la compilation des réponses :

1. Le recours à une structure hiérarchisée est en général considéré comme bénéfique.
2. Nombreux sont ceux qui sont d'avis que la structure des documents relatifs à l'EIP pourrait probablement être la même aux différents stades de l'aménagement d'un dépôt, encore que certaines parties du rapport doivent être plus détaillées aux stades ultérieurs. D'autres laissent entendre qu'aux premiers stades, l'EIP est axée sur les problèmes et les orientations futures des travaux de recherche et de développement, alors qu'au stade de l'autorisation on pourrait escompter une structure qui privilégie les prescriptions réglementaires.
3. Les auteurs des réponses s'accordent à considérer que la liste des éléments à faire figurer dans l'EIP, qui a été proposée par l'IPAG-1 [AEN, 1997], demeure valable et n'a pas besoin d'être révisée.

2.4 Orientations d'ordre réglementaire

Les autorités de sûreté comme les exploitants ont cerné un certain nombre de finalités pour des orientations d'ordre réglementaire et d'avantages à en tirer.

Nature des orientations requises

Il convient de mettre au point par étapes des orientations d'ordre réglementaire à partir de principes très généraux pour aboutir à des orientations applicables à l'examen d'une demande d'autorisation. Le fait de soumettre un projet d'orientations à un processus officiel de consultation des parties intéressées, notamment les exploitants, d'autres autorités de sûreté et le public, devrait contribuer à faire en sorte que ces orientations soient pragmatiques et suscitent l'adhésion nécessaire. Cela est aussi de nature à rendre le processus ultérieur d'examen réglementaire plus crédible aux yeux du public.

Les orientations d'ordre réglementaire doivent indiquer clairement les exigences, les attentes et les options afférentes à la démonstration de la conformité aux principes et critères réglementaires. Elles constituent la base du dialogue entre autorités de sûreté et exploitants qui devrait s'instaurer pendant le processus d'aménagement du dépôt.

Ces orientations ne devraient pas revêtir un caractère par trop directif. La charge de la preuve incombe aux exploitants et, en conséquence, les exploitants ne devraient pas se trouver indûment limités quant aux types de méthodes et de techniques utilisées pour démontrer la sûreté à long terme. Les orientations peuvent cependant présenter et examiner les opinions et les préférences générales des autorités de sûreté concernant l'évaluation des performances et l'établissement du dossier de sûreté. Une certaine souplesse est souhaitable afin de tenir compte des progrès de la technologie et des modifications éventuelles apportées au mode d'évacuation. Des orientations souples exigeront des révisions moins fréquentes, ce qui peut aussi accroître la crédibilité aux yeux du public.

Les grandeurs de référence réglementaires en matière de doses et de risques, par exemple, sont normalement définies dans des règlements impératifs. Des orientations d'ordre réglementaire sont nécessaires pour commenter et clarifier des prescriptions réglementaires, et décrire des méthodes acceptables pour démonter la conformité aux grandeurs de référence. Il convient aussi de fournir des avis sur la façon de satisfaire des exigences plus qualitatives, ayant trait, par exemple, à la sélection du site, à la mise au point du modèle de dépôt et à l'application des prescriptions en matière de barrières multiples.

Ces orientations peuvent indiquer des méthodes ou des techniques préférentielles pour l'exécution de l'EIP ou fournir des conseils visant des aspects spécifiques comme l'analyse de scénarios, le traitement des incertitudes ou la définition des groupes critiques ou des biosphères de référence. En particulier, les exploitants ont exprimé le souhait d'avoir des orientations visant le traitement de questions « abstraites » et de problèmes entachés d'une incertitude élevée et irréductible, tels que l'intrusion humaine. Les éléments qu'il est recommandé d'inclure dans les EIP pourraient aussi être ébauchés dans des orientations réglementaires, spécialement au stade de la démonstration formelle de la conformité.

Une cohérence des orientations réglementaires au plan international est souhaitable. Les organisations internationales, en particulier l'AEN, l'AIEA et la CIPR, ont notablement contribué à une telle harmonisation. La nature et le contenu des orientations sont cependant influencés par des facteurs nationaux, tels que la pratique réglementaire, le mode d'évacuation et le stade d'aménagement du dépôt. Les différences apparentes relevées entre les orientations formulées dans différents pays peuvent en grande partie s'expliquer par ces facteurs.

Observations complémentaires

En ce qui concerne l'élaboration d'*orientations réglementaires,* les observations suivantes sont également formulées :

1. Les auteurs de réponses s'accordent à considérer qu'il appartient aux autorités de sûreté d'élaborer des orientations et que les exploitants et autres parties prenantes devraient pouvoir formuler des commentaires sur les propositions avant que les orientations ne soient définitivement arrêtées. Le processus à suivre pour élaborer des orientations réglementaires est souvent prescrit dans la législation en vigueur. Dans certains pays, les exploitants jouissent d'un statut spécial dans ce processus en tant que l'une des parties prenantes concernées au premier chef. Dans d'autres pays, le statut des exploitants n'est que le reflet de leurs compétences spécifiques en matière d'évacuation des déchets radioactifs.
2. Tous sont d'accord pour estimer que les autorités de sûreté ont le droit d'actualiser ou de modifier des orientations réglementaires. D'une façon générale, les mêmes procédures s'appliquent à la mise à jour des réglementations qu'à leur publication initiale. Le formalisme de ces procédures varie d'un pays à un autre. Les exploitants insistent sur la nécessité de procédures transparentes pour la révision des orientations réglementaires. Certains autorités de sûreté estiment que les orientations réglementaires et autres notifications formulées avant une décision d'autorisation sont inopposables aux autorités de sûreté.

3. CONSIDÉRATIONS FINALES

3.1 L'expérience de l'IPAG-2

La méthode du groupe de travail appliquée dans le cas de l'IPAG-2, offre un excellent cadre pour compiler, examiner et analyser des informations, et pour formuler des conclusions et des recommandations, comme ce fut aussi l'une des conclusions du rapport antérieur de l'IPAG-1 (AEN, 1997). En particulier, la méthode du groupe de travail a donné aux participants la possibilité de prendre conscience des pratiques et des opinions d'un certain nombre d'agences des déchets et d'autorités réglementaires concernant l'établissement des EIP et leur examen, et d'obtenir des connaissances de première main des données d'expérience obtenues par ces organisations à la suite de leurs processus d'examen des EIP. Le nombre d'organisations qui ont pris part aux travaux, la qualité et le caractère approfondi des réponses au questionnaire et les contributions fournies en temps voulu à l'établissement du présent rapport, témoignent de l'intérêt de l'IPAG-2.

Le délai qui s'est écoulé entre la première réunion du groupe de travail ad hoc chargé de l'IPAG-2 (mai 1997) et la session thématique du PAAG récapitulant les résultats du groupe (octobre 1998) a été inférieur d'un an approximativement au délai correspondant pour l'IPAG-1 (février 1994 à octobre 1996). Cette efficacité accrue peut être attribuée aux enseignements tirés de l'exécution de l'IPAG-1. En particulier, l'IPAG-2 a gagné du temps en chargeant un groupe restreint d'élaborer et de tester le questionnaire avant d'y associer les autres participants de l'IPAG-2.

Les observations et recommandations formulées à la suite des travaux de l'IPAG-2 ne sont peut-être pas aussi ciblés et précis que ceux résultant de l'exécution de l'IPAG-1 (voir AEN, 1997). Cela dénote le caractère plus subjectif et plus subtil du processus d'examen des EIP par rapport à l'activité technique que constitue l'exécution réelle d'une EIP pour laquelle on a amassé une plus grande expérience. Ce fait peut aussi s'expliquer par les démarches plus variées adoptées à l'égard de l'examen et des pratiques de l'EIP par les différentes organisations nationales qui ont participé à l'IPAG-2.

3.2 Comparaison des résultats de l'IPAG-1 et de l'IPAG-2

La seule question directe dans le questionnaire de l'IPAG-2 visant le bien fondé des observations et recommandations de l'IPAG-1 avait trait aux éléments devant figurer dans une EIP. La plupart des participants à l'IPAG-2 ont souscrit à la liste générale de ces éléments proposée par l'IPAG-1, quelques-uns estimant nécessaire de réviser cette liste. Les mises à jour suggérées portent principalement sur l'intégration d'informations concernant la phase opérationnelle et la fermeture du dépôt. Des prescriptions réglementaires propres à chaque pays auront aussi un effet sur la structure d'une EIP. Certaines autorités de sûreté n'ont pas l'intention de diffuser de quelconques orientations visant la structure ou le contenu des EIP, car elles estiment que les exploitants devraient avoir la latitude d'adapter la structure et la liste des éléments de manière à présenter au mieux le dossier de sûreté.

Plusieurs questions concernant la traçabilité et la transparence, ainsi que le traitement des incertitudes, ont été évaluées aussi bien par l'IPAG-1 que par l'IPAG-2. Les enseignements tirés et les recommandations formulées par l'IPAG-2 à propos du traitement des incertitudes confirment les constatations faites par l'IPAG-1. Toutefois, l'IPAG-2 traite de manière plus approfondie un certain nombre de sujets, notamment l'argumentation à lignes de force multiples, le recours au principe des barrières multiples, l'utilisation de méthodes stylisées et standardisées, ainsi que la place relative faite à l'EIP technique et à la sûreté « intrinsèque ou inhérente » d'un dépôt, sur lesquels il formule des recommandations

L'examen de la traçabilité et de la transparence, dans le présent rapport, s'appuie sur les définitions établies et les conclusions dégagées au sein de l'IPAG-1. Il a toutefois été possible d'approfondir les enseignements et les observations à l'aide des connaissances et des opinions des autorités de sûreté (soulignant le besoin de traçabilité), de récentes expériences de la recherche d'un équilibre entre traçabilité et transparence dans les EIP, et grâce à la communication des contenus des EIP au public ainsi qu'à d'autres parties prenantes de non-spécialistes.

3.3 Suggestions relatives à une nouvelle phase de l'IPAG

Les participants à l'IPAG-2 ont examiné les activités éventuelles qui pourraient utilement être poursuivies dans le cadre de l'IPAG et ont mis au point un certain nombre de suggestions qui ont alors été débattues lors de la quatorzième réunion du PAAG en octobre 1998.

La possibilité de recommencer un examen du type de celui de la Phase 1 de l'IPAG a été envisagée. Il a été décidé que cela n'est pas opportun pour le moment, mais que cela pourrait être reconsidéré à l'automne de l'an 2000, époque à laquelle un ensemble plus important de nouvelles EIP devrait être disponible.

La Phase 1 a porté sur l'exécution des EIP et la Phase-2 sur l'examen par des pairs des EIP, principalement à l'appui de l'examen réglementaire. Un prolongement logique pour une Phase 3 pourrait par conséquent consister à réfléchir aux besoins du public et des autres parties prenantes dans l'EIP. Il s'agirait de couvrir des questions telles que :

- comment convient-il d'associer d'autres parties prenantes à l'EIP et au processus de décision ?
- de quelles informations ces autres parties prenantes ont-elles besoin ?
- comment les résultats et conclusions de l'EIP peuvent-ils être présentés aux autres parties prenantes ?

Il a été conclu que l'exécution appropriée de cette activité exigerait la mobilisation d'un ensemble de compétences et d'organisations plus large que celles qui sont représentées au sein du PAAG. En outre, ces travaux vont dans le sens de la ligne d'action à laquelle le RWMC est en train de réfléchir. Le PAAG estime par conséquent qu'il appartient davantage au RWMC d'examiner les possibilités de travaux dans cette voie. Le PAAG apportera le soutien technique nécessaire.

Il ressort des débats au cours de la séance thématique sur l'IPAG-2 lors de la 14ème réunion du PAAG, que les membres du PAAG sont très intéressés par le maintien du groupe de travail IPAG, mais que ce groupe devrait s'en tenir à des questions techniques. En particulier, l'IPAG pourrait poursuivre l'étude de sujets qui, au cours de l'IPAG-2, ont été jugés d'une importance critique lorsqu'il s'agit de susciter la confiance dans les EIP. Parmi ces domaines figurent :

- la démonstration de la sûreté et de la qualité intrinsèques du site et du modèle – quelles sont les stratégies permettant de démontrer la sûreté et la qualité intrinsèques et comment convient-il de cibler l'EIP pour faire cette démonstration ?

- la présentation et l'évaluation des données et arguments qualitatifs – réfléchir à des méthodes permettant de présenter et d'évaluer des données et des arguments qualitatifs de manière à en accroître la valeur dans les EIP et la prise de décision au plan réglementaire ;
- les autres axes possibles d'argumentation – étudier les méthodes et techniques utilisées par les exploitants, les autorités de sûreté et d'autres examinateurs afin de fournir d'autres axes possibles d'argumentation démontrant que les systèmes d'évacuation seront sûrs à long terme. Il pourrait s'agir de calculs exploratoires et visant à déterminer des valeurs limites supérieures, d'autres indicateurs de sûreté, de la paléogéologie, des analogues naturels, d'arguments simplifiés établis à l'intention des parties prenantes de non-spécialistes, du recours à des informations qualitatives, d'informations sur la sûreté intrinsèque et inhérente d'un mode d'évacuation et des données environnementales existantes ;
- la mise au point d'exemples destinés à éclairer le cadre proposé dans le document de l'AEN sur les aspects techniques de la confiance dans la sûreté à long terme des dépôts dans des formations géologiques profondes (AEN, 1999)

Tous ces aspects pourraient relever d'une rubrique générale intitulée :

« Arguments utilisés pour asseoir la confiance dans les EIP ».

Il a été convenu, à l'assentiment général, d'établir un groupe de travail ad hoc chargé d'approfondir ce thème en 1999 et de faire rapport au PAAG lors de sa réunion de l'automne 1999. La nouvelle phase de l'IPAG consisterait donc à inventorier et à classer par catégorie les méthodes et les arguments utilisés à l'appui, et à déterminer comment et pourquoi ils ont été employés. Les avantages qui en résultent devaient être documentés, parallèlement aux limitations connexes.

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Appendix A

COMPILATION OF THE ANSWERS TO THE QUESTIONNAIRE

1. CONTEXT AND APPROACHES

1.1 Context

Participating organisations and IPAs reviewed

The experiences and views of both implementers and regulators on regulatory reviews of Integrated Performance Assessments (IPAs) are the focus of Phase 2 of the OECD/NEA Working Group on the Integrated Performance Assessments of Deep Repositories (IPAG-2). In total 7 different reviewers and 10 different producers of IPAs, listed in Table 1.1, have responded to a questionnaire prepared within the project. This appendix compiles the answers to those questions. Table 1.1 also displays which IPAs were reviewed and the main purpose of these IPAs. The Annex at the end of this appendix contains full references to the IPAs and reviews concerned.

All IPAs reviewed were produced by organisations developing or seeking to develop repositories for nuclear waste. All reviews were domestic. Apart from GRS, who act as a consultant to the licensing authority, the reviewers participating in IPAG-2 are the national regulator. Usually, but not always, both the developer of the IPA and the corresponding reviewer have both answered the questions. As further discussed in section 1.1 most IPAs have also been reviewed by other bodies. The experiences of these other reviews are generally not covered by the IPAG-2.

It is also acknowledged that the information provided in the answers and in this compilation only represents a snapshot in time. IPAs and reviews of IPAs are expected to further evolve in the future.

Purpose of IPA and expectations

Table 1.1 outlines the purposes of the different IPAs and their reviews. The different IPAs concern different types of waste and have been prepared and reviewed in different stages of repository development.

In one case (NRI) the purpose has been to provide feedback to R&D in an early stage of development. In some cases (TVO-92/TILA-96, NR337, TSPA-95, PNC H3) the IPA was issued as a step in the R&D programme and the role of review was mainly to obtain feedback to this programme. In one case (AECL EIS) the IPA was part of an environmental impact statement prepared in order to evaluate the safety and acceptability of a disposal concept. In one case (Nagra Wellenberg) the IPA was used in support of an application for general license and site selection. For the remaining cases (SKB SFR, DOE/WIPP and BfS Konrad) the IPA has been prepared directly in support of an operational license application. The reviews have generally been performed in a context corresponding to the respective IPA objectives.

Table 1.1: **Organisations providing answers to questionnaire; IPAs reviewed; and purpose of IPA and reviews.** (*The Annex contains full references to the IPAs and reviews concerned*)

Implementer	Reviewer	IPA	Purpose of IPA and review
VTT (on behalf of Posiva the Finnish implementer), Finland	STUK, Finland	TVO-92 and TILA-96 on spent fuel disposal in crystalline rock.	Background for selection of sites for more detailed investigation. Feedback to R&D.
SKB, Sweden	SKI, Sweden	SFR repository for operational waste (LLW and ILW).	To permit full-scale operation. (Operational license had stipulations).
Nagra (on behalf of GNW) Switzerland	HSK, Switzerland	Repository for LLW and ILW at Wellenberg.	Application for General license (site selection and general outline of project) and Cantonal concession for the use of the underground.
NRI, Czech Republic		EIA documentation.	Feedback to R&D at an early stage of development.
Ontario Hydro, Canada (IPA was prepared by AECL)	AECB, Canada	AECL EIS on the concept for disposal of Canada's nuclear fuel waste.	Safety and acceptability of AECL's concept for disposal. A federal review panel made recommendations on the future steps to be taken with respect to the management of nuclear fuel waste in Canada.
DOE/YM, USA	USNRC, USA	TSPA-95 evaluation of the potential Yucca Mountain repository.	Aid regulator and applicant to prepare for licensing. TSPA-1995 focused on components determined by previous analyses to be most significant.
DOE/WIPP, USA	US EPA (did not participate in IPAG-2)	Compliance Certification Application (CCA) for the WIPP repository for TRU-waste.	The IPA served as the basis in the CCA for demonstrating compliance with the quantitative requirements of the EPA's regulations, 40 CFR 191 and 194.
BfS, Germany	GRS, Germany	Konrad repository for LLW and ILW.	Part of license application of the repository.
UK Nirex, UK	UKEA ,UK	NR 337, a preliminary assessment of the post-closure performance of a potential deep waste repository at Sellafield.	HMIP (now UKEA) undertook a review of the Nirex documents to test and develop its regulatory assessment capabilities.
PNC, Japan (Implementer will be decided after 2000)	ACRWM of AEC, Japan (did not participate in IPAG-2)	H3, updated knowledge on Japan's geological environment, the technology of geological disposal and the performance assessment of the multi-barrier system.	A basis for the further research and development with the objective of confirming scientific and technical feasibility of the geological disposal concept in Japan.

Update of assessment

Most of the IPAs reviewed will be updated. All IPA updates will also be reviewed.

Clearly all IPAs mainly being part of the implementers' R&D programmes (TVO-92/TILA-96, DOE/YM TSPA-95, Nirex NR 337, PNC H3) were followed by updates, or will be in the relatively near future (between 1998–2000). Also for assessments carried out at a specific stage of repository development an updated assessment is expected at the next major step in development. The NRI review of the reference disposal system is not finished. By law in the Czech republic, updated IPAs and reviews are related to final site definition, start of construction, pre-operational state, start of operation, operation and closure. For Nagra Wellenberg the next IPA will be produced after an exploratory drift has been excavated and the corresponding data have been analysed. No update is foreseen on the AECL EIS.

It is stipulated that the SKB's SFR IPA has to be updated every 10 years, starting in 2000, and the assessment must be updated again at closure. The Konrad IPA is considered final, although the license may include certain conditions concerning further verification of data, etc.

Reviewed by others

Most of the IPAs were also reviewed by other bodies. Such reviews range from voluntary internal reviews, international reviews carried out by OECD/NEA or IAEA, reviews or oversight by national committees and to an extensive review process including a broad range of government departments, organisations and members of the public.

Compilation of answers

Some IPAs were only reviewed by one body. The SKI reviewed the SKB SFR jointly with the Swedish Radiation Protection Institute (SSI), but no other body reviewed the assessment. The UK Nirex NR 337 was only reviewed by UKEA. The PNC H3 was reviewed by the Atomic Energy Commission of Japan.

The TVO reports and plans of 1992 were reviewed also by a review team of IAEA's Waste Management Assessment and Technical Review Programme (WATRP). The reviews were co-ordinated by the Ministry of Trade and Industry.

The safety analysis as well as HSK's review were reviewed by the Swiss Federal Nuclear Safety Commission (KSA), an advisory body to the Federal Government. HSK kept KSA informed of the progress during the HSK review. The IPA was also evaluated by an oversight group of the canton and an opponents' group to the repository.

In the Czech Republic the following organisations, under co-ordination of the Radioactive Waste Repositories Authority, are involved in the review process: State Organisation for Nuclear Safety, Ministry of Environment, Ministry of Trade and Industry, Czech Power Board, Nuclear Research Institute, and Czech Mining Company.

The AECB review was part of a review conducted to provide advice to a federal Panel that made recommendations to the Federal Government on the future steps to be taken with respect to the management of nuclear fuel waste in Canada. The Panel was assisted by a Scientific Review Group (SRG). A broad range of Federal government departments, professional associations, aboriginal and public interest groups and members of the public also provided the Panel with written submissions. At the request of the proponent, an OECD NEA review group also provided comments to the Panel. All reviews were submitted to the Canadian Environmental Assessment Agency (CEAA, formerly FEARO), which provides administrative support for the Panel, and all submissions to CEAA were made public.

TSPA-1995 was also informally reviewed by the U.S. Nuclear Waste Technical Review Board (NWTRB) and by an independent group organised within the U.S. DOE Management and Operating contractor. Presentations were also made to the U.S. NRC Advisory Committee on Nuclear Waste. The State of Nevada also reviewed TSPA-1995. Because each reviewer group has a distinctly different role to play in the national program, their reviews are not formally co-ordinated; however, the review comments of each group, including the regulator, are available to the others

The Konrad reviews have been discussed amongst the experts from the various organisations involved and the licensing authority who will have to make the final decision. Certain aspects have also been brought before the Reactor Safety Commission for further discussions. But no formal oversight committee has been established to look into the complete IPA or its review.

The reviews of the Compliance Certification Application (CCA) for the WIPP were made by the regulator, the U.S. Environmental Protection Agency (EPA), and as mandated by EPA Requirements there was an independent peer review of conceptual models, waste characterisation analysis and engineered barriers. There was independent oversight by the State of New Mexico (the Environmental Evaluation Group and the State Attorney General), by various stake-holder organisations and members of the public during the public comment phase for the CCA. Finally, there was a DOE-requested review performed jointly by the NEA and IAEA.

1.2 Performance measures considered in review

Regulatory criteria are country specific, which generally reflect which performance measures were calculated in IPAs and assessed in reviews. However, despite differences in regulations there are some commonalties.

Most assessments evaluate individual dose. Some evaluate total risk. In addition, some countries where the basic end-point is individual dose, consider a risk based approach for low probability scenarios. Other safety factors include the total activity inflow of radionuclides, the total cumulative release as defined by US regulations, the use of subsystem performance measures such as waste package performance or groundwater travel time. Some regulators point out that also the quality of the argument including the comprehensiveness of the scenario analysis and the appropriateness of the calculational methods and tools used were important factors in the review.

Compilation of answers

Individual dose was evaluated in the TVO-92/TILA-96, SKB SFR, Nagra Wellenberg, DOE/YM TSPA-95, DOE/WIPP CCA and BfS Konrad IPAs according to current or suggested regulations. The CCA addressed all requirements in 40 CFR 191 and 194 for certification of the WIPP. In short this regulation stipulates individual protection requirements of 40 CFR 191.15, in terms of individual dose for an undisturbed-performance scenario, and groundwater protection requirements of 40 CFR 191.24 in terms of maximum levels of radioactivity. Also, UK Nirex NR337 and PNC H3 calculated individual dose even if this was not a regulatory endpoint. However, UKEA did not review the assessment against criteria. Japan has not yet established criteria. Individual dose will be evaluated by NRI.

AECB Canada applies a risk criterion for the first 10 000 years. Also UKEA considered radiological risk. Both HSK and STUK apply a risk approach to low-probability events. For some high consequence low probability scenarios SKI (and SSI) applied a comparison with individuals handling radon-contaminated drinking water. For long times Finland puts a limit on the inflows of the disposed radionuclides into the biosphere. For times longer than 10 000 years AECB require reasoned arguments to show that there will be no sudden or dramatic increase in release.

Apart from calculating individual dose, which may be the focus in revised regulations, TSPA 95 focused on the cumulative release of radionuclides at the accessible environment boundary normalised to the limits presented in Table 1 of US Code of Federal Regulations, 40 CFR Part 191.

NRC also promulgated requirements on three subsystems potentially affecting long-term safety. These subsystems include the waste package, the engineered barrier system, and the geosphere. The first two of these subsystems were directly addressed in the definition of the source term used in TSPA-1995, but not the third. NRI suggest applying subsystem criteria on the system components. Also GRS and UKEA considered groundwater travel time as endpoints. GRS considered temperature at the host rock interface.

The AECL EIS also evaluated potential chemical risk.

Finally both SKI and HSK point out that the important issue was not only whether the criteria were met or not, but the quality of the analysis. HSK notes that the quality of the argument was underlined as regards the comprehensiveness of the scenario analysis and the appropriateness of the calculational methods and tools used.

1.3 Conduct of review

Formal review period and resources spent

The formal review period ranged between 6 months to two years in most cases. For the Konrad case the review period was 12 years, but the major part of the IPA review took place during the first 6 years. GRS attribute the main reason for this long review period to the absence of formal steps in IPA development and review.

The resources spent on the reviews range between 6 person months to 12 person years. Typically 2 person years were spent in reviews. In one case (UKEA) there was in the order of 20 person years spent on the review, but most of these resources were spent on conducting an independent IPA. The review itself needed some 3 person years.

Other sources

Most reviewers, but not all, considered and were expected to consider, other sources of information than the written IPA. Such information include meetings with the implementer, background documents and general knowledge.

Compilation of answers

> In the US the meetings between implementers and reviewers are formal and the documentation from the meetings is part of the written documentation. AECB only considered the written information in the submitted EIS and cited reports. This is according to their normal procedure. GRS notes that in Germany all evidence has to be documented in writing in a transparent and traceable form, but for general aspects "general knowledge" may be used. For the WIPP case the only information which the regulator, US EPA, could consider in their certification decision is the information contained in the public record at the close of the public comment period on the CCA. However, later during the public comment period on the proposed certification rule more information was provided to the public record by both the EPA and the DOE, and this too became part of the technical basis for EPA's final certification rule.

Own calculations

Almost all reviewers carried out own calculations although the scope of these calculations varied. They ranged from simple checking calculations made in order to control the order of magnitude of results to independent IPA capability. However, regulators with the own IPA capability basically use this to focus on aspects of the IPA reviewed rather than re-running the IPA itself. Some, however, also view their own calculations as complements to the analysis provided in the IPA. Most regulators published their own calculations in connection with the review report, but not all.

Compilation of answers

> STUK made simple checking calculations to find order of magnitude correctness of results.
>
> The calculations carried out by SKI (and SSI) were used as a basis for comparison with SKB´s results, but were also seen as a complement. The results were published as part of the evaluation. HSK explored additional variants, and based on these calculations the implementer was usually asked to supply more detailed comments. Some, but not all investigations were formally documented.

AECB used their own calculations to identify safety-critical data, modelling approaches, FEPs and scenarios in order to focus the review of the AECL EIS on safety-critical factors. Several of the analyses have been published separately, but not how they were used in the EIS review.

NRC has an independent IPA capability and applied it both prior to and during the course of a review. The calculations performed during the review had the objectives of either verifying DOE calculations or extending them, using different data and assumptions, to assess their robustness. Most calculations, whether performed prior to or during the review process, are documented as open reports.

For UKEA a significant part of the work was an independent analysis project. This gave detailed understanding and highlighted deficiencies in the report reviewed.

Access to DOE/WIPP computers to exercise PA codes was granted to EPA and EEG. DOE contractors assisted with calculations as requested by EPA, but under the direction of EPA staff.

External experts

Most reviewers, but not all, used external experts in part of the review work. The reason for using experts is typically to cover identified needs for special expertise, to supplement expertise within the regulator and to alleviate the short term extra work load. In general the regulatory staff manage the review and make the final decisions, but there are cases were external experts have been involved also in more final evaluations.

Compilation of answers

STUK employed four foreign experts for the review of TVO-92. In some stages SKI used specialists on specific issues to complement their internal competence. Also HSK employed external experts to clarify various questions regarding specific issues, but external experts were also employed to help prepare the judgement on parts of the safety analysis. The NRC staff relies on its technical assistance contractor, the CNWRA, to help develop its IPA capability and to help in the review of DOE's performance assessment program. The reason is to complement and enhance the existing staff capability.

The UKEA review was set-up as an independent analysis project with over 40 contractor reports. Lead contractors were appointed for both the peer review process and the independent quantitative risk assessment studies. Regulatory staff managed the work programme, undertook some review work and provided the link between the contractors and Nirex. The reason for using external experts was the time of the review, the limited size of the in-house team of regulators and the possibility to get a multi-disciplinary team approach.

In Germany, the technical review is done by consultants since the licensing authority has not sufficient technical expertise to cover all areas needed to carry out a complete review of the licensing documents. A framework of non-profit expert organisations has been established in the past for the purpose to license all types of nuclear installations, consisting mainly of the local TÜVs (testing laboratories), GRS and some other specialised institutes.

AECB did not use external experts because it was judged that the internal staff expertise was sufficient in most safety-critical topic areas, that no AECB regulatory decision was required in the Federal Environmental Assessment Review Process; and that a number of external experts were participating in the review with the Scientific Review Group (SRG) and under contract to Environment Canada.

1.4 Public involvement

Reviews publicly available

Most review documents are publicly available. This is also required by legislation in several countries. In many cases the reviews were also discussed in a public hearing. In contrast the review carried out in Germany was not open to the public. However, objections from the public affected by the facility which were submitted in written from and received before the specified deadline were discussed in a public hearing by the authority and its technical consultants.

Compilation of answers

The 1992 STUK review is published in the open STUK series. The review of the 1996 interim assessment (TILA-96) was not published. For the SFR case (SKI/SKB) all reviews were published and all correspondence between SKB and the authorities are open to the general public. A voluntary public hearing was also organised. For the Wellenberg case (HSK/Nagra) all reviews were published as official documents. The review was discussed in public by the canton. In the Czech republic, hearings are required by law and comments of public have to be taken into account. The AECB review is publicly available. It was also summarised in the Panels public hearings. All NRC review comments are publicly available. Meetings in which clarifications were provided, and in which the reviewers comments were made available to the U.S. DOE were conducted in public forums, as mandated by the charters, and/or procedures under which the bodies operate. All the WIPP reviews became part of the public record or were made available to the public. The UKEA review reports were made available to the public through the library of the UK Department of the Environment. The ACRWM review report for H3 was opened to the public.

In Germany, regulations do not require the review to be published. Objections from the public affected by the facility which were submitted in written from and received before the specified deadline were discussed in a public hearing. At the hearing the authority and its technical consultants made comment on the objections based on the reviews. In principle, this is the only form in which the results of the reviews were communicated to the public.

Actions to identify special audiences

Evidently the regulators were the main addressee of the IPAs. In addition, some implementers took action to identify special audiences other than the regulatory agencies. They made efforts to make the IPA more transparent to these audiences. Some tried internal pre-reviews. In one case (Canada), several organisational meetings were held to discuss the contents, structure and audiences of the EIS and IPA in a process partially determined by federal guidelines. Some did not take special action, but would like to do so today.

Compilation of answers

> VTT tried to write the reports in such a way that they could be of use for the scientific community in general, local decision makers, and interested members of the public. To that effect, the reports aim to be easy to follow, inspect, and reproduce. SKB made an effort to make a logic and clear presentation of the safety case, mainly for the regulators but also for the local politicians and authorities. Nagra recognised the importance of the public debate and the text in the safety assessment report was in some areas complemented with more background information.
>
> Ontario Hydro notes that, four years prior to the completion of the documents, several organisational meetings were held to discuss the contents, structure and audiences of the EIS and IPA. These meetings were significantly affected at an intermediate stage by the arrival of federal guidelines. Prior to the hearings external peer review was sought actively through means that included presentations at professional society meetings, publications in international journal articles, co-operative agreements with other waste management organisations and the use of external contractors for technical input and review.
>
> DOE/YM did not undertake effective efforts to identify special audiences. This is now noted as a deficiency. UK Nirex recognises the need, but the assessment reviewed by UKEA (NR377) was developed for a highly specialised technical audience.
>
> The IPA documentation developed by BfS was shared with a variety of different Federal Government and State authorities in the framework of the licensing procedure. A simplified version of the IPA documentation was made available to the public. In the process to provide scientific and technical basis for the H3 IPA, PNC involved many experts for independent review of models and databases.

The IPA for the WIPP (the CCA) was written specifically for the EPA and its' contractors, and not for any other audience. Technical exchanges including code training sessions on PA codes, were held with EPA, other review panels, and stakeholders to help them with their review processes.

2. FINDINGS AND MESSAGES

2.1 Key messages, least and most satisfactory issues

Key messages

Overall the key messages as expressed by the reviewers are not in conflict with how the implementers describe which key messages they got. However, in some cases the key technical issues listed by the implementer and reviewer differ. Also, the messages showed that implementers and reviewers sometimes had different interpretations on the priorities and expectations for improving the IPA for the next iteration. Usually the reviews document the issues found to be the least satisfactory, whereas some of the most satisfactory findings were never documented by the reviewer.

Compilation of answers

Some implementers and reviewers (VTT/STUK, UK Nirex/UKEA) are in good agreement on which were the key messages of the reviews. However, it appears that in these cases the answers to the IPAG questionnaire were co-ordinated.

SKB and SKI both agree that the IPA sufficiently supplemented the safety case for the SFR repository, but SKI also found some new issues (most importantly the potential effect of complexing agents) which needs further attention. SKB did not list this as a key message. HSK agrees that the level of analysis is sufficient at the current project stage, but notes that there are a lot of questions requiring more attention. Nagra has a more positive tone in their answer stating that HSK has no objections to granting a general license and notes that there are a number of issues that will have to be addressed in more detail at the next licensing step. AECB and Ontario Hydro both note that the review stated the AECL EIS failed to demonstrate its objective, but Ontario Hydro also notes that the review stated that the AECB staff still believe that the deep geological disposal concept is safe and viable.

DOE/YM state that key messages include general messages on the use of TSPAs as a tool for program strategic planning. In addition, there is a list of issues concerning the procedures for conducting and documenting TSPAs as well as a list of specific technical issues. Some NRC comments agree with the list provided by DOE/YM, but not all. Issues noted by DOE/YM and not by NRC concern a need to include thermal effects, sensitivity analysis of thermal loading concepts and subsystem abstraction. Issues noted by NRC and not by DOE/YM concern reliance on multiple barriers, formal use of expert elicitation, margin of safety in design and performance and scenario selection and screening.

GRS notes that there was a considerable modification of the original assessment as a consequence of written comments to the applicant as well as of meeting between all involved parties. BfS simply states that (in the end) the IPA was found to be in agreement with national and international standards.

Least and most satisfactory aspect of IPAs reviewed – reviewers' perspective

The issues found least satisfactory by the reviewers are of course specific to each IPA reviewed. Still it is possible to identify some typical examples of issues noted by reviewers. These include, insufficient integration between IPA and site investigations programme, potentially non-conservative assumptions in modelling, insufficient scenario and uncertainty analysis, lack of data, particular technical issues (like impact of complexing agents, matrix diffusion) and insufficient scenario analysis. In one case only, the reviewer (AECB) found the IPA failed to demonstrate feasibility and thus did not fulfil its objectives.

The issues found most satisfactory by the reviewers are of course also specific to each IPA reviewed. Examples of issues found most satisfactory include, the IPA fulfilled its objectives (valid for some), resolution of specific issues, identification of issues where more attention is needed and the transparency (clarity) of documentation (valid for some). This was usually stated explicitly in the review report but not always (in particular not comments on clarity of documentation).

Compilation of answers

STUK found the least satisfactory aspects of the IPAs they reviewed to be the weak coupling between PA and site investigations, the lack of explicit scenario analysis, that it only was a single canister analysis, that deficient behaviour of bentonite buffer was not considered, that the overly simplified and conservative modelling of far-field transport undervalues the role of the geosphere barrier, and the use of constant geoparameter values irrespective of time period. The most positive aspects were that the IPAs strengthens confidence in the disposal concept, that conceptual models are established, the scientific justification and consistence of input data has improved, and that the IPA is robust, traceable and transparent.

SKI found some non-conservative assumptions (on complexing agents) and the lack of a systematic approach in handling scenarios and uncertainties to be the least satisfactory aspects. The most positive aspect was that some previously identified critical issues were resolved which enabled approval of full scale operation of the repository.

The least satisfactory issues noted by HSK include the status of the research on hydrogeology, hydromechanical processes and the structure of water transport paths, and the lack of some data on barrier interactions and on gas-related effects. HSK also saw a need for more attention on uncertainty analysis. The most positive issues were that the level of analysis was found sufficient for the project stage and the confidence that the proponent will be able to convincingly demonstrate the safety of the repository in due course. Other positive aspects listed include the clear organisation of the main report, the level of understanding of the general geology and the openness about problem areas.

According to AECB the stated the scope of IPA reviewed was not consistent with the purpose of the EIS, the IPA did not fulfil its stated scope, and the results of the IPA were not interpreted comprehensively. In summary AECB found the IPA to provide inadequate evidence and arguments to demonstrate feasibility of the concept. The positive issues of the IPA was considered to be the clarity of the documentation, the evaluations of facility operations and engineering and the biosphere.

In their reviews NRC has noted several issues concerning the multiple barrier concept, modelling the near-field environment, handling of variability and uncertainty, treatment of matrix diffusion, the formal use of expert elicitation, margin of safety in design and performance, proper integration of site characterisation programmes, waste package performance and scenario selection and screening. The NRC staff has been developing Issue Resolution Status Reports (IRSRs) which documents issue by issue areas where agreements have been reached and areas where differences remain. However, at present the staff is not in a position to specifically identify which aspects of DOE's TSPA it finds satisfactory nor is it required to do so. In fact, such a decision on the adequacy (or sufficiency) of DOE's TSPA would not be reached formally until the time when DOE submits a License Application. NRC find the reviewed IPAs generally comprehensive and provide some level of modelling detail for each of the principal processes and events believed to affect geologic repository performance.

GRS noted that there was a need for variations in hydrogeological parameters and a need to extend analyses beyond 10 000 years. The most satisfactory aspect was that it was possible to accept the applicant's view that the long groundwater travel times were a strong indicator of the safety of the facility.

The least satisfactory aspects found by UKEA were a difficulty in following arguments and a lack of clarity in relationship between IPA and underlying research and site investigation programmes. The satisfactory aspects are mainly to be inferred from lack of comment by the reviewer.

For the WIPP case the key messages received were difficult-to-follow documentation, lack of transparency in the PA, lack of traceability from information/data source to the PA, some disagreement with conceptual models and parameter distributions, some disagreement on a few FEP screenings, and some disagreement on quality assurance procedure implementation. DOE/WIPP states that all disagreements were resolved to the satisfaction of the EPA.

Least and most satisfactory aspects of review – implementers' perspective

Evidently the aspects of the reviews found least satisfactory by implementers are specific to each case. There are, however, some common themes. Some have the view that the reviews unnecessarily highlight issues that may originate from misunderstanding or poor communication. They would rather have these problems resolved separately in order for the written review to concentrate on the real potential problems (if any). Some see a failure to focus on fundamental performance issues and instead focus on small scale issues at a level of detail not warranted in relation to performance. Others see a potential desire for a more complex analysis which would not improve the safety case. The long review period in Germany is seen as a problem there. The scope of review may not be understood by people not directly involved.

In general the most satisfactory aspect of the review, according to the implementers, is when it agrees on the basic approaches to IPA or is used to approve a license (when applicable). Many implementers also have the view that the review they received was able to focus on the integrated aspects and the safety case. Other positive aspects noted on specific reviews included that it provides independent feedback, that the reviewer was able to reproduce results in independent calculations, that it suggests improvements, and that it highlights issues that needs improvement in coming IPA iterations.

Compilation of answers

VTT is not happy with the criticism on single canister analysis, overly simplified and conservative modelling and the use of constant geoparameter values irrespective of time period. The VTT view is that these simplification still allow the safety case to be made. The suggestions by the regulator would introduce unwarranted complexity in the safety analysis. VTT regards it as positive that the regulator has similar positions on the basic approaches to safety analysis.

SKB is not happy that questions and requirements were highlighted in the comments. They should have been treated as separate issues. Most satisfactory is that the previous restrictions on the use of repository analysed (SFR) could be removed.

Nagra finds that the most satisfactory aspect was that, based on the IPA and the review, HSK has no objections against the granting of the general licence, that the reviewer was able to reproduce results in independent calculations and the possibility to comment on the review is also regarded as positive.

Ontario Hydro finds the least satisfactory aspect of the review process to be the diffuse and obscure nature of many comments and the lack of opportunity to explore and unravel issues with the reviewers. Positive aspects is that it was useful to receive independent feedback from a variety of technical experts in order to assess the validity of the various reviewer comments.

According to DOE/YM the reviews sometimes fail to focus on fundamental performance issues and instead focus on small scale issues at a level detail not warranted in relation to performance. Positive aspects include, the explicit suggestions for improvement and the pointing out of weaknesses in documentation that can be prevented in future TSPA documentation.

BfS finds the long duration of the review process as the most negative aspect. The most positive aspects are that the results of the IPA were confirmed and the ability to develop the safety case and the review in parallel.

PNC found that the review was not carried out in depth for some specific technical areas, but found it positive that the review focused not only on individual technical areas but on the integrated part of R&D, i.e. IPA and the safety case.

According to DOE/WIPP the EPA review was comprehensive, very detailed, and resulted in a proposed certification of the WIPP. Therefore, the DOE found the EPA review to be most satisfactory.

2.2 Resolved issues and new issues

Most IPAs and the relevant review resolved some issues and in some cases new issues were identified. Evidently, IPAs submitted for a license application that was accepted by the regulator implied a resolution of major issues. For the IPAs being part of R&D programmes some issues were resolved and some others added. It could also be noted that for the Yucca Mountain project the reviewer and the implementer have developed issue resolution tables which document issues clarified and resolved, and in other cases identify the path forward to resolution.

Compilation of answers

In the WIPP CCA there were a number of issues raised by US EPA and formally documented in the public record. These issues were all resolved as evidenced by the EPA's proposed rule to certify the WIPP. According to GRS all critical issues brought up were satisfactory discussed and included in the applicant's IPA or their own. The SKB SFR IPA resolved issues raised in a previous review and thus allowed removal of some restrictions on use of the repository. However, some new issues were identified which resulted in some new stipulations concerning the operation of the facility.

According to STUK the VTT IPAs resolved some old issues, but the review identified some new ones. According to Nagra some minor technical issues were clarified during the review. HSK notes that although hardly any new issues were identified, its views regarding the importance of certain issues underwent change during the review. DOE/YM notes that in two subsequent technical exchanges with the U.S. NRC and its contractor, and follow-on meetings with the NWTRB and its TSPA Peer Review Panel, a number of issues were expanded, clarified, and/or resolved. For other issues, the path forward to resolution was identified, and will be addressed in either TSPA-VA (FY98) or TSPA-LA (FY01-02) depending on investigation/testing and/or design information availability. PNC notes that through the review it was officially accepted by the AEC in Japan that the technical feasibility of the concept for safe geological disposal of HLW in Japan has been demonstrated. New issues were also identified.

Ontario Hydro notes that several issues from the AECL EIS were identified for systematic evaluation in the auxiliary IPA assessment or "second case study". The second case study used a 2-dimensional vault model to simulate in-room emplacement of long-lived copper containers in a relatively ineffective geosphere, and illustrated the flexibility of the concept in which engineered barriers can compensate for a less favourable host plutonic rock that is characterised by a (postulated) relatively high permeability. Other issues were carried forward from both the EIS and second case studies, notably those issues related to the geosphere model and the overall system model in IPA.

In contrast, AECB did not find that the AECL EIS resolved any issues, however it was noted that the EIS was not specifically intended to resolve outstanding regulatory issues. No new issues were identified. Finally, UKEA notes the IPA was at an early stage and the review was not intended to resolve issues, but to inform the regulator.

2.3 Change of views as a result of review

Examples of views changed as a result of the review are the need for transparency of the IPA documents and the traceability of data, decisions etc. Furthermore, reviews usually result in questions and unresolved issues highlighting the need to have a stepwise approach to the development of an IPA, with many iterations of IPAs and reviews. To some, the reviews stress the need for reviewers to have independent IPA capability. The need to ensure that the ongoing site characterisation and design programs are properly integrated with IPA activities is also noted. Some have the view that due to the potential difficulties in altering overly conservative values (potential loss of credibility) one should aim for as realistic values as possible (see also 3.4). Another observation is the recognition that the

IPA serves the needs of many audiences. Others claim that they have not changed views as a result of the review.

Compilation of answers

> As a result of the review process SKB became even more aware of the need for transparency of IPA documents and traceability of data, decisions etc.
>
> SKI notes that questions and restrictions will probably always follow a careful review. It is therefore important to have a stepwise approach to the development of an IPA. One should be prepared for new and unexpected scenarios or issues even late in the review process although the chance that a critical issue is found should decrease with time.
>
> To the NRC the reviews demonstrate the need for their independent IPA capability. The need to ensure that the ongoing site characterisation and design programs are properly integrated with the performance assessment activities is also recognised.
>
> UKEA see a need to develop internal procedures to provide a structure and general direction to future review work to ensure that the regulator takes “ownership” of any review comments and to respond to documents submitted by the operator in a reasonable time scale. Thereby they also see a need to maintain an in-house team.
>
> Ontario Hydro now recognises that an IPA must serve several different audiences, including the regulatory authority, scientific community and the public, and that these audiences will have quite different expectations and capabilities. DOE/YM notes that some previously published IPAs were not detailed or clear enough for the type of regulatory and oversight reviews expected at licensing.
>
> BfS remarks that even in its initial phase the IPA should be based on realistic approaches as far as possible to avoid the reduction of conservatisms. BfS suggests it is always difficult to justify new results which lead to lower consequences.
>
> DOE/WIPP found that user-friendly documentation, transparent PA, and electronic-information-management systems to facilitate the reviews are essential.

3. TREATMENT OF UNCERTAINTY

3.1 Definitions of uncertainty

IPAG-1 provided the following definitions of parameter uncertainty, conceptual model uncertainty and scenario uncertainty:

- A scenario represents a set of FEPs and interactions. *Scenario uncertainty* results from difficulties in identification of a complete set of scenarios, a complete set of FEPs for each scenario and correctly identifying which interactions between significant FEPs must be considered in a PA.

- *Conceptual model uncertainty* refers to uncertainty about the model used to represent a given set of FEPs and interactions, or choice of models. Simplifications introduced, for example by applying one- or two- dimensional PA-models is part of the conceptual model uncertainty as is the uncertainty introduced by selecting a scale of spatial/temporal representation.

- *Parameter uncertainty* refers to uncertainty in the parameter values to be used in a (given) conceptual model.

Most organisations use definitions very close to the IPAG-1 definitions. However, it should be noted that for the WIPP case the requirements of the applicable regulation (40 CFR 194) imply a specific treatment of uncertainty, and the terminology used here is not fully applicable. UKEA has the view that it is up to the developer to define the terminology.

In particular there is a wide consensus (with small modification) on the definition of parameter uncertainty and conceptual model uncertainty. Some suggest that numerical (or algorithmic) uncertainty should be introduced to cover errors in numerical modelling.

There are some deviations on the view on scenario uncertainty. A suggestion to reserve this for uncertainty only in external future events and to cover completeness of the system description by system uncertainty does not find support by others. Many connect scenario uncertainty as “uncertainty in the development in time”.

Compilation of answers

> DOE/YM note that both the variability and uncertainty in parameter values contribute to the parameter uncertainty considered in models, being a function on the sampling employed. This view is not in conflict with the IPAG-1 definition of parameter uncertainty. SKI, HSK and NRI suggest that numerical (or algorithmic) uncertainty should be introduced to cover errors in numerical modelling.
>
> SKI tend to reserve scenario uncertainty for uncertainty in external future events, but are then forced to introduce *system uncertainty* to cover completeness of the system description, which is covered within scenario uncertainty in the IPAG-1 definitions.
>
> Many connect scenario uncertainty as “uncertainty in the development in time”. Nagra, AECB, Ontario Hydro, and NRC note that an important element of scenario uncertainty is the uncertainty in FEPs (i.e. following the IPAG-1 definition). Furthermore, HSK note that the distinction between conceptual model uncertainty and scenario uncertainty is not clear cut but that scenario uncertainty usually concern large scale events and conditions that act as boundary conditions to the more local analyses.
>
> Finally, one should note that (UKEA) holds the view that the uncertainty terminology mainly arise from operational decisions in an analysis and that it should be up to the developer to set out their operational definitions of classes of uncertainty that they apply in a given analysis. The developer needs to systematically identify all relevant sources of uncertainty. Some uncertainties may be left implicit, others may be eliminated from further consideration by making specific assumptions based on reasoned arguments or exploring effects on the safety case by scoping calculations, other uncertainties may be quantified and incorporated into assessments of probability and risk.

3.2 Confidence building techniques

Multiple lines of reasoning, robust design, etc..

Most consider confidence building techniques such as multiple lines of reasoning, simplified bounding calculations that use a wide variety of simple and independent methods, robust design and analysis and use of multiple safety indicators to be important tools in preparing a robust, traceable and transparent safety case. There are, however, some different nuances in opinions both between different regulators and between regulators and implementers. Some regulators stress that sufficient assurance of safety over the very long time scales which may need to be considered is likely to be achieved only through multiple and complementary lines of reasoning. Others stress that the focus of the safety case should be on the "real evidence", requiring a clear "fool-proof" line of reasoning. Some implementers stress the benefits of bounding calculations, other express a worry that they can be overly conservative and thus could be potentially misleading.

Compilation of answers

Some regulators (AECB, UKEA) stress that although in general a developer will be expected to submit a quantitative assessment of risk, a risk assessment is likely to form only part of the overall safety case. Sufficient assurance of safety over the very long time scales which may need to be considered is likely to be achieved only through multiple and complementary lines of reasoning. Ontario Hydro intends to develop the safety case considering this.

The review of the PNC H3 concluded that conservative design and bounding calculations could be acceptable to assess the feasibility of the disposal concept at the stage of the generic assessment, but in the future there is also a need for more realistic modelling and field and experimental support (in engineering scale), discussion of design alternatives, further use of natural analogues and a more transparent review process.

Other regulators (HSK, NRC) appreciate the benefits of multiple lines of reasoning but stress that the focus on the safety case should be on the "real evidence". A clear "fool-proof" line of reasoning is needed. The focus is to investigate the system behaviour under plausible and reasonable conditions that will challenge the ability of the repository to contain and isolate waste. Supplementary arguments could be used to promote system understanding and to appreciate the magnitude of certain risk components or the safety contribution of a certain barrier. However, it could be questioned if one can quantify the safety margins. SKI wants to be very cautious in giving specific guidelines regarding the choice of confidence building techniques.

Some implementers (Nagra, SKB) stress the benefits of bounding calculations. Although SKB states that the primary matter is a clear and logic description of the assessment work. Bounding calculations were an important part of the safety cases for the SFR (reviewed by SKI) and the Konrad (reviewed by GRS) facilities. Others (DOE/YM) note that too much conservatism can make for a poor showing in safety space and are potentially misleading. BfS note that confidence building or multiple barriers were not tackled by reviewer and that more attention on this should be given in the future.

Multiple barriers and defence in depth

All organisations emphasise the need for a multi-barrier concept. Furthermore, multiple barriers are usually required in regulations. The most common regulatory view is that deficiencies in one barrier or predictable changes should not significantly impair the overall safety in disposal. All appreciate that repository barriers cannot be totally independent, but regulators stress that there is need for some redundancy. Apart from a demand on "some redundancy" few make direct remarks on the "defence in depth" principle.

Compilation of answers

> The most common regulatory view, exemplified by the draft STUK regulations, is that deficiencies in one barrier or predictable changes should not significantly impair the overall safety in disposal. In addition, NRC note that an important aspect of the concept is that the various barriers have different responses to both anticipated and unanticipated challenges to the integrity of the repository; thus compromise of one barrier may be balanced by the continued performance of another. UKEA requires it be shown that, even with an adverse interpretation of any given aspect of the evidence taken in isolation, the overall system performance would still provide acceptable assurance of safety.
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> All agree that barriers cannot be totally independent. VTT stresses that barriers may evolve with time. SKI point out that different barriers exhibit widely different functions as regards transport of different radionuclides, the barriers can in actual fact be dependent on each other with regard to chemical and mechanical stability, and the function of several barriers may consequently be affected simultaneously by the same mechanism. The regulators still require some degree of redundancy.
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> SKB note that, in the review, the multiple barriers have justified acceptance of some disruptive events in one barrier provided a second barrier is intact. Nagra finds the concept suitable to demonstrate long-term safety. Ontario Hydro notes that review comments from AECB (and others) agreed in principle with the multibarrier concept in terms of its acceptability and effectiveness, but were critical of the manner in which some barriers were modelled, how the barrier is expected to perform, how it might fail, how its performance would change after failure, and what other barriers provide redundant protection. The ACRWM review report on H3 concluded that the assessment demonstrates technical and scientific feasibility of the disposal system in which the multi-barrier concept is applied for the Japanese geological environments.
>
> Apart from a demand on "some redundancy" few make direct remarks on the "defence in depth" principle. SKI remarks that the "defence in depth" concept of independent barriers protected by different operational measures and technical systems stems from reactor safety and is not directly applicable to repositories. NRC notes that many factors important to "defence in depth" are not readily quantifiable and are therefore not necessarily included in a quantitative performance assessment, but would expect these qualitative factors to be described in the documentation of the safety case. The H3 review report did not refer to defence in depth. PNC notes that the multi-barrier concept should also be a basis for the disposal system in the future IPA. Each of the barriers in the disposal system have multiple safety-related functions and can not be viewed as totally independent. It is therefore not straightforward to apply the concept

of defence in depth in the reactor safety to the repository system. However, discussion on redundancy of performance from a certain aspect, e.g. radionuclide retardation, would be possible and useful to explain how robust the multi-barrier system is.

Balance between site, IPA and robust engineered barriers

The regulators stress that a well supported performance assessment demonstrating safety is always needed and that both engineered barriers and the geosphere should contribute to safety. The exact balance between favourable site properties and need for robust engineered barriers is site and concept specific. The implementers generally agree and some stress that initial evaluation and repository siting can be facilitated by selection of robust engineered barriers. This would allow the performance assessment to concentrate on the site aspects relevant for the engineered barriers. The assessment and the EBS, could then be optimised at later stages of development.

Compilation of answers

According to the draft regulations suggested by STUK the geological characteristics of the disposal site shall, as a whole, be favourable for the containment of the nuclear waste to be disposed of. Areas having features that are substantially adverse to safety, shall be avoided in the selection of the disposal site. The safety of the repository should be demonstrated by a safety assessment. SKI states that performance assessment is always necessary and should adequately reflect the chosen safety enhancing aspects. This could well be the engineered barriers but in that case it also has to be shown that neither the waste nor the surrounding rock will impair the function of the engineered barriers. HSK notes that all three components are necessary. AECB notes that the balance will be very site- and concept-specific, but no matter what the balance between the two, both engineered and natural barriers will have to be included in a disposal concept, and a convincing and well-supported PA will be needed to demonstrate safety. NRC expects to allow for broad flexibility, but notes that the performance assessment is the analysis and documentation in which the degree of site characterisation and robust engineering are shown to work synergistically to achieve the performance goals for the repository. A multiple barrier approach would mandate that the natural system also contributes to the isolation, if not the containment, of the waste. GRS notes that the ultimate goal of a PA is to demonstrate safety of the facility. Referring to the multiple barrier principle UKEA states that the developer shall carry out a programme of investigations to provide information necessary for the safety case and to demonstrate the suitability of the site. NRI notes that the host rock in connection with the engineered barriers system has to be safe with respect to the disposed inventory.

According to SKB there is always a balance between the knowledge of the site, the source term, the design of the repository and the conceptual and numerical models used to demonstrate safety. Nagra's view is that the balance depends on the particular phase of the repository development. For example at an early phase with limited reliability of the geosphere data set, there will likely be more emphasis on the engineered barrier system and a robust design. More site specific knowledge will allow for optimisation. In the view of the uncertainties on the properties of the geological barrier in the generic assessments carried out so far, PNC thinks it is prudent to minimise requirements on the geosphere and emphasise the weighting of the performance of the engineered barriers. If the siting would be carried out so that the geological environment could provide favourable conditions for the engineered barrier performance (i.e., physical stability, low water flux and favourable chemistry), the safety of disposal would be ensured by the barrier performance of a small volume of good near-field host rock in the vicinity of the repository combined with the strong engineered barriers. More site specific knowledge will allow for optimisation.

On the other hand Ontario Hydro's view is that the PA must be integrated to include both the site and barrier properties to ensure that synergistic effects are properly evaluated. That is, the site must always be sufficiently well characterised to support its role. Likewise the engineered barriers must always be sufficiently well understood to support their role. DOE/YM states that the need is to evaluate safety in a defensible manner. Whether the site or the engineered system dominate the safety level being demonstrated is a moot point. The engineered system is evaluated inside the natural system. The natural system protects and is affected by the emplaced engineered system. BfS notes that long-lived robust engineered barriers can balance a lack in site characterisation only for a limited period of time. A convincing and well-supported PA is not able to balance a weak site. Also DOE/WIPP states that all three must be balanced to provide confidence in the safety of the repository.

3.3 Handling of conceptual model and scenario uncertainty

Conceptual model uncertainty

Generally, conceptual model uncertainty is handled by making conservative assumptions and by applying a diverse range of models. Evidently, the difficulties lie in really proving conservatism and to prove that the analysis of variants is comprehensive. In addition, there are some varying opinions whether analyses of different models should be aggregated into a single risk estimate.

Compilation of answers

SKI notes that conservative assumptions are reasonable as long as clearly conservative values can be assigned, but a natural development would be to gradually modify and refine the models when an improved understanding of individual processes and reasonable parameter values become accessible. HSK remarks that one does not begin with perfect knowledge about the repository system. The real system is approached by more and more reducing the simplicity of the models, but often without really knowing from which side, conservative or not, one is coming. PNC develops more sophisticated models for specific processes to support the simplified system model.

AECB does not accept handling conceptual model uncertainty by switches in the probabilistic model and then combining the results. Ontario Hydro notes that the treatment depends on the nature and extent of the uncertainty. One future approach would be to conduct several analyses, each using a different conceptual model, and to calculate the conditional risk associated with each conceptual model.

In contrast, for conceptual models that are discrete DOE/YM consider two approaches. In the first (previously used) approach the cases are kept separate and many Monte Carlo simulations are used to evaluate various combinations of assumptions. In the second approach, all possibilities are rolled up into one distribution function that is sampled, conceptually lumping all system uncertainty into the simulation. Still, the separate contributions of the alternatives will be demonstrated through generating conditional CCDFs. NRC has not yet developed any guidance on acceptable methods for dealing with conceptual model uncertainty. Two approaches are under consideration: (a) assign probability to alternate conceptual models and combine results; or (b) present results separately for each conceptual model.

In the CCA for WIPP alternative conceptual models were considered through the FEP process and screened with decisions documented as required by regulation. In some cases decisions between alternatives could not be made, and conceptual model uncertainty was included through subjective (parameter) uncertainty.

Scenario uncertainty

In general, the favoured means of identifying scenarios is to apply a structured and transparent approach for FEPs and scenario identification. Additional techniques have also been applied. There are also some varying opinions on the need and possibilities to estimate scenario probabilities.

Compilation of answers

In their review HSK made an independent reassessment of scenarios in order to check the comprehensiveness of the scenarios chosen. Based on review comments, Ontario Hydro conclude that one needs to take care to document the rationale for the scenario selection, and to show that the scenarios analysed are relevant.

Additional techniques suggested include using conservative assumptions and explore different variant “what-if” cases (SKB, VTT), or indirectly by observing natural systems (AECB). PNC separate between direct impact mode and indirect impact mode scenarios. The direct impact mode are scenarios in which radionuclides would be directly borne to the human environment, whereas the indirect mode are those scenarios in which radionuclides would be transported by a certain vehicle (such as groundwater).

NRC note that scenario uncertainty includes, but is not limited to, uncertainties in: (i) estimating the probabilities (or likelihood) of the various scenarios; (ii) determining that the set of scenarios is sufficiently complete; and (iii) estimating the consequences of the various scenarios. DOE/YM handles scenario uncertainty through the evaluation of alternative sub-scenarios and through sensitivity analyses that are part of probabilistic calculations for some scenarios. Other scenarios, like human intrusion, will be evaluated deterministically with only limited attention to uncertainties.

In the CCA for WIPP the uncertainty in retained FEPs is incorporated through stochastic uncertainty in the PA. For excluded FEPs uncertainty is shown to be not important through FEP-screening process.

SKI questions whether it is possible to assign probabilities to individual scenarios.

In the Konrad case (GRS/BfS) only very few scenarios were analysed (groundwater flow and human intrusion).

Finally, UKEA maintains that handling of scenario uncertainty is an operational matter for the developer to address in their safety case.

Completeness of system description

It has been proposed to introduce the concept of "system uncertainty" to cover the issue of completeness of the system description. For most participants, however, the issue is covered by the definitions of conceptual model uncertainty and scenario uncertainty. The issue as such is certainly recognised by many, but not all, and regarded essential. FEPs databases and system tools like influence diagrams or interaction matrices are mentioned in this context. Written documentation is essential, but other types of communication should be considered to deal with the more important issues in order to avoid misunderstandings. Others highlight the need for peer review.

Compilation of answers

SKI states that the completeness of the system description can most effectively be checked by a systematic treatment of Features, Events and Processes (FEPs) using tools like PID or interaction matrices. BfS notes that an adequate and complete system description is essential to achieve reasonable assurance in the results of an IPA. The UKEA is currently investigating the potential use of the NEA FEP Database as a possible tool to audit completeness of a developer's analysis.

Nagra notes that, for the current licensing step, the system description was adequate and complete in the regulator's view. Ontario Hydro notes that comments on the adequacy and completeness of the system model were quite variable. Some reviewers thought that most components of the system model were adequate, while other reviewers found fault with each and every component. Written documentation is essential, but other types of communication should be considered to deal with the more important issues in order to avoid misunderstandings. DOE/YM puts forward that the system description should be a conceptual overview that helps orient the reader.

DOE/WIPP notes that EPA regulations require a peer review of conceptual models. This review addressed the adequacy and completeness of the conceptual models for the PA purpose.

3.4 Modelling

Probabilistic versus Deterministic approaches

The most common view is that deterministic calculations are more transparent, whereas probabilistic models can assess parameter uncertainties in a more comprehensive manner. Probabilistic models may be necessary in case conservative models do not support the safety case, or they can be used to support conservatism in deterministic models. Deterministic calculations can be used to illustrate the system behaviour in a complex probabilistic assessment. Also countries with essentially deterministic safety targets need resort to uncertainty arguments for rare (and adverse) events. The two approaches are complementary. There are some diverse opinions whether it is possible to mix well founded probability estimates with more subjective ones.

Compilation of answers

Many (SKB, VTT, SKI and others) claim that the deterministic approach, with the consistent use of conservative parameters, in analysis is in general more clear and transparent, and straight forward. SKI notes that a probabilistic approach can add a more detailed understanding of the system behaviour, potentially closer to the real system. HSK and Nagra see the need for probabilistic arguments when dealing with rare events. They can also help to assess the influence of combinations of multiple uncertain parameter values, and Nagra will consider this more in future assessments. In this context, HSK does not see it relevant whether the probabilities are derived from statistics or simply represent an opinion on the likelihood. The result is still an opinion on the likelihood. Also in the German case (GRS/BfS) the evaluations are essentially deterministic and conservative, but probabilistic analyses are viewed as very useful to support the conservatism of a deterministic data set. PNC apply probabilistic methods to the low-probability/high-consequence cases according to the guidelines of the AEC in Japan. They will also apply the probabilistic method to uncertainty analysis of the parameter distributions.

According to Ontario Hydro both deterministic and probabilistic analyses will be required in future IPAs. Deterministic analysis are relatively simple and transparent and could deal with uncertainty through simplifications and conservatisms, coupled with conventional sensitivity analyses. However, experience has proven that it is difficult to develop a simple system model whose simplifications and conservatisms can be proven and, at the same time, whose conclusions support a case for safety. Probabilistic analyses provide a systematic and thorough methodology to deal with parameter uncertainty. For a given system model, the probabilistic analysis has demonstrated that the overall behaviour of the system can be uncovered, that the net effects of uncertainty can be quantified and that the parameters most contributing to the uncertainty can be identified. There is still a challenge in communication.

The DOE/YM approach is essentially probabilistic, but they see different roles for the two approaches and state that they can be used in a complimentary fashion. It may be misleading to discuss relative merits for the two approaches. That is really an application-dependent issue. For example, a simplified deterministic calculation can illustrate a process within the probabilistic calculation. According to NRC, a probabilistic approach is very useful because it permits consideration of a wide range of uncertainties and allows comparison of a distribution of performance to regulatory limits. A deterministic approach has the advantage that it is usually simpler to execute. In general, parameters may be fixed if: (i) variability in those parameters has little or no effect on the estimate of performance and (ii) if values are picked for them that will assure that the results are suitably conservative.

AECB favours the use of a variety of deterministic approaches to explicitly take into account the uncertainty amongst conceptual models and simplifications. Probabilistic assessments are seen as complementary analyses to assess the effect of data uncertainty i) due to stochastic variables or ii) due to heuristic "what-if" scenarios. As pointed out in the review, probabilistic assessments of these two sources of uncertainty should not be combined, since the *shape* of the predicted distribution can have significance in an assessment of stochastic variables, but only the *range* of predictions has meaning in analysis of "what-if" scenarios.

According to UKEA all uncertainties need to be explored and the models analysed. According to NRI deterministic modelling shall not be used for long-term processes evaluation, but can be used to have the input data in integrated models where it is defensible.

DOE/WIPP notes that the EPA regulations require a probabilistic risk assessment.

Conservative versus Realistic

The general view is that both conservative and attempts at more realistic analysis is necessary in a IPA. Clearly, a more realistic analysis may be complex and hard to prove, which makes conservative simplifications necessary in order to make a safety case. However, to remove unreasonable conservatisms, approximations and assumptions, more realistic analysis is needed. The conservative description may also be a misleading starting point for a proper engineering design or for understanding the relative importance of different uncertainties and for optimisation considerations. It is suggested that for complex non-linear systems, it is easier to defend assumptions directed at characterising uncertainty realistically than it is to defend a conservative assumption. Others discuss the difficulties in actually proving that parameters are realistic and suggest that assessments either should be conservative or probabilistic.

Compilation of answers

NRC points out that realistic estimates of performance are more likely to satisfy, not violate, a regulatory limit. However, this better picture comes at a price compared to conservative calculations: (i) the calculations are likely to be more complex, to have a greater number of parameters that may vary, and to require more computational resources; and (ii) there is a higher level of scientific support (laboratory and field study, site characterisation) needed to demonstrate that the models and parameter distributions or values are truly realistic.

According to SKB realistic calculations should be used if possible and in particular to quantify the normal, most probable, situation. To deal with uncertainties, conservative approaches shall be used or, in some cases, the probabilistic approach. SKI states that the description of the repository will be completely unrealistic with a consistent selection of conservative models and that a higher degree of realism will provide a better basis to judge the role of different uncertainties. According to GRS/BfS conservative calculations are only relief actions to demonstrate the safety of a repository system, but realistic calculations are necessary to verify/validate models. Nagra states that more thought is needed regarding the probability of combinations of conservative parameters leading to high consequences will have to be made in future assessments.

According to DOE/WIPP for complex non-linear systems, it is easier to defend assumptions directed at characterising uncertainty realistically than it is to defend a conservative assumption. Since the system analysed is highly non-linear, it was difficult to convince the reviewers that the system is understood when results are compounded by multiple conservative assumptions, and the uncertainty and sensitivity analysis results may produce misleading guidance.

VTT and STUK stress that regulations call for conservative IPA. HSK states that with a realistic calculation one does not know how far off from reality and on which side of the real value the result is. One really has only the choice between a full probabilistic analysis and a deterministic analysis with a lot of conservatism. According to AECB the use of conservative assumptions would enhance confidence in the ability of the performance assessments to ensure that potential risks or impacts will not be underestimated. On the other hand realistic calculations can be useful for aspects of repository design where the implementer wants to assess the impacts of design changes on the long-term performance. However, the remaining uncertainty in the more realistic calculations will likely limit the extent to which the system can meaningfully be optimised. The AECB will use the conservative calculations as the basis for regulatory decisions. NRI states that conservative calculations limit the system with respect to economy and feasibility, realistic calculations describe the system performance with higher reliability.

High consequence low probability scenarios

The most general view on high consequence low probability scenarios is to evaluate them in isolation (in a disaggregated manner) and then consider the net implications of the probability and the consequence. Here some see a need to apply semi-quantitative analyses or reasoned arguments. Questions still arise whether risk estimates of such cases need to be cumulated before being compared to a risk limit. In some regulations, notably the USEPA regulations that apply to WIPP, some low probability scenarios are screened out.

Compilation of answers

VTT states that an IPA needs to include "what if" analyses of high-consequence cases. SKB, SKI, and NAGRA see the need to handle high consequence and low probability scenarios in a semi-qualitative manner. Probabilistic weighting of the consequences of low probability scenarios is favoured by HSK, but they require that risk estimates for such individual scenarios be cumulated before comparing them to the risk limit. The NRI view is that such cases should not be decisive in formulating criteria and/or operational limits and conditions, but they have to be evaluated and interpreted.

AECB states that reasoned arguments should be used to compare the consequence to the risk criterion. In contrast, Ontario Hydro states that the regulatory criteria in Canada specify the need to calculate risk by summing risk contributions over "all significant scenarios", which implies that those scenarios that are "significant" must be aggregated and quantified.

DOE/YM applies a mixture of disaggregated and aggregated calculations, with both quantitative and qualitative modelling inputs. According to NRC for some scenarios, e.g., human intrusion, for which there is a weak scientific basis for evaluating the probability, a separate evaluation of consequences may be appropriate. The NRC staff has called for both aggregated and disaggregated results to be presented, as this provides more information about the functioning of the system. According to UKEA the analyses need to be disaggregated. PNC will discuss merits of both.

DOE/WIPP notes that under EPA regulations low probability FEPs may be screened out. Sometimes these limitations are criticised internationally.

Failure mode analysis

Few advocate a full failure mode analysis of the system, but aspects of such analyses are often favoured and are often brought forward into scenario analysis and FEPs identification exercises. These analyses thus cover the essentials of failure mode analysis. Some are more directly negative to failure mode analysis. It is stated that such an analysis is not really applicable to a geologic repository as it is difficult to conceive how the rock might "fail". Other note that such an analysis is not consistent with the risk-based methodology usually practised.

Compilation of answers

VTT, and also GRS, state that PA practitioners need to think thoroughly what could make the system fail. In site selection, HSK suggests it may be useful to assess the tolerable bandwidth of, for example, geosphere parameters. Nagra, and also DOE/YM suggest that increased confidence in the IPA was obtained by applying a broader range of parameters than justified from observations to see when the system could "fail".

According to Ontario Hydro it is difficult to conceive how the rock might "fail", it undergoes gradual change and it is not intended as a barrier to provide absolute protection. NRC has a similar view but are not against DOE trying a failure mode analysis. SKB applied an inverted fault tree in the SFR assessment but this was not regarded successful by the reviewer (SKI). They have now resorted to FEPs and scenario analysis. DOE/WIPP states that such analysis is not consistent with the risk-based regulations and suggests that such analyses are misleading, and not appropriate for communicating safety to the layman public.

In contrast, AECB were concerned that the AECL post closure assessment did not include scenarios in which barriers fail. Failure mode analysis is viewed as a complement to FEPs-derived scenarios. It is suggested that they can help to confirm that all important scenarios and FEPs have been considered. This last point is also made by PNC.

3.5 Support for uncertainty estimates

Level of support for data and assumptions

All regulators stress the key importance of data, assumptions and models to be adequately justified and tied to actual field and laboratory data. In general the implementers support these views, but some state that it is also necessary to find a balance on how much evidence is needed before it is possible to close an issue.

Compilation of answers

Suggested inabilities to make such connections (STUK, AECB) or alternative interpretations of the existing data (SKI) are important examples of issues remarked in reviews. It is also a common regulatory view that the IPA should use all the relevant available information. If there is not sufficient data AECB require reasoned arguments.

In future IPAs Ontario Hydro will require a clear and exhaustive set of documentation that supports all data, assumptions and models to the extent required by the regulatory agency and other stakeholders. DOE/WIPP states that IPAs should include traceability from measurements to the PA and Quality Assurance. Formal Expert Judgement to elicit information in the absence of measurements should not replace measurements if they are possible. The approach (support) should be graded by importance for both the applicant and the regulator. PNC will focus more on developing more reliable models and databases. However, some implementers point out that (i) the need to know more must be balanced against the various other pressures that lead management to a programmatic decision for closure on an issue (DOE/YM) and that (ii) data interpretation takes time and it was not possible to include all new data since the previous assessment (VTT).

Use of qualitative and soft information

Many see the importance of using soft qualitative information such as paleohydrogeology or results of expert elicitation exercises. It can be used for selection of conceptual models or scenarios or for motivating conservatism. It may also serve as a complement or corroboration to a quantitative analysis. Others (some regulators) are more hesitant on how to assess soft information. For them the most useful assessments are those based on the "real evidence", and they require a clear "fool-proof" line of reasoning. Furthermore, they state that all data should be sufficiently supported to provide a reliable basis for use in models, the results of which may be used in regulatory decision making.

Compilation of answers

NRI see its use for assessing long term safety in relation to biosphere future evolution. According to PNC it should play an important role, on issues such as seismic activity. For AECB soft information are typically the basis for reasoned arguments need to support the analysis. DOE/YM see the need for soft information in this context but remarks it is a challenge to document the basis for all assumptions. According to SKI it is often difficult to distinguish what is "soft" information and what is "hard" information, since there is generally a gradual scale.

On the other hand HSK are not sure on how to assess soft information. For them the most useful assessments are based on simple and undeniable facts. UKEA states that all data should be sufficiently supported to provide a reliable basis for use in models, the results of which may be used in regulatory decision making. NRC states that soft information should be used with care.

Use of natural analogues

Some see little direct use of natural analogues as a first line arguments in the safety case. Their main use is to provide knowledge of individual processes. Others see a more direct use of natural analogues. They may be used to make reasoned arguments as they can integrate events and processes over long time frames and/or large spatial scales.

Compilation of answers

> For example, NRC states that studies of natural analogues provide ancillary reasoning for certain conceptual models and their parameter values. However, because large uncertainties are inherent in interpreting natural analogue data, it is rare that a natural analogue will provide the mainline argument for the safety case. UKEA has a similar standpoint. SKI and SKB note that analogues were not directly used for SFR, but knowledge of individual processes could have been derived from studies of natural systems. NAGRA indicates that analogues were used in the safety report but not explicitly mentioned in the review. HSK note that analogues were not used, but that, in principle, they are very valuable. NRI suggest that migration parameters for natural radionuclides can be derived from analogue data. GRS note their indirect role in validation of transport codes in studies like HYDROCOIN and INTRAVAL. VTT sees no great prospects of direct use of analogues in IPA.
>
> Others have a more positive attitude. According to AECB natural analogues can be used to make reasoned arguments as they can integrate events and processes over long time frames or large spatial scales. There is a need to know the paleohydrogeology both of the site and analogue. For Ontario Hydro natural analogues will continue to play an important and unique role in IPAs of used fuel disposal, primarily in supporting validation of models, data, assumptions and assessment results. DOE/YM notes that the lack of use of analogues in TSPA-95 was cited by reviewers. The next assessments will discuss at least one. DOE/WIPP notes that natural analogues were used to build confidence in many assumptions but especially in descriptions of future states of the waste, and were effective in defending assumptions concerning waste strength and particle size with peer reviewers.

Stylised and standardised approaches

All have applied (and accepted) that at least some aspects of human actions preferably should be handled by stylised and standardised approaches. Some have a quite restricted view and basically only accept concepts like the ICRP “standard man”, whereas others accept a wider use of standardised approaches such as the application of a standard biosphere. Regulators generally state that the application of stylised approaches need to be motivated for the specific application. It could also be noted that there is some divergence in the understanding of the word stylised. Some (AECB and WIPP) point out that all PA and scenario analysis is stylised to a degree.

Compilation of answers

VTT applied the stylised WELL-96 scenario for indicative dose assessment in TILA-96, and suggested that it would be sufficient. Still STUK noted that the analysis should be complemented with a stylised biosphere scenario on a self-sustaining community and sea scenarios for the coastal sites.

For the SFR case SKB assumed that human behaviour, biosphere development and climate essentially will stay as today. The dose calculations used the ICRP intake factors and the assessment was based on the concept of critical group and a self-sustained farm. SKI notes that apart from these assumptions no other stylised approaches were used.

HSK did not directly comment on the use of stylised approaches in the review and notes that changes of climate that obviously have and are taking place have to be considered in the safety analysis. For human intrusion HSK think one has to consider using as a guide some standard contemporary patterns of needs and behaviour. Nagra would recommend considering the possible ranges for climate and topographical developments at a site, but for future human behaviour related to the biosphere and for human intrusion stylised (but not necessarily simplified) approaches should be used.

NRI consider a reference biosphere only.

AECB is supportive of using stylised approaches, bounding a broad range of plausible human intrusion scenarios and biosphere conditions. They suggest that the transparency of safety assessments, as well as possibilities for inter-comparison, would be enhanced. According to Ontario Hydro, stylised approaches will be required in future IPAs and notes that they are especially useful in "what-if" scenarios and they are currently used in many aspects of the system model, especially in the biosphere.

According to DOE/YM human intrusion is to be addressed in a stylised fashion, based on recommendations by the National Academy of Sciences in their report on Technical Bases for Yucca Mountain Standards (1995), but not for other scenarios. NRC agrees with this view.

GRS and BfS notes that stylised approaches are used in conversion dose factors using a German regulation (AVV) and for handling human intrusion.

UKEA states that stylised approaches can only be used when site- and facility specific data are lacking and could not reasonably be obtained. The use of stylised approach needs to be justified by developer.

PNC is now applying a reference biosphere and stylised approaches for human intrusion in the next PA.

4. DOCUMENTATION AND TRANSPARENCY

4.1 Traceability and transparency

Experience in tracing results

Traceability implies an "unambiguous and complete record of the decisions and assumptions made, and of the models and data used in arriving at a given set of results. To be complete, this should include information on when and by whom various decisions and assumptions were made, on what basis, how these decisions and assumptions were implemented, what version of codes and data sets were used etc." (IPAG-1).

All agree with the need for IPAs to be traceable and reproducible. However, out of experience reviewers often find it difficult to trace results and logic in IPAs. Regulators note that care is needed to trace the original source of data (and its rationale) since references in IPA reports do not always cite the original work. Some reviewers also see a need for additional meetings with the implementers in order to improve traceability. Many implementers, on the other hand note the difficulties in obtaining traceability, especially since extensive bookkeeping could obscure transparency to other audiences. An hierarchy of reports is generally suggested, but there still seems to be a need for improvements (see also the following sections). It is also suggested traceability would be facilitated for both the applicant and regulator through Electronic Information Management.

Compilation of answers

AECB expended a great deal of effort to trace results in the IPA reviewed, but with limited success. One of the regulatory requirements will be a decision-making process for the implementation, complete with quality assurance procedures to ensure traceability and auditability of all decisions, assumptions and calculations. According to NRC traceability is especially important in deciding on conceptual models. Experience indicates that scientists and technologists frequently make assumptions or establish a paradigm, without careful documentation, even though such choices may be very well-founded. References cited in an IPA document are often not the original source and often, the reviewers find that a value was originally merely an assumption, but by its repeated use (and subsequent referencing) has become essentially as "fact". To UKEA the traceability of information and decisions was a significant concern for reviewers, but efforts will tend to make documents unwieldy, or even obscure and several levels of documents may be required. SKI notes that in the SFR review a more comprehensive record of the decision taken in arriving at the final set of calculation cases and the corresponding results would have been helpful. For HSK it was often necessary to clarify the background of the data with the implementer. HSK states that traceability is a very difficult and very important state to reach. They are not in favour of an extensive book-keeping of each and every argument as some arguments are easily rediscovered or simply not of much interest. However, it is important that each and every number, geometric information, etc., entering into the final chain of arguments making up the safety demonstration be traceable down to the scientific facts that allowed their choice. For GRS the traceability was assured through meetings between reviewer and applicant. These meetings were recorded. Sometimes there were difficulties when changes in hardware/software occurred over the course of the review. For NRI the traceability is followed by the QA system and calculations in decisive steps are double checked using different codes and different expert teams.

VTT states that the safety analysis needs to be reproducible, and this is a basic requirement of scientific work. In their view traceability is easier obtained with simple models, which also enhances transparency. Nagra agrees there is room for improvement in traceability. DOE/YM notes that traceability is a must in the regulatory world. PNC states that structured documentation with justifications for decisions and assumptions in sub-reports are needed. It is also necessary to have direct communication between the practitioners of the IPA and the reviewer. In contrast, SKB suggests that sometimes it appears that reviewers are more interested in basis for a decision than the decision itself. DOE/WIPP states that traceability is critically important and suggests it would be facilitated for both the applicant and regulator through Electronic Information Management.

Ontario Hydro stresses that IPAs have many audiences (regulators, members of the public at sites, design engineers) having different needs and expectations, which will change with time. All analyses and documents should have a common basis which would likely consist of a detailed, exhaustive technical study, but only selected audiences will have high expectations regarding traceability, and require that all information is recorded, including information on decisions made and the reasons for, assumptions made and rationale for those decisions.

Transparency and its potential conflict with traceability

According to IPAG-1, transparency implies that the PA report “be written in such a way that its readers can gain a clear picture, to their satisfaction, of what has been done, what the results are, and why the results are as they are. Transparency is audience-dependent, i.e. a document that is transparent to a regulator or practitioner of PA may not be transparent to a member of the public and vice versa”.

Most reviewers found the reports transparent in relation to their needs. Most recognise, however, that there are different needs for other audiences. Some, mainly implementers, see a potential conflict between traceability and transparency such that too much background information in the report would obscure its main content. It is suggested that this conflict can be handled by an hierarchical system of reports. Others suggest that an Electronic Information Management system would help solve this conflict. Additional suggestions are 1) to assure openness of the whole review process, including relevant documents and discussions and communications between implementers and reviewers, 2) to help the audience to better understand the meaning of the disposal problem and why IPA is needed, or 3) by making the safety analysis as simple as possible. In contrast, other suggest the PA can be defended even if the documentation is not entirely transparent as long as it is traceable.

Compilation of answers

SKI found the transparency generally adequate in the IPA reviewed and suggests that transparency seems to have been more important than traceability for the implementer. HSK found the IPA reviewed to be in general clear and logically organised. AECB found transparency to be conditioned by the staff's monitoring or familiarity with the AECL programme. Given that, the documentation in general provided a clear picture of the arguments presented. AECB notes that traceability can be applied in a broader scope to an entire project, whereas transparency refers to the documentation of a performance assessment. For GRS the review and analysis was meant to be transparent to educated technical audience, but not transparent to the public since they were not addressed. In contrast, UKEA found transparency as a major concern. Most reviewers, suggest that the potential conflict with traceability and transparency for different audiences can be alleviated or avoided by good organisation of documentation with a hierarchical organisation of documents and referencing.

Also, most implementers stress the role of an hierarchical system of reports in order to combine traceability and transparency to different audiences. SKB states that the approach to overcome the conflict is a hierarchy of reports. Nagra chooses to emphasise transparency in the main report and traceability in the project documentation. Ontario Hydro suggests that a transparent report can point to more detailed references which eventually lead to a complete database of information.

DOE/YM agrees with the need of producing different level reports, but also notes, out of experience, that as an issue is framed for presentation, questions arise even in the mind of the preparer of that presentation that are not always readily answered by the documentation. According to PNC different levels of information, adjusted to different audiences, should be provided in a coherent way, but also stress other factors. Openness of the whole review process, including relevant documents and dialogue and communications between implementers and reviewers would increase the transparency to the public.

DOE/WIPP suggests that transparency is easier to define than to accomplish since all regulators and PA practitioners are not equal. The documentation cannot satisfy everyone, but if the technical basis is sound DOE/WIPP suggests the PA can be defended even if the documentation is not entirely transparent. The documentation should at a minimum be transparent to the applicant's team. Any PA has to be accomplished and documented within a schedule and under the applicable resource constraints. Common sense must determine how to do the best job given the constraints at the time. Transparency and traceability are in conflict. Electronic Information Management would help solve this conflict.

According to VTT traceability and transparency are closely related to robustness, reproducibility, non-complexity, and reporting. They suggest that given that the main PA report does not exceed 300 pages as recommended by IPAG-1 and given that the models employed in a licensing-related PA are not very complex, the requirements on traceability, transparency, robustness and reproducibility are in concert with each other.

Needs of other audiences

In general, the regulators do not think that documentation serving their needs would also serve the needs for other audiences such as the technical community or the general public. The need for special attention when addressing the general public is widely appreciated, but some suggest the confidence of the public will not be improved if the argumentation is too simplistic and categorical. In contrast, some implementers suggest that these needs can be combined. Others state that the regulator is the only audience who really matters.

Compilation of answers

According to SKI experiences a genuinely transparent documentation has to be produced in order to attract members of the general public, but the confidence of the public will not be improved if the argumentation is too simplistic and categorical. HSK suggests that an explanation to the members of other communities may require much more attention to language, to the basic philosophy and to explaining conservatisms that are obvious to the insider. NRI see a need for concise reports for the public. AECB suggest that documents serving the regulatory needs can also serve the needs for the technical community, but the opposite may not be true. According to NRC different types of documentation are needed for different audiences. GRS suggest that the report directed to regulators could be readable to the technical community, but not to the public. UKEA finds it unlikely that a single set of documents will meet the needs of all parties, but states that it is up to the developer to decide what audiences need to be served and how. PNC notes that there is a wide spectrum of other audiences, and their needs are often different from the regulatory needs.

Ontario Hydro states that all analyses and documents should have a common basis which would likely consist of a detailed, exhaustive technical study. Results and conclusions from this study would be organised into several different views that are customised to suit the expectations and needs of all potential audiences.

VTT comments that the report first of all serves the need of the regulator, but it has been tried to write the report such that could be of use for the scientific community in general, local decision makers, and interested members of the public. Nagra considers that the needs of other audiences have to be taken care of in the report. DOE/YM suggests that needs for other audiences can be combined in the early stages of project reporting, but not later on when there is a lot of complexly coupled information that needs to be discussed in the documents serving the regulatory needs. BfS suggests they provide documentation serving the needs of the regulator as well as the general public. According to DOE/WIPP, the report will not serve the needs of other audiences, but the regulator is the only one who really matters.

4.2 Structure of documentation

Effect on review

In most cases it was not felt that the structure of the documentation or the distribution of information within the structure affected the efficiency of the review. There are few specific remarks. The use of a hierarchical structure is generally regarded as positive.

Compilation of answers

> AECB and HSK experienced difficulties with some of the lower level documents. The AECB noted that the hierarchical structure of the AECL EIS documents enhanced overall clarity, and thereby aided the review. However, there was considerable repetition with paraphrasing amongst the various documents, and this added to the effort required to complete the review. UKEA, has not made specific guidance, but expect that the developer would submit a document plan at an early stage and this could be discussed to ensure the requirements of an efficient review would be met. According to DOE/WIPP the structure of their IPA was a definite hindrance and easily criticised.

Dependence on end-point and stage of development

Many hold the view that the IPA document structure could probably be the same in different stages of repository development, although some parts of the report will be more detailed in later stages. Other suggest that at an early stage, the IPA focuses on issues and future direction of R&D, whereas at a licensing stage a more stylised structure would be expected. Operational issues and sealing of the repository will also gain weight at later stages. However, there may still be some general structure of the IPA common to all stages. Most agree with the general list of content proposed by IPAG-1 and few see any immediate need to revise this list. Suggested updates mainly concern the inclusion of the operational phase and sealing of the repository. Specific regulatory constraints will also impact the structure of the IPA. Out of policy, some regulators do not want to issue any guidance on structure or contents.

Compilation of answers

> SKI notes that, in principle, the content should not depend on the stage of development. The modification of the different SFR assessments rather reflects a learning process on what an IPA should address. NRC states that there is a general structure for documentation. More detail may be needed for later stages, or specific issues may be addressed for specific end-points (such as subsystem requirements). According to Nagra one should try to follow a general structure. Neither does HSK see a clear dependence on stage of development, but emphasis may change and be shifted more towards backfilling and sealing in later stages. NRI notes that there is general structure given by law in the Czech Republic.
>
> DOE/YM notes that there is a minimum requirement that always should be there. In addition there is a need to adjust to specific demands and end-points. According to PNC at an early stage the IPA focuses on issues and future direction of R&D. At the licensing stage a more stylised structure would be expected. However, there should be a general structure for the IPA according to the general framework of the safety assessment. According to SKB the level of detail increases as the site characterisation progresses and while approaching final licensing. VTT states that a universally valid table of content is not possible since structure and content depend on external factors (but accepts the IPAG-1 list as a skeleton). DOE/WIPP notes that the structure of course depends on regulatory constraints. The document is written to show compliance with the regulatory requirements.

In contrast AECB states that the structure depends more on the implementer objectives. As a policy, there should be no prescribed structure, it should be determined by the proponent. A similar view is held by UKEA. The Agency has not made general guidance on document structure and would expect to have to structure its review according to the document plan and structure submitted by the developer. It is expected, however, that the developer would submit a document plan at an early stage and this could be discussed to ensure the requirements for an efficient review would be met.

All, except AECB, UKEA and SKB, who do not answer the question, generally accept the IPAG-1 suggestion of a general IPA content. HSK states that the IPAG-1 list is a good example, but thinks that certain details could have been handled otherwise. The list is covered by the structure of content provided by law in the Czech Republic (NRI). According to VTT the structure is an applicable skeleton. According to NRC the IPAG-1 list seems to include all the necessary elements, except an Executive Summary. GRS notes that for PA alone the IPAG-1 contents lists seems to be sufficient.

In Germany there exists guidelines for the documentation of safety (BfS), and GRS notes that the safety file for licensing a radioactive waste repository must contain more information than is needed for a PA alone, namely also operational aspects, design and constructional aspects, quality assurance, waste acceptance criteria etc. Partially these aspects also form the basis of the long-term safety assessment. The main difference is the pre-operational stage where operational limits have to be defined. SKB remarks that the IPA needs to address operation and closing of the repository, impact on the environment, recording keeping and post closure institutional control actions (if any), and closing of the repository.

Structure of review comments

The structure of the review report often follows the structure of the IPA reviewed. Some reviews however, are structured following the issues commented on. The implementers do not generally have problems with the structure of review comments, but some complain that reviews documented issues which could have been clarified in meetings between reviewer and implementer. A need for a transparent and well defined review process is identified by some.

Compilation of answers

Many (including STUK, SKI, HSK, GRS) use a review report structure similar to that of safety report, with the addition of a section with overall judgements. SKI notes that their report was written such that a reader should not have to frequently compare with the IPA. HSK notes that dependability and traceability of the results from the site characterisation was discussed in some detail, both as regards geology and hydrogeology. Then the results from the calculation of the release and dose were discussed, including variations resulting from the treatment of parametric, conceptual and scenario uncertainties.

In contrast the AECB review did not follow the EIS structure for documents nor the structure of the AECL report. Instead it was configured to present the comments and issues in a logical manner by grouping individual comments on different parts of the EIS into issues statements.

The NRC review comments are hierarchical. They first address broad base issues such as overall compliance and then the technical issues. The structure of the review will focus first on the issues most important to overall safety.

The review conducted by UKEA involved several different experts who each presented their separate review reports. There was also a summary report. However, in the now ongoing review work UKEA intends to collect all comments into a single review document.

SKB suggests that some of the comments could have been treated as separate issues, and not as part of the licensing review. Ontario Hydro concludes that many of the issues arose because the IPA was complex and voluminous, but the review time quite short. The IPA focused on the end results of the analysis and referenced an even larger volume of prior or intermediate studies. Some of the comments were confusing and the review process did not allow for an adequate discussion between the regulator and proponent of potential issues in the IPA before the final comments were issued.

DOE/YM notes that several detailed technical exchanges with the regulators and other reviewers have taken place and are still scheduled. They will reduce the number of surprises and misunderstandings.

DOE/WIPP notes that a graded approach from the beginning would have been more efficient. The review eventually adopted a graded approach.

PNC suggests that for transparency it would be preferable to define the review process in advance. The past review was carried out by a team consisting of members from neutral, technical organisations such as universities. In the view of the feedback to R&D activities, it would be favourable to provide another framework of review in which relevant people who would be involved in the implementation of disposal and formulation of regulations can state their opinions.

5. REGULATORY GUIDANCE

5.1 Need for guidance

Type of guidance

All see a need for some regulatory guidance on IPA and most regulators have, or are in the process of preparing, such guidance. Regulatory guidance would not only be a help for the implementer but would generally increase the traceability and transparency for different audiences of the review process. The guidance could refer to clarification of judgmental concepts such as handling of uncertainty or acceptable methods to assess inadvertent human intrusion, as well as more general guidance on regulatory expectations affecting models, data, quality assurance, and siting and assessment approaches.

Some implementers welcome guidance to assure a common understanding of the content of a performance assessment and how that content matches regulatory expectations, but would not like formal regulations or overly prescriptive regulatory guidance on the conduct of a system performance assessment, or on the design, or on the allocation of performance to components of the design.

Compilation of answers

According to Nagra regulatory guidance demonstrates to the public that clear rules exist for the implementer and the regulator. HSK notes that guidance also helps channel discussions taking place in public. GRS notes that in the German system regulatory reviews are carried out by consultants and the only guidance are the specific safety criteria. Pre-licensing discussions between reviewer and applicant would be desirable, but would require change in legislation. SKB see a role for guidance but would not like it to take the form of formal regulations.

Regarding content of guidance HSK generally prescribes few details, but notes that the regulator needs to express his expectations clearly. This may include the accounting for uncertainty, model validation, or comprehensiveness and availability of the supporting documentation.

Ontario Hydro sees a need for guidance on issues such as the meaning of "significant scenarios", "sudden and dramatic increases in radionuclide release", "acute risk" and an acceptable method to assess inadvertent human intrusion, as well as more general guidance on regulatory expectations affecting models, data, quality assurance, siting and assessment approaches.

DOE/YM sees a great need for regulatory interaction to assure a common understanding of the content and how that content matches regulatory expectations, but states that overly prescriptive regulatory guidance on the conduct of a system performance assessment, or on the design, or on the allocation of performance to components of the design, is neither needed nor helpful. The burden of proof should be on the applicant. During development it could be useful to state agreement on specific issues in order to direct attention to other issues, but it is understood that any issue could still be re-opened at licensing.

NRC sees no need to develop detailed, comprehensive guidance related to performance assessment, but suggests it might be useful to develop specific staff guidance on, scenario selection and screening, treatment of conceptual model representativeness, treatment of uncertainty in model parameter values, abstraction and simplification in mathematical models, validation of mathematical models and prediction of future states.

BfS see a need for guidance in particular on how to handle hypothetical high-consequence/low-probability scenarios, including human actions and how to investigate and judge consequences in the very far future.

PNC notes that issues on time frames and application of different safety indicators for safety assessments, biosphere modelling, scenarios to assess inadvertent future human intrusion, validation criteria and handling of low-probability and high-consequence events would need regulatory guidance.

According to DOE/WIPP guidance should be codified if it is necessary to clarify ambiguity.

Relation to stage of development

There are some diverse opinions on the need to adopt guidance to specific stages. All agree that the priorities shift during the course of repository development. (See also answers under 4.2).

Compilation of answers

According to VTT, more detailed guidance is required as the project proceeds from site selection into construction, operation and final sealing. SKI suggests that the structure of guidance will be the same in different stages, but there will be a shift in priorities. NRC suggests that the level of detail depends on stage, but the guidance should be flexible enough to be adaptable. HSK, SKB, NRI essentially share this view. In contrast, Nagra would like guidance on what is acceptable at different stages.

The AECB states that while different guidance is required at different stages of repository development, general guidance is also required to help the implementer keep the PA activity at a specific stage of repository development consistent with the overall regulatory expectations and requirements for licensing the repository through its life cycle. According to Ontario Hydro, guidance should adapt to different stages in repository development. UKEA only issues very general guidance since each PA performed will be in respect of a specific proposal and at a specific stage of repository programme.

Benefits of stylised approaches

There are different views on the benefits of stylised scenarios and approaches. The only generally accepted ones concern dosimetry and concepts such as ICRP standard man and the critical group concept. Many accept their use in handling future human actions. Some express concern that stylised approaches may distort the uniqueness of specific geological settings. Regulators generally have the view that any assumption or approach has to be motivated with respect to the actual site and concept, even if some recognise benefits of standardised approaches to the analysis. (See also 3.5).

Compilation of answers

VTT see the use of stylised approaches for treatment of human intrusion and the biosphere. Nagra suggests such approaches can be very helpful, in particular concerning human actions. NRI suggest they would simplify the IPA report agreement process. Also GRS notes that stylised approaches would be beneficial. BfS notes that policy decisions should not be site specific.

NRC notes that the National Research Council (NAS) recommend the use of “critical group” concept and stylised human intrusion scenarios. The NRC staff believes there is a benefit in defining those scenarios as stylised scenarios for which scientific evidence is not obtainable, but not for scenarios that can be based on geological record (such as tectonics, seismicity, volcanism, …). According to DOE/YM any guidance regarding things that are unknowable, such as the future state of human society, is beneficial to both sides as long as it is defensible. Other guidance is potentially useful, but if sites have little in common, it may have little meaning and may even distort the uniqueness of a geologic or geographic setting. According to DOE/WIPP removal of uncertainty which is pointless and costly for the applicant to characterise and defend is the responsible thing for regulators to do.

According to SKB stylised approaches are not needed, the IPA work itself should aim at development of applicable scenarios. SKI essentially agrees and states that such approaches need to be underpinned by a consensus of their usefulness. HSK only see their use with regards to interpretation of safety goals. AECB already specify the use of "critical group" concept and the ICRP "standard man", but do not anticipate specifying more explicit stylised scenarios. Ontario Hydro suggest it is up to the regulator to specify if they wish. UKEA would not define stylised scenarios and states that implementers would need to justify the relevance and applicability of the scenario to the particular site- and facility specific circumstances.

5.2 Development of guidance

Responsibilities for development

All agree that it is the task of the regulator to develop guidance and that the implementer and other stakeholders should be allowed to comment on the proposals before the guidance is finalised. These conditions are usually regulated in the national legislations. In some countries the implementer has a special status, being identified as one of the most affected stakeholders. In other countries the implementer status is only a reflection of their specific expertise.

Compilation of answers

STUK notes that the role of implementer, among others, is to present their views and to comment on proposals made by the regulator. SKI notes that the implementer and others must be allowed to express their opinions. By law development of regulations is made in public. The implementer is responsible for developing the EIS. HSK notes that, in general, they solicit opinions of affected organisations. The implementer has a special status as the main (but not the only) affected body. NRI notes that the implementer is involved on an advisory level. GRS notes that all parties involved provide their expertise and views.

Implementers and other stakeholders are requested to comment on proposals made by AECB. Implementers have no special status per se, but sometimes have greater weight due to technical expertise and being one of (but not only) the most affected stakeholders. In developing any guidance the NRC staff will issue it for public comment and consider such comments as part of its deliberations. To the extent that comments are received, the staff also has to explain how such comments were treated as part of its deliberations. The implementer has no special status by law, but in practice as a consequence of its technical expertise and ongoing pre-licensing discussions. UKEA states that public consultations on proposals are taken into account in developing the final document. There is no special status of implementer, only to the extent that they may have a special knowledge. For a specific proposal there will be a dialogue, which may take account of practicalities identified by the implementer.

According to SKB development should be made in co-operation between all parties. A special role should given to regulator and implementer. Nagra expresses that the implementer must be allowed to provide comments. DOE/YM notes that the implementer has no special status, but is involved in an open review of guidance documents before they are finalised. According to DOE/WIPP there should be close involvement throughout the process between the regulator and the applicant and an opportunity for the public to comment. According to BfS implementers should be asked for their views but not be involved in the development.

Update of guidance

All agree that regulators have the right to change views and guidance. In general the same procedures apply for updating regulations as for issuing them in the first place. The formality of these procedures may change between different countries. Implementers stress the need for open procedures for these changes. Regulators seem to stress that guidance or other statements by regulators are non-committal. In practice, some regulators fear loosing credibility if guidance is changed too often. They instead intend not to be too categorical in their advice.

Compilation of answers

In Sweden change in regulations is made through a formal and open process. Development of guidance is less formal. SKI notes that the regulators must make provisions to modify previous guidance, but suggest that making such changes could be difficult without loosing credibility. Consequently the regulator should not be too categorical in its statements and guidance. According to HSK the guidance should not fluctuate, but be adjusted to take account of progress in knowledge or change in paradigms. UKEA notes that present guidance is deliberately non-prescriptive, as far as possible, in order to avoid frequent revision. New information or new government policies may cause revision of regulatory guidance.

As noted by AECB and Ontario Hydro, the regulators should have a mechanism to periodically review their statements, guidance and requirements, in order to account for scientific and technological advancements and changing societal paradigms. Any changes should be done after consultation with affected stakeholders and other interested parties.

NRC (and DOE/YM) notes that in the USA to the extent that previous policy and guidance apply, the NRC staff is bound to it. Potential updates proceed through a formal, as specified by law, open rule making process where the public, industry, interest groups, the applicant, and other branches of government have a chance to give their views.

According to DOE/WIPP the regulator should maintain their own corporate history and be subject to the same quality controls that the regulation imposes on the applicant. Similarly the regulator should require the same quality controls on the stakeholders providing comment. Comments without technical basis are a waste of resources to provide responses.

GRS notes that only statements given at the end of the licensing process can be considered to be final. Discussions and guidance before submission of the license application are non-committal.

VTT notes that there is always a need for updates in the course of time. SKB has similar views. According to DOE/YM guidance should be flexible, and subject to change when change is warranted by new insights and new information. According to Nagra the regulator should present convincing arguments why a given guideline has to be changed, and that the implementer be made aware of impeding changes at the earliest possible time. According to BfS the regulator should announce updates or changes of guidelines well in advance to allow the implementer time to adjust.

Annex

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Appendix B

REGULATORY ENDPOINTS

This appendix summarises the regulatory endpoints that were used in the IPA Reviews studied in this report. As shown below, the regulatory endpoints are for reviews conducted between 1992 and 1999. As such, the regulatory endpoints describe the regulatory requirements and guidance in place in the various countries at different times. In some cases, the regulatory endpoints described below have been superseded or augmented by newer regulatory requirements or guidance.

Canada – IPA Review completed in 1995

The general requirement in Canada for radioactive waste disposal facilities is that the predicted radiological risk to individuals shall not exceed 10^{-6} fatal cancers and serious genetic effects in a year. In the long term the individual risk requirement should be applied to a hypothetical critical group assumed to be located at a time and place where the risks are likely to be greatest. The critical group is based on present human behaviour using conservative, yet reasonable, assumptions. The requirement is limited to 10 000 years. If the predicted risks do not peak before 10 000 years, there must be reasoned arguments that beyond 10 000 years the rate of radionuclide release to the environment will not suddenly and dramatically increase, and acute radiological risks will not be encountered by individuals. Also, there shall be no predicted future impacts on the environment that would not be currently accepted.

Czech Republic – IPA Review not yet completed. To be completed in 1999

The Czech Republic has defined basic principles of safe disposal using the reference deep geological disposal system in a granitic body. NRI used additional safety indicators, such as groundwater travel time, underground water flow, container lifetime, isolation and retention capacity of backfill, radionuclide concentration in the accessible environment, and population dose.

Finland – IPA Review completed in 1997

The regulatory endpoints adopted for the review of TVO-92 and TILA-96 assessments were based on a recommendation document published by the Nordic regulators in 1993. It specifies an individual protection requirement that is applied for a time period of about 10 000 years after the closure of the repository. An individual dose constraint of 0.1 mSv per year is set for the expected evolution of the repository and a corresponding individual risk constraint (i.e. risk of death of about 5×10^{-6} per year) for unlikely disruptive events. For the time period beyond about 10 000 years, nuclide specific constraints are defined for the flux of radioactivity that enters the biosphere. These constraints, ranging from 0.1 GBq to 10 GBq per year, are set so that the radioactivity originating from the repository may not result in any significant changes in the radiation environment of the disposal site. It is, however, recognised that all potential exposure scenarios cannot be assessed in quantitative terms but must be judged on the basis of qualitative considerations.

Germany – IPA Review completed in 1997

The only legislated regulatory limit for the Konrad repository was the dose limit of 0.3 mSv per year to an individual. To guide the implementer and regulator in the planning, safety assessment and licensing of a repository, the "Safety Criteria for the Final Disposal of Radioactive Waste in a Mine" have been issued by the Federal Government. Other site specific safety indicators were used by the implementer in the licence application to demonstrate the safety and robustness of the site and the level of conservatism in the safety and performance assessment calculations.

Japan – IPA Review completed in 1993

At the time, Japan had no regulations or guidance documentation for the deep geological disposal of radioactive waste.

Sweden – IPA Review completed in 1992

The regulatory guidance for the assessment of SFR was a dose target of 0.1 mSv per year to an individual. This target was applied to realistic, reasonably conservative scenarios. For unlikely and extreme scenarios and events, higher doses were permitted, based on qualitative assumptions of the probability of occurrence. The analyses were performed for a time period of 100 000 years, however the first 1 000 years were analysed in greater detail. For longer time periods (>1 000 years) the analyses were more indicative. The collective dose commitment was integrated over 100 000 years. Quantification of probabilities for different scenarios and events was not done. In addition to the analyses of radiological impact, the release of non-radiological materials from the repository was estimated and reported to the national franchise board for environmental protection.

Switzerland – IPA Review completed in 1996

Swiss regulations require that individual doses from a repository, based on realistically expected processes and events, at no time exceed 0.1 mSv per year. Doses dependent upon unlikely processes and events may alternatively be assessed against a total fatality risk limit of one in a million per year. The repository must be such that after it has been sealed, no further measures are necessary to ensure safety. Swiss regulators highlight the difficulties in estimating doses far into the future, and refer to such estimates as indicators of impact rather than realistic estimates. However, it is recommended that long-term calculations be performed, at least until the time of maximum impact of the repository. For such calculations, they recommend assuming suitable reference biospheres. They reserve the right to increase or lower the dose limit in cases where the affected population group is very small or very large.

United Kingdom – Partial IPA completed 1994

The regulatory guidance, under which the reviewed work was performed, (published in 1984) set the objective that the risk to any member of the public in any one year, from exposure to radiation from all sources other than background and medical exposure, should not be greater than that associated with a dose of 1 mSv. However, for the post-institutional management phase of a repository, the guidance stated that in order to take account of exposure pathways and health effects not at present recognised, and avoid prejudicing any future decisions that might lead to other activities which cause radiation exposure to members of the public, an additional margin of safety was required. The appropriate target applicable to a single repository at any time was, therefore, a risk to an individual in a year equivalent to that associated with a dose of 0.1 mSv; about a chance in a million. (Note: the dose risk relationship used pre-dated ICRP 60, 1990) Risk being defined as the probability that a given dose will be received multiplied by the probability that such a dose will result in a fatal cancer. The risk from a dose of 0.1 mSv would be substantially less than those arising from variations in natural background radiation within the United Kingdom. Revised regulatory guidance, taking account of ICRP 60, was published in 1997.

United States (WIPP) – IPA Review completed in 1998

The Waste Isolation Pilot Plant (WIPP) was assessed against environmental regulations that mainly consider the release of radionuclides to the accessible environment over 10 000 years. There are requirements for calculations of peak dose to individuals in the accessible environment from an undisturbed repository, with individual doses less than 15 millirem/yr (0.15 mSv/yr). There are also groundwater protection limits of 5 pCi/L (0.19 Bq/L) for Ra-226 and Ra-228 together, and 15 pCi/L (0.56 Bq/L) gross alpha activity including Ra-226 but excluding radon and uranium. The limit for beta particle and photon radioactivity is 4 millirem/yr (0.04 mSv/yr).

United States (Yucca Mountain) – IPA Review completed in 1996

Five performance measures were addressed in TSPA-95. The waste package failure distribution over time was used to address a regulatory subsystem performance requirement for "substantially complete containment" for a period ranging from 300 to 1 000 years in the U.S. Nuclear Regulatory Commission's (NRC's) regulation (Chapter 10, Code of Federal Regulations, Part 60, or 10 CFR 60). The peak fractional release rate of radionuclides from the failed waste packages, based on the 1 000-year inventory, was calculated to address another regulatory subsystem performance requirement in 10 CFR 60. The requirement was for this fractional release rate to be below one part in 100 000 per year for 10 000 years.

In addition to these two subsystem performance measures, three total system performance measures were also addressed. The first was based on a regulation remanded by the courts and not to be applicable to a Yucca Mountain repository. That regulation, 40 CFR 191, was promulgated by the U.S. Environmental Protection Agency (EPA) in 1985, and required the 10 000 year cumulative radionuclide flux across a geosphere boundary up to 5 km from the repository to be below a specified Curie value. The specified Curie value was, in turn, based on a population-risk limit.

Another system performance measure was addressed for two separate time periods. An all-pathway dose to an individual at a specified location, intercepting the contaminant plume with a well, and using the water for drinking and for some livestock, and for irrigation of self-consumed crops, was addressed. This dose-based performance measure was used to give both dose histories and peak dose values, for the first 10 000 years as well as for a million years. These performance measures were intended to indicate how the system would perform under potential new regulations being drafted under a Congressional directive to create a risk-based EPA standard and NRC regulation, specifically for a Yucca Mountain repository.

Appendix C

THE IPAG-2 QUESTIONNAIRE ON PERSPECTIVES FROM REGULATORY REVIEWS OF INTEGRATED PERFORMANCE ASSESSMENTS

Background

Regulatory reviews and perspectives of Integrated Performance Assessments (IPAs) are the focus of Phase 2 of the Working Group on the Integrated Performance Assessments of Deep Repositories (IPAG-2). The purpose of the attached questionnaire is to collect information to be used to organise a topical session at the 14th meeting of PAAG in October 1998 and prepare a progress report to RWMC, PAAG and SEDE on perspectives from regulatory reviews of IPAs for deep repositories and other major, related studies.

This IPAG-2 questionnaire is being circulated to PAAG members only, but it is understood that PAAG members will *jointly* compile the questionnaire with their SEDE counterparts.

How to answer the questionnaire

The questions are organised around five main topics. Answers are elicited from all organisations represented in PAAG that have participated (either in an implementer or regulator capacity) in an IPA that has been formally reviewed. It is acknowledged that, as source material, some organisations may want to refer to the reviews of more than one IPA study or, alternatively, to relevant documents other than IPA reviews, e.g. regulatory reviews of major R&D programmes related to IPAs, or existing or contemplated regulations/guidelines concerning IPAs. The international peer reviews carried out by NEA and IAEA are also of interest. The actual selection of the source(s) of information is left to the judgement of each answering organisation. However, the following guidance is provided for completing the questionnaire:

1. If multiple regulatory reviews are available for IPAs or related documents for the *same proposed repository*, the set of regulatory reviews for the proposed repository can be treated as one review for the purposes of IPAG-2. The response to each question should be based on the most recent IPA and IPA review that contained information relevant to that question.
2. If an organisation wishes to make reference to regulatory reviews for IPAs or IPA-related documents for more than one proposed repository, the same source of information should be consistently used when answering a series of questions. This implies that several answers may be needed for the same question. In all cases, the IPA and IPA review being referenced should be clearly stated.
3. "Yes" and "No" answers are not sufficient, as they do not provide a useful basis for preparing the topical session or progress report. While the appropriate length of the response to each question is left to the discretion of the participating organisations, it is suggested that most responses should be between a paragraph to a half-page in length. If

an organisation wishes to provide more detailed information for some questions, it may be appropriate to provide the information in appendices to the main questionnaire responses.

4. Some of the questions may overlap, in that portions of responses could be applicable to more than one question. If this occurs, the information can be presented once, and cross-referenced between responses. Please note, however, that unique and specific information is being requested in each question. Please read the questions carefully, and *try to address the nuances* in each question.

5. When referring to future work directions and needs for regulatory decision making, the focus should be on the next step in the repository development process.

1. Context of, and approach to, conducting the review(s)

This first set of questions aims at clarifying the context of, and the approach to, conducting the review(s) that you have been subject to or undertaken. If any of the specific questions are not applicable to you, or you do not have an answer, please leave it blank and proceed to the next one.

1a. Which IPA (or other major, relevant study/document) did you review or receive a review on? Was it an international or domestic peer review? If you were a reviewer, are you a regulator?

1b. What was the intended purpose or context of the IPA and its review. For example: feedback to an R&D programme at a particular stage of repository development, support to site characterisation, justification of design, support to licensing, etc.

1c. What regulatory end-points, performance measures/goals, or safety indicators were considered? (Please also mention non-numerical criteria, if applicable)

1d. *For regulators only:* What were your expectations of the IPA? Did any of the expectations relate to the specific stage of repository development (i.e. level/completeness of safety demonstration required for an early stage of repository development)? In other words, did your expectations reflect a stepwise approach to repository development and the demonstration of long-term safety? Were your expectations made known explicitly to the implementer? If so, how? If not, why?

For implementers only: What expectations (from the regulator and any other groups) were you trying to satisfy with the IPA? Were these expectations made known to you explicitly? If so, how?

1e. How long was the formal review period? What resources were spent in carrying out this review? Do you anticipate an updated IPA and corresponding updated review? If so, when?

1f. Was the IPA reviewed by others, e.g., an oversight committee, or the technical community in general? If so, were those reviews co-ordinated?

1g. *For regulators only:* In preparing the formal written review response to the IPA, did you take into consideration information other than that in the IPA and the documents referenced in the IPA(e.g.: presentations by implementer, the implementer's overall program and/or information from other programs)? If yes, how important was this information to your formal written response?

For implementers only: Did you expect the regulator to take into consideration information other than that in the IPA and the documents referenced in the IPA in preparing the formal written response to the IPA? If yes, what other information did you expect the regulator to consider?

1h. *For regulators only:* To what extent did you perform your own calculations/analysis prior to, or during, the review? How were they used in the review? Did you document them along with any other ancillary analysis/evidence?

1i. *For regulators only:* To what extent did you use external experts (i.e., not regular employees of the regulatory authority) to assist you with the review? What were the reasons for using or not using external experts?

1j. Were reviews shared with the public? If so, how?

1k. *For implementers only:* Were actions taken to identify specific audiences other than the regulator and address their needs in the documentation of the IPAs (e.g.:, specific sections of the scientific community, non-technical decision makers and general public)? What actions were taken (e.g., external technical input, subject matter experts, presentations at professional societies, inclusion of public or decision makers input, etc.)?

2. Findings and messages from the review(s)

This set of questions addresses key messages given in, and obtained as a result of, the review. Some of the answers are elicited either from the regulator or the implementer. If you do not belong to either category, you may still answer by identifying whether, for the purpose of the review, you were closer to the regulator or the implementer side.

2a. Based on the review comments, if you are a regulator: what were the key messages to the implementer? If you are an implementer, what were the key messages you got? Were these messages explicitly conveyed in writing or in conversation, or were they implied in the formal comments on the IPA?

2b. For the regulator: What aspects of the IPA were found least satisfactory? For the implementer: What aspects of the IPA review were found least satisfactory?

2c. For the regulator: What aspects of the IPA were found most satisfactory? Was this stated explicitly, or was it to be inferred by lack of comment? For the implementer: What aspects of the IPA review were found most satisfactory?

2d. Were issues resolved and/or were new issues identified as a result of this IPA review? Which ones?

2e. In what ways, if any, have your views as a regulator, implementer or technical expert changed as a result of this (these) review(s)?

2f. To the regulator: In your reviews, do you allow yourself to make positive statements for aspects of IPAs that you consider acceptable? If not, why?

2g. If a regulator makes a positive statement about an aspect of an IPA, to what extent would you consider it a definitive agreement or approval? Under what conditions should the regulatory agency be allowed to reverse or change its statement?

3. Treatment of uncertainty and other aspects of the safety case

This set of questions addresses whether and how the review explicitly commented on the treatment of uncertainty and other aspects of the safety case. Also, your views (based on reviews done/received, regulations/guidelines, or current thinking) are sought on how uncertainty and other aspects of the safety case should be handled in future IPAs to allow for regulatory decision making.

If a question is not applicable or you do not have an answer, please leave it blank. To the extent possible, please structure your response according to the questions below.

3a. To aid interpretation of the responses in this section, please give your definitions of the following:

- i) data uncertainty;
- ii) conceptual model uncertainty;
- iii) scenario uncertainty; and
- iv) any other types of uncertainty that you consider to be distinct from i), ii) and iii).

3b. Summarise (1) what was said in the review regarding the following, and (2) your current perception of the ways that the following should be used/addressed in future IPAs:

- i) the use of confidence building techniques (e.g. multiple lines of reasoning, simplified calculations to check complex modelling, bounding calculations, robust design and analysis, multiple safety indicators, etc.)
- ii) the application and meaning of the multi-barrier concept and defence in depth
- iii) the handling of conceptual model uncertainty
- iv) the adequacy and completeness of the system description (answer this only if you consider the completeness of the system description to be distinct from conceptual model uncertainty)
- v) the handling of scenario uncertainty
- vi) the relative merits and roles of deterministic versus probabilistic modelling
- vii) the relative merits and roles of realistic versus conservative calculations
- viii) the handling of high-consequence/low-probability cases in the assessment of overall safety (i.e.: in an aggregated or disaggregated manner, quantitatively or qualitatively)
- ix) the use of failure mode analysis (i.e.: assess what can make the system fail as opposed to what it can tolerate)
- x) level of support for data, assumptions, and models by measurements from field and laboratory
- xi) the use of qualitative and soft information
- xii) the use of natural analogues
- xiv) the use of stylised approaches (climate scenarios, reference biosphere, human intrusion)

3c. To what extent can an implementer balance a good, well-characterized site, a convincing and well-supported PA, and long-lived robust engineered barriers in demonstrating safety?

For example, if an implementer chooses to emphasize the engineered barriers in meeting safety, can the characterisation of the site be limited to that needed to show that the host rock will provide a suitable long-term environment for the engineered barriers? State your views on the minimum requirements, if any, for the site and its characterisation, the PA and the engineered barriers.

4. Documentation and transparency aspects

The following set of questions has been formulated to elicit your views on regulatory expectations concerning structure and content of an IPA.

In responding to the questions specified hereafter, please also indicate the basis for your current thinking, i.e., is it based on reviews done or received, on existing regulations and guidelines, etc.? If a question is not applicable, or you do not have an answer, leave it blank.

4a. Traceability, as defined in IPAG-1, indicates "an unambiguous and complete record of the decisions and assumptions made, and of the models and data used in arriving at a given set of results. To be complete, this should include information on when and by whom various decisions and assumptions were made, on what basis, how these decisions and assumptions were implemented, what version of codes and data sets were used etc..." Please comment on your experience in tracing the results of the reviewed IPA and your views on traceability.

4b. By transparency, as defined in IPAG-1, it is understood "the PA report to be written in such a way that its readers can gain a clear picture, to their satisfaction, of what has been done, what the results are, and why the results are as they are. This is a more subtle requirement than that of traceability. .... transparency is audience-dependent, i.e. a document that is transparent to a regulator or practitioner of PA may not be transparent to a member of the public and vice versa." Please comment on your experience in gaining a clear picture of the contents of the reviewed IPA (analysis, presentation, ease of finding information, possibility to follow logic) and your views on transparency.

4c. Are traceability and transparency in conflict? If an implementer meticulously justifies and cross-references all decisions and assumptions made, the document may become difficult to read, and transparency could be reduced. If you consider traceability and transparency to be at least partially in conflict, describe any approaches or techniques to document preparation that you believe would enhance both traceability and transparency.

4d. Will a documentation that serves the regulatory needs also serve the needs of audiences other than the regulators (i.e., technical community, general public)?

4e. Did the structure of the documentation (hierarchical set of documents or in a single level) or the distribution of information within the structure affect the efficiency of the review? (Please be specific if the structure was a hindrance).

4f. Does the structure of the documentation depend on the end-points/regulatory constraint/stage of repository development; or is there a general structure for documenting safety?

4g. Should the internal structure of a IPA depend on the end-points/regulatory constraints/stage of repository development; or is there a general structure that is applicable to all IPAs? Is the proposed list of contents in IPAG-1 acceptable (see attachment)? If not, what needs to be changed and why? Describe your ideal list of contents.

4h. For the regulator: How did you structure the IPA review comments, and why did you chose the structure? For the implementer: Did the IPA review structure allow you to understand the regulator's comments and concerns? Would you have preferred a different IPA review structure? If so, describe your preferred structure and the reasons for your preferences?

5. Need for regulatory guidance

5a. Based on current experience as well as performed or received reviews, do you see a need for regulatory guidance on IPAs in general and/or on specific aspects of IPAs? Is the need solely for the benefit of the implementer, or are there other audiences for the guidance (eg: to help the public understand the regulatory process)? Please elaborate.

5b. Is the needed guidance on IPAs dependent on the specific stages of repository development (e.g.: site acceptance, construction of the underground facility, etc.)?

5c. How and to what extent should the implementer and other stakeholders be involved in the development of the regulatory guidance? Should the implementer have a special status in the development process?

5d. Is there a benefit in policy decisions on stylised scenarios (e.g. for human intrusion, future climates, reference biosphere)? Should regulators specify stylised scenarios for use in their national context, or is there value in stylised scenarios only if there is general acceptance of them in the international community? Please elaborate.

5e. Should regulators make provisions to maintain (and stick to) statements or guidance given in the past? How should regulators proceed with updates to previous guidance that needs to be changed?

Appendix D

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