European Pilot Study on
The Regulatory Review of the Safety Case for Geological Disposal of Radioactive Waste

Case Study: Uncertainties and their Management

Johannes Vigfusson
Hauptabteilung für die Sicherheit der Kernanlagen (HSK), Switzerland

Jacques Maudoux
Federaal Agentschap voor Nucleaire Controle – L'Agence fédérale de Contrôle nucléaire (FANC – AFCN), Belgium

Philippe Raimbault
Autorité de sûreté nucléaire (ASN), France

Klaus-Jürgen Röhlig
Gesellschaft für Anlagen- und Reaktorsicherheit (GRS) mbH, Germany

Robert E. Smith
Environment Agency, UK

January 2007

Gesellschaft für Anlagen-
und Reaktorsicherheit
(GRS) mbH

Preface

A number of countries within Europe are developing or giving consideration to the development of geological disposal facilities for the disposal of high level radioactive waste. The safety authorities in these countries are interested in exploring how far it is possible to achieve a mutually consistent approach to the demonstration of safety of such facilities and the regulatory review of documentation providing such demonstration. As such and with technical support organisations and international bodies they have initiated a Pilot Study on how the important elements of the safety case should be presented for regulatory review and approval. The study is thus focused on regulatory expectations for the different milestones of repository projects and corresponding safety cases.

Uncertainties concerning the safety of repositories are unavoidable due to the complexity of the phenomena of concern and the scales in time and space under consideration, and their management is central when developing a repository system and assessing its safety. Therefore, the issue of uncertainties and their management has been chosen for a more detailed examination in the framework of the Pilot Study in order to identify the level of commonality on this subject among the participating countries, to better understand differences, and to strengthen and develop common grounds for guidance. This document presents the results of this case study. It focuses on the handling of uncertainties in the context of the different elements of a safety case: safety strategy, safety assessment and assessment of compliance.

The regulatory frameworks differ considerably between countries. The group concerned with this case study however observes that regulatory attitudes towards the achievement and demonstration of safety differ to much less an extent. **This is evidenced by the statements typed in bold face which provide views and conclusions shared by the authors.**

1 Introduction

In general, uncertainty about the performance of a system comes from the absence of specific knowledge or data regarding one or more of the components of the system, or from the variable character of certain phenomena. For the performance of a deep geological disposal system for radioactive waste, it usually involves lack of knowledge of parameter values, limited understanding of certain mechanisms, modelling difficulties, or the general difficulty of predicting the future.

Conscious accounting for uncertainties and analysis of their possible consequences is a required part of any safety assessment for a radioactive waste repository. How this is achieved and the relevant regulatory requirements may, however, differ between countries.

Recognising these differences, the aim of this document is to identify the level of commonality on this subject among a number of European countries involved in the development of deep disposal projects and to propose some common grounds for guidance. The document focuses on the handling of uncertainties in the context of the different elements of a safety case: safety strategy, safety assessment and assessment of compliance.

Regarding the safety strategy, the basis of the stepwise approach for development of a repository is presented. It is emphasised that the implementer should account for the effect of uncertainties and provide a clear process for managing them.

Regarding the effect of uncertainties on the safety assessment, emphasis is placed on those elements of the assessment which are not yet fully included within guidance provided by international organisations such as IAEA or NEA (IAEA 2005a, NEA 1999, NEA 2004), namely:

- The strategy of scenarios and its important role in a) structuring the safety case and the review of the safety case, b) capturing uncertainties effectively and efficiently, and thus c) identifying the need for further work to avoid, mitigate or reduce uncertainties and to evaluate their effect. By this means, the link between safety assessment and safety strategy is maintained. Deterministic and probabilistic approaches both have a role to play in the strategy of scenarios.

- The contribution to be made by best estimate, conservative and pessimistic approaches for determining models and parameters, depending on the part of the repository system, the scenario and the time frame being considered. Within the framework of the stepwise approach, the regulator is advised to clarify at each decision point his expectations on the relative importance of these different approaches.

The assessment of compliance in the presence of uncertainty is also an important aspect of the subject. The approach differs depending on the country. For example, some countries apply dose standards and others apply risk standards. Whatever the standards, the issue remains that many uncertainties in the post-closure safety case cannot reliably be quantified. Calculated doses or risks can only be regarded as broadly conservative indicators of impact rather than anything more definite or concrete and, accordingly, the post-closure safety case needs to be based on multiple lines of evidence.

It is considered that at times longer than those for which the conditions of the engineered and geological barriers can be modelled or reasonably assumed, a formal demonstration of compliance with radiological protection objectives becomes meaningless against the background of uncertainties. Accordingly, the developer may need to fall back on more general lines of reasoning.

The document also deals with other topics connected with the subject of uncertainties, including sensitivity studies, human actions, expert judgement, confidence building and optimisation.

2 Safety Strategy

2.1 Stepwise approach

It is now widely accepted that development of a repository and its safety case should take place in a stepwise manner with well-defined decision points. It is also common understanding that information about uncertainties and perspectives on how they can be managed form an important input for the decisions to be taken at these points. The ways in which a stepwise process is implemented in regulations vary from country to country, and so do the requirements concerning the involvement of regulators and licensing authorities at decision points.

The Group is however of the opinion that it is important to keep regulatory and licensing authorities and their technical support organisations informed about the state of development at each step and to involve them in the major decisions to be made, no matter whether or not there is a formal requirement for doing so. This is also in the interest of the implementer since it prevents "unpleasant surprises" at later stages of repository development when formal agreement by authorities is needed.

Accounting for the effect of uncertainties and providing a clear process for managing them has become a widely accepted requirement for the development of a safety case. How much uncertainty can be accepted at a certain stage depends on the decisions to be taken at this stage. At every stage, there needs to be an assessment of the scope for further reduction of uncertainties and/or mitigation of their effects, and a continuing commitment to this, as witnessed in various documents of IAEA and NEA. The following quotations provide examples [emphasis added]:

"The geological disposal system (the disposal facility and the geological environment in which it is sited) is developed in a series of steps in which the scientific understanding of the disposal system and of the design of the geological disposal facility is progressively advanced. At each step, safety assessment is important in evaluating the prevailing level of understanding of the disposal system and ***assessing the associated uncertainties****."* (IAEA 2005a, 1.10)

"Safety assessment is the process of systematically analyzing the hazards associated with the facility and the ability of the site and the design of the facility to provide for the safety functions and to meet technical requirements. Safety assessment includes quantification of the overall level of performance, ***analysis of the associated uncertainties*** *and comparison with the relevant design requirements and safety standards."* (IAEA 2005a, 3.41)

"Decision making requires only that a safety case has been compiled that gives adequate confidence to support the decision at hand, and that an ***efficient strategy exists***

***to deal at future stages with any uncertainties** in the description which have the potential to compromise safety."* (NEA 1999, p.9)

*"… the connection needs to be made between **key uncertainties** that have been identified and the specific measures or actions that will be taken to address them, especially with regard to the R&D programme ..."* (NEA 2004, p.29)

For programme decisions which require formal regulatory approval (e.g. a licence) a clear regulatory position is required on whether uncertainties can be accepted or not. Regulations vary with regard to the degree of detail and the way they address this issue. The Group, however, feels that regulatory practice varies to a much lesser degree. The ensuing sections of this paper attempt to provide evidence for this statement by providing shared positions and opinions about this issue.

The Group considers that regulatory involvement is necessary for major decisions about the repository concept or about R&D priorities based on the outcomes of safety cases and/or safety assessments (i.e. supported by sensitivity analysis results).

2.2 Management of uncertainties

2.2.1 Uncertainty identification, tracking and forward management strategy

Uncertainties need to be carefully identified and tracked and **it is recommended that a register of significant uncertainties is required as part of the safety analysis for a disposal system.** Once uncertainties have been identified, the question of their further management arises. **It is thus also recommended that the developer of the disposal facility should present a clear forward strategy for managing uncertainties.**

Developing such a strategy involves asking at least the three following questions for each uncertainty:

- Is the uncertainty important?

- Can the uncertainty be avoided, mitigated, or reduced?

- Can the uncertainty be quantified?

Is the uncertainty important?

It is not acceptable simply to dismiss an uncertainty as unimportant. Instead, one or more reasons for regarding it as unimportant need to be recorded in the register of uncertainties. One reason might be, for example, that a sensitivity analysis has shown it to be unimportant (see section 3.5 below). **If good reasons can be recorded as to why an uncertainty is unimportant, no further steps need be taken to avoid, mitigate, or reduce it, or to quantify it.**

Can the uncertainty be avoided, mitigated, or reduced?

These issues are discussed in section 2.2.3 below.

Can the uncertainty be quantified?

Quantification of uncertainties is discussed in section 3.3 below.

2.2.2 Sources of uncertainties

The following can be distinguished as sources of uncertainty[1]:

- **Uncertainties regarding the intrinsic features of a repository component,** possibly associated with measurement inaccuracies or the spatial variability of a component. This is usually dealt with by quantitative analysis.

- **Uncertainties regarding the processes governing repository evolution**. How the various components interact and affect the system evolution needs to be properly understood and modelled. Modelling proceeds by simplification of

[1] The authors recognise that there is no unique way to describe and categorise the various sources of uncertainties, cf. e.g. (NEA 2005). They believe, however, that the ensuing categorisation is an appropriate one for the purposes of achieving and assessing long-term safety for radioactive waste repositories.

detailed representations of the phenomena, thereby introducing uncertainties, and also may entail extrapolations in time and space.

– **<u>Events</u> that may affect repository evolution**. These include phenomena of natural origin (climatic, tectonic events, etc.) usually displaying patterns of variability, but often involving large uncertainties, and events due to human activity (e.g. intrusion, greenhouse warming), which are largely unpredictable. Typically, stylised approaches (see section below on *Future human behaviour*) are adopted to deal with the latter. For example, it is often assumed that human behaviour in the future will largely be the same as today.

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

Many uncertainties of the second type may be characterised as “insufficient knowledge” (epistemological uncertainty), one example being cases where the ensemble of possibilities underlying the uncertainty (the event space) is poorly known.

2.2.3 Avoidance, mitigation and reduction of uncertainties

In many cases, steps can be taken to avoid, mitigate or reduce uncertainties. This can apply whether or not the uncertainty concerned is amenable to quantification. Systems in which uncertainties that would otherwise be important are avoided or mitigated are often called “robust systems”.

Some examples are discussed below.

Variability

In general, it is preferable to choose an environment and take relevant design steps which avoid or mitigate variability. It is, however, in principle not possible to reduce variability.

Variability may be less important on a large scale than it is on a small scale, although this is not always true. Sometimes variability follows a power law, i.e. the size of features or events encountered depends on spatial or temporal distance raised to some power. In these cases, variability is scale-free.

Statistical inexactness

It is in principle possible to reduce statistical inexactness by gathering more data, but there may be practical limitations on the amount of data that can be gathered, e.g. because of cost, because it is necessary to wait for events to occur, or because more investigation would do unacceptable damage to the subject of the investigation (too many boreholes into the host rock for a disposal facility).

Data relevance

When we improve the relevance of data (e.g. by using data specific to a repository site rather than data from literature), we reduce the related uncertainties. It is always, however, an exercise of judgment as to whether the relevance of data has been improved, since it is generally not possible to quantify the uncertainty related to the relevance of data.

Understanding of processes

Any safety case for a repository system is dependent on understanding of the processes involved in the evolution of the system. Conceptual uncertainties will be introduced by insufficient understanding of these processes. Some of these uncertainties can be avoided or mitigated by choosing or designing systems for which the processes in question are less significant (e.g. by use of chemical buffering). Process understanding can be improved by research but it is an exercise of judgment as to when this understanding is sufficient. The related conceptual uncertainties cannot be quantified.

<u>Future human behaviour</u>

Future human behaviour is unpredictable. The concept of reducing uncertainties is meaningless in this context. Steps can be taken in repository siting or design to limit the potential for, or the consequences of, human action affecting the repository. However, the assumptions underlying such steps are essentially speculative. For this reason, these assumptions have to be postulated in the virtual absence of relevant evidence (referred to below as a stylised approach). The regulator will need to agree to these assumptions and in some cases he will be their source.

3 Assessment Strategy

3.1 Approach to demonstrating compliance

The overall objective of radioactive waste disposal is the protection of humans and the environment from the effects of ionising radiation. Protection concepts start from those of classical radiation protection but have to be adapted for the particular situations under consideration. The important point is that the long-term evolution of a disposal system is assumed to occur without human control or intervention. The safety case needs to demonstrate that humans and the environment are adequately protected without such control or intervention.

This has led to assessment strategies focussing on potential radionuclide releases from the repository to the biosphere and evaluating potential consequences by means of concepts such as radiological dose or risk. There are significant differences from safety assessments for other nuclear installations: Safety concepts for deep repositories rely to a large extent on geological components which are less amenable to characterisation than engineered components. In addition, the timescales of concern exceed by far those considered when assessing other nuclear installations. As acknowledged e.g. in (ICRP 2000), calculated dose or risk values can therefore only be seen as "indicators of the protection afforded by the disposal system".

The main focus of safety assessments is usually on the modelling of potential radionuclide migration to the accessible environment, so that the **potential consequences to human beings and other species** can be assessed.

Moreover, safety cases also seek to provide **multiple lines of evidence** for the isolation capability of the system, calculated migrations and their potential consequences thus becoming one in a set of arguments for repository safety. Nevertheless, calculated consequence values usually remain the one element for which numerical compliance is demonstrated while other arguments, even if they can be supported by performance indicators, may be less amenable to formal numerical compliance evaluation. **The question of which calculated indicators should be used and the standards against which they should be judged remain central to a regulatory framework.**

There is a wide range of regulatory attitudes with regard to this question. Concepts are different not only with respect to the indicators to be considered (e.g. concentrations, dose, risk), but also to the degree and way they prescribe how these indicators should be calculated (deterministic vs. probabilistic approaches, requirements to consider certain scenarios, critical groups etc.) and the rationale for the standards to be applied. Differences also exist about the roles of such standards as limits, targets, or constraints and – in the case of a probabilistic approach – about which statistics are appropriate for demonstrating compliance.

Broadly, all these concepts rely on the calculation of radionuclide migration and resulting concentrations in, or fluxes into, the accessible environment. If such indicators are considered at locations in the repository system for which justifiable long-term prognoses can be made, there is a relatively high degree of confidence in the results even for long timeframes. This changes, however, for concentrations in near-surface aquifers: at the times when the calculated radionuclide releases will occur, these aquifers may no longer exist in the form we know them today (e.g. due to glaciation, erosion …).

3.2 Strategy of scenarios

Understanding the possible evolution of a disposal system may be gained by illustrative calculations under different assumptions about key events or properties of the system (i.e. exploring different scenarios). Defining scenarios may be viewed as making definite assumptions about uncertain events or properties. The aim is to choose a number of different scenarios that, taken together, illustrate the behaviour of the system and its safety in a variety of circumstances. The selection of scenarios entails a good qualitative understanding of the features, events and processes that significantly affect the evolution of the disposal system. Gaining such an understanding through exploring such scenarios is usually an iterative process.

Scenarios may be explored not only to gain an understanding of future situations that might realistically happen, but also to examine the reaction of the disposal system or its components to different assumptions in order to increase understanding of how the system functions.

Several types of scenario can be identified: scenarios that seek to represent evolution of the repository system within the expected range, scenarios that represent less likely but still plausible modes of repository evolution, scenarios that portray extreme events but that are still within the range of realistic possibilities (bounding cases) and scenarios that do not aim to be realistic but rather explore the robustness of the system ("what-if" cases, section 3.7).

An example of the second type of scenario is barrier degradation more rapidly than expected. Examples of the third type are an extreme ice-age or a major seismic event. An example of the fourth type of scenario is postulated failure of a confinement barrier for undefined reasons. Because future human actions are unpredictable and scenarios that involve them need to make stylised assumptions, these are put into their own separate fifth type.

There is general agreement in the Group that defining a set of illustrative scenarios is important to a safety case since it enhances understanding of the repository system and its evolution. It also helps to structure the review of the safety case and is a valuable tool to identify where further work should be directed to avoid, mitigate or reduce uncertainties and to evaluate their effect. By this means, the link between safety assessment and safety strategy is maintained.

3.3 Quantification of uncertainties

3.3.1 Scenario development and management of uncertainties

In the preceding section, several types of scenario have been identified. Quantitative assessments of these scenarios may be wholly **deterministic** or may seek to capture a range of uncertainties within them using **probabilistic** methods.

The underlying assumptions may be **best estimate, conservative or stylised**, or some combination of all three. A stylised approach may be used either for a whole scenario or for only part of a scenario (e.g. for representation of the biosphere or for representation of the very long term evolution of the repository system). Quantitative assessments may, for example, calculate doses, probability distributions of doses, or risks.

Approaches in which the attempt has been made to build all scenarios into a single overall probabilistic assessment (variously called Total System Simulation, Environmental System Simulation, System Simulation Approach, Probabilistic System(s) Assessment, Global Probabilistic Risk Approach, Total System Performance Assessment) (THOMPSON 1989, THOMPSON 1999, THOMPSON & SAGAR 1993, DOE/HMIP 1992, SANDIA 1991, DOE 1998, AECL 1994) have been explored in the past and have proved unsatisfactory for a number of reasons, including:

1. Although they might appear to do so, they do not take the burden of scenario development away from the developer of the safety case since all scenarios must be explicitly built into the probabilistic model.

2. Probabilities need to be generated, often by arbitrary means, for every feature, event, and process (FEP) considered including those which, as discussed previously, are not amenable to quantification.

3. Results are presented in an aggregated manner which may be difficult to understand and communicate. Judgements are hidden where they ought to be made explicit.

4. There is difficulty in completely exploring probability space. For example, adequate exploration of low probability FEPs, and their combinations, potentially requires a sample size too large to be computationally tractable.

5. There is lack of flexibility, e.g. regarding the possibility of exploring different scenarios in different ways, or late discovery of FEPs which were not included in the initial analysis, requiring a re-run of the whole assessment.

At the other extreme, it might be possible to envisage a safety analysis that attempted to deal with all uncertainties by a multitude of different scenarios, each wholly deterministic. Such a proliferation of different scenarios would probably be equally difficult for anyone to understand.

The opinion of the Group is that the solution is a safety analysis involving a limited number of different scenarios, some possibly being wholly deterministic and others seeking to capture a partial range of uncertainties. Uncertainties not included within scenarios would be captured by differences between scenarios.

The deterministic scenarios could include those that portray extreme events but that are still within the range of realistic possibilities (bounding cases), and those that do not aim to be realistic but rather explore the robustness of the system ("what-if" cases). Some deterministic scenarios might also be of the type that seeks to represent the expected evolution of the repository system.

The scenarios that attempt to capture a partial range of uncertainties would mainly be those representing evolution of the repository system within the expected range, or those representing less likely but still plausible modes of repository evolution.

The aim would be to develop a set of scenarios that:

- Captures uncertainties effectively and efficiently in a technical sense, by whatever means is deemed best for any given uncertainty;

- Captures uncertainties effectively and efficiently in a presentational sense; and

- Minimises the total number of different scenarios, consistent with the preceding two objectives.

There is a requirement to establish and maintain a clear structure for the safety analysis throughout its development, including the presentation of scenarios. In particular, the developer of the disposal facility should not present isolated pieces of work (such as isolated scenarios) to the regulator, or to a wider audience, divorced of a clear statement as to how these relate to the safety analysis as a whole.

3.3.2 Probabilistics vs deterministics

A safety analysis will in general benefit from including both probabilistic and deterministic assessments, because each has an important contribution to make.

Probabilistic assessments

Uncertainty in parameter values can, in principle, be described by a probability density either derived from observed statistics or more generally introduced as an expression of the degree of belief in the value. Actually, many uncertainties that are not associated with a specific (physical, chemical, …) property of the system can nevertheless be parameterised and a probability density derived that represents the uncertainty in terms of degree of belief (e.g. in the validity of a model assumption). A probabilistic calculation derives the probability density of the outcome of the safety assessment from the probability densities of the parameters (using similar model equations to the corresponding deterministic (i.e. a single scenario) calculations).

The strength of the method, properly applied, is its ability to derive the most likely outcome (which in general may be different from the outcome of a calculation with the most likely values for all parameters) together with an assessment of its uncertainty. All quantifiable uncertainties are treated within a uniform, systematic, and logical framework. Thus the understanding of the overall behaviour of the system is strengthened. Probabilistic assessments are useful for exploring a wide variety of situations, including a continuum. They can illuminate what are the main contributors to risk.

A characteristic of the method is that it requires assumptions about the input probability distributions. Another characteristic is that the method aggregates a large number of outcomes tending to obscure the individual pathways by which the system may evolve.

This consideration leads to some degree of disaggregation of the calculation, i.e. fragmenting it into a number of separate scenarios, making different assumptions in order to gain a better understanding of the system.

Probabilistic assessments may also fail to make a proper distinction between probabilities that are objectively known and those that are not, thus giving the false impression that all uncertainties can be satisfactorily quantified. Quantification of uncertainties that are not objectively known may lead to results that are not meaningful because they are artefacts of the assessment. However, if such uncertainties are excluded from a probabilistic assessment, they remain as reservations on that assessment.

Probabilistic assessments can generate concerns about complex but potentially important issues such as risk dilution where it is hard even for specialists in the area to reach a clear understanding (NEA 2005).

Probabilistic assessments often fail to make a clear distinction between unconditional and conditional probabilities. Use of a risk measure does not distinguish between small doses that may be received with a high probability and large doses that may be received with a low probability, where the resultant risk is the same. These are problems that can be resolved, however, by skill in disaggregating such an assessment (NEA 2005).

It can often be difficult to convey the meaning of a probabilistic assessment to a non-specialist audience.

For the probabilistic approach to be useful the implementer needs to show that the system is well understood, the processes are adequately modelled and the parameter variations are within the range of validity of models.

Probabilistic assessments may help to guide what deterministic assessments should be carried out, for example they can help to identify typical and bounding cases.

Deterministic assessments

Deterministic assessments are useful for exploring the general properties of the repository system and the calculational model(s), in other words for initial scoping calculations. They are also useful for exploring typical situations, bounding situations and illustrative extreme situations. They can explore these in depth, thus providing a vivid and thorough understanding which is easy to convey, even to a lay audience. In particular, they can illustrate that a disposal system is safe even when conservative assumptions are made.

Understanding of the possible evolution of the disposal system is gained by making different assumptions about FEPs that are poorly known. The aim is then to choose a number of different situations in such a way that they together illustrate the behaviour of the system and its safety in a variety of circumstances that encompass the future evolution.

The weakness of the method when considering a particular time evolution is that an arbitrary choice is made about the possible combination of FEPs to consider. This choice may be based on the likelihood of each FEP when it is known. There is also some arbitrariness in the choice of the magnitude of each FEP that builds up the scenario.

Purely deterministic assessments are less able to provide an understanding of uncertainties than probabilistic and deterministic assessments taken together. There is also a danger, if reliance is placed exclusively on deterministic assessments, that combinations of FEPs that make an important contribution to risk are overlooked altogether.

In practice, whether a safety analysis is mainly focused on probabilistic assessments or deterministic assessments is likely to depend on how regulatory acceptance criteria are framed.

Mixed analysis strategies

The key message is that probabilistic and deterministic assessments have important but different contributions to make. The Group therefore recommends a

mixed analysis strategy in which both probabilistic and deterministic assessments are included.

3.3.3 Best estimate versus conservative approach

For compliance with regulatory requirements it is usually necessary to show that the radiation dose or risk from the possible release of radionuclides from a repository is below or consistent with some set target value. It is then sufficient to demonstrate that an upper estimate of the release lies within the target value.

Where there are uncertainties (or where there is a desire to simplify the approach), a consistent choice of assessment assumptions in favour of an upper estimate of the release (i.e. by making consistent conservative or pessimistic assumptions) may be made. If this approach succeeds, the effect may be greatly to reduce the uncertainty associated with whether the results of the assessment are compliant with the regulatory target. If, however, the approach does not succeed (i.e. the results of the assessment are inconsistent with the regulatory target) it could lead to rejection of a sound design concept because the assessment is misleading.

In addition to such a demonstration of compliance, another key objective of the safety case is to obtain a thorough knowledge of the processes liable to take place in the repository and an adequate understanding of its long term behaviour. This entails investigating the most likely performance of the system and implies a need for caution in applying a conservative approach.

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

- are considered likely to reflect the real system as well as possible to the best knowledge of the modeller without any reference to the calculated consequences (“best estimate / best belief”);

- are considered less likely to do so but are still within the range of conceivable possibilities, thereby being deliberately chosen so as to lead to an upper estimate of consequences ("conservative");

- are considered to bound all conceivable possibilities and lead to calculated consequences more severe than any that could actually be realised ("pessimistic / penalising").

The last category has some parallels with a stylised approach. However, a stylised approach is not necessarily pessimistic with regard to consequences. There is also a conceptual overlap of this category with "what-if" cases. The difference is, however, that "what-if" cases are not designed to demonstrate or bound any realistic future evolution of the repository system, but rather to explore or illustrate certain properties of the system, e.g. properties of the barriers, or its robustness to hypothetical disruptive events.

Feedback from implementing these different approaches in safety assessments leads to more practical definitions concerning the choice of models and parameters for each category:

– **best estimate**: A best estimate model can be defined as: - Either, the model that is based on the most comprehensive understanding of the phenomenon to be modelled, and whose ability to account for direct or indirect measurements has been confirmed. This type of model includes all the relevant phenomena at the most detailed level, and include the most influential parameters; – or, in comparison with the other available models, it might be the one offering the best match between the reality that it is supposed to represent and the numerical results that it generates in the impact calculation, within the parameter variability range adopted for the study. A best estimate value for a parameter is the value most likely to represent reality. It may be obtained from statistical analysis of probability distribution functions of parameters or from expert judgement.

– **conservative:** For a conservative model it is possible to demonstrate that its use, all else being equal, tends to overestimate the repository's impact, compared to the results that would be obtained by taking into consideration all the relevant phenomena in the chosen parameter variation range. A conservative parameter value is a value, chosen among those generated by the studies and measurements, which gives a calculated impact in a range of high values (all other parameters being unchanged).

- **pessimistic (or penalising)**: A model or parameter value not referring to phenomenological knowledge, chosen to lead with certainty to an impact greater than that calculated with possible values. For example, this may correspond to a physical limit.

In practice, safety assessments usually employ a combination of the best estimate approach with the strategy of conservatism, in that certain conservative assumptions are made during “best estimate” scenario analysis or scenario analysis using a probabilistic approach.

The model selection strategy is usually based on the following principles:

- in case of low uncertainty, the most scientifically supported model ('phenomenological' model or **best estimate model**) is selected

- in case of high uncertainty, a **conservative or pessimistic model or value** is selected

- the most simple and robust models are privileged, as long as this choice does not lead to underestimating the impact

The notion of 'low' or 'high' uncertainty inevitably entails a degree of subjectivity, even though in certain cases it may involve statistical considerations (dispersion of experimental values, level of confidence, etc.). The experts in charge of proposing the models and values discuss decisions regarding uncertainty on a case-by-case basis. The approach adopted yields a description as accurate as possible of the choices made and the reasons for these choices, so as to make the relationship between the conceptual models and the safety calculation model as explicit as possible.

In the stepwise approach the evolution of the safety case will take into account results flowing from R&D which will allow understanding to be gained of the detailed phenomenology and allow conservative assumptions to be replaced progressively by best estimate calculations in the different components of the system model.

It should however be recognised that an overall best estimate approach is likely to be out of reach and that some conservative assumptions leading to simplifications will always be necessary for some parts of the system (e.g. when stylised models are used or due to limitations of site investigations). In particular, where uncertainties are large the concept of a best estimate may have little meaning. **Although it may seem to be a desirable objective, it is often inappropriate to insist on assessments that are best estimate or conservative throughout. In the framework of the stepwise approach the regulator is advised to clarify his expectations on the matter at each decision point.** (In practice, this may be best accomplished through an iterative dialogue with the developer.)

3.3.4 Model development (inherent uncertainties)

Despite the knowledge acquired through research programmes, it needs to be recognised that the ability to map the long-term evolution of the repository system by numerical modelling in a safety assessment will always remain limited due to the complexity of the components and processes considered as well as the spatial and temporal scales of concern. The question of the validity of the models used was subject to a number of modelling exercises in the 80s and 90s of the last century. These exercises were focused on confidence building for numerical models of groundwater flow and contaminant migration. Attempts were made to verify and validate models by means of benchmarking, comparative studies, calibration and “blind predictions”. A discussion ensued about whether or to what extent model validation was possible, resulting in a less formal understanding of “confidence building” replacing the stronger requirement of “validating” models.

The Group considers that safety assessment cannot be expected to produce a detailed, step-by-step description of the evolution of the whole repository system over millions of years covering the full complexity of all the phenomena involved. Implementers are, however, requested to demonstrate comprehensive understanding of the safety functions like e.g. isolation and containment, i.e. of the processes central to repository safety.

In order to understand the system, more or less complex scientific models are used that take into account each process within the repository and its environment. A detailed numerical modelling of these processes, taking into account the important couplings, serve as means to demonstrate understanding and, at the same time, supports the more simplified modelling used to map the repository system as a whole ("integrated modelling") in order to demonstrate compliance to criteria like dose or risk targets or limits. Such a support can be gained e.g. by benchmarking the results of the detailed process modelling against the simplified components for the integrated modelling.

The integrated model will usually also cover components and processes less central to safety functions, which are, however, needed to calculate safety indicators like dose or risk (e.g. the surface aquifer system). Simplifications will be unavoidable when modelling especially these components and processes. **It needs to be shown that all such simplifications are sufficiently conservative or pessimistic not to compromise demonstration of compliance** (cf. 3.3.3). This holds as well for the case that certain phenomena or components are completely discarded from integrated modelling.

The models and parameters that best reflect the physical reality as can be understood must be clearly distinguished from those intended to provide a pessimistic representation (referred to as 'conservative' or 'penalising or pessimistic').

Implementers need to provide support for confidence in their models. Appropriate means for doing so are:

- **traceable and transparent documentation of the elicitation of scientific knowledge underlying the modelling;**
- **traceable and transparent documentation of the transfer of this knowledge to conceptual and from there to numerical models, thereby substantiating the assumptions (e.g. about simplifications) made on this way;**
- **the test of alternatives if doubts exist concerning the validity of modelling assumptions;**
- **the application of appropriate QA measures for software development;**

- **the documentation of measures enhancing confidence into models (e.g. benchmarking, comparison with lab or field tests or to observations in nature);**
- **a comprehensive discussion about the range of applicability (scales in space and time, parameter ranges, heterogeneity, …) of the models;**
- **the application of peer reviews.**

3.3.5 Parameter uncertainty

As discussed earlier, parameter uncertainty comes from natural variability in the repository system, statistical inexactness, lack of data relevance, or insufficient knowledge. The first two may be evaluated by statistical methods which allow ranges of values of parameters or probability distribution functions to be obtained. Other kinds of uncertainty that are not associated with a specific (physical, chemical …) property of the system may in principle be parameterised and a probability density derived that represents the uncertainty in terms of a degree of belief. However, particular care needs to be taken in attempting to quantify uncertainties that are not objectively known and it should be recognised that this may lead to results that are viewed differently by different experts. In the case of stylised situations or "what if" cases, a single value for a parameter has to be chosen, often on the pessimistic side.

Whatever the type of uncertainty, expert judgement may play an important role where quantification is attempted and this needs to be approached with care (see section 3.5).

Whereas it may be possible to assess, if not always to calculate, the probability of a particular situation, this can be much more difficult – and not necessarily meaningful – for a whole scenario. This is especially the case for "What if" scenarios that are not meant to represent a realistic situation but to test the robustness of the design.

Implementers should demonstrate sufficient confidence in the choice of parameter values they use for quantitative assessments. Appropriate means for doing so are:

- **traceable and transparent documentation of the elicitation of scientific knowledge underlying the choice of parameter values or probability distribution functions;**

- **the application of appropriate QA measures for data recording, processing and statistical treatment;**

- **the application of peer reviews.**

3.4 Qualitative treatment of uncertainties

Some uncertainties with a significant effect on assessed levels of safety may be difficult to quantify reliably and must be dealt with in a manner that is at least in part qualitative.

If an uncertainty cannot be quantified, in some cases it may be possible to bound it. For example, it may be possible to make the argument that a specified FEP cannot be worse than a certain level, even though it may not be possible to assign a probability to that level. A drawback of such an approach is that it introduces an unquantified conservatism.

In other cases, the uncertainty may be such that even bounding it is difficult. In such cases, a stylised approach may be adopted, in which arbitrary assumptions are made that tend to err on the side of conservatism. The evolution of the biosphere and future human actions (both discussed further below) provide examples of where stylised approaches are typically used. Stylised approaches may be regarded as justified where neither the choice of repository site nor the design of the repository would greatly affect the uncertainties concerned. If a stylised approach is used for modelling part of a repository system (e.g. for the biosphere), care must be taken that the use of this approach does not distort the modelling of the remainder of the system, so that important properties of other parts of the system are obscured in the overall model.

Further methods that at least partly address, or in some cases avoid, uncertainties that are difficult to quantify include the use of safety and performance indicators complementary to dose and risk, e.g. radionuclide fluxes and environmental concentrations (EC 2002, IAEA 2003a, IAEA 2005b).

3.5 Expert judgement

Expert judgement may sometimes be useful in both the quantification of uncertainties and in their qualitative treatment where reliable quantification is not possible. This is because experts are potentially capable of bringing information together from a range of sources and distilling it into a relevant form. Experts, however, can obviously not generate new information outside the range of their knowledge and experience. Thus, expert judgement is not a substitute for scientific research.

To facilitate the application of expert judgement, systematic elicitation techniques have been developed which help to eliminate or minimise personal bias. Formal expert elicitation may be described as a "set of techniques designed to gather knowledge about a domain from human experts" (CNWRA 1993, p. 2-1). The role of the experts is "not creating knowledge, but instead to synthesize disparate and sometimes conflicting sources of information to produce an integrated picture" (HORA 1993).

Historically, expert judgement has sometimes been used to provide probability distribution functions for uncertain events, where data are lacking or unclear. Meaningful data cannot, however, be conjured out of thin air and there must always be an identifiable basis for any expert judgement.

In practice, expert judgement is widely used in subtle ways. For example, expert judgement based on underlying scientific knowledge is fundamental to the construction of analytical models. Seen like this, the use of expert judgement may be unavoidable. As identified in section 3.3.5 above, the elicitation of the relevant scientific knowledge needs to be documented in a traceable and transparent manner.

The Group takes the view that it is a matter for the implementer to decide whether, where and how to use expert judgement. If expert judgement is used, the implementer must apply appropriate quality standards, both formally and in terms of ensuring that the results of using expert judgement make sense in the context to which they are applied.

3.6 Sensitivity analysis. Feedback to safety strategy

The importance of an uncertainty for the outcome of an assessment can be explored using sensitivity analysis calculations. Different methods are in use, some akin to deterministic scenario analysis and others employing probabilistic analysis (see discussion in section 3.3 above). The aim is to test the robustness of the system safety against the uncertainty and to identify those uncertainties that have the potential to call the system safety in question, and thus are in need of further management.

In methods akin to deterministic scenario analysis, the sensitivity to uncertainties is explored through generating different scenarios by varying the assumptions underlying the scenarios. A different scenario may be generated by varying either a single assumption or by varying a set of assumptions. If a whole set of assumptions is varied it may be difficult to identify which change or changes are of principal importance. On the other hand, assumptions may be linked logically, so that it may not make sense to change them individually. Sensitivity analysis through generating different scenarios by varying assumptions is closely linked to exploration using “what if” scenarios (see section 3.7 below).

In sensitivity analysis methods employing probabilistic analysis, the model input parameters are varied over suitable ranges to determine the effect of these variations on the model result. This improves the understanding of which parameters have the greatest impact on calculated consequences, and thus helps prioritise research and / or derive conclusions for repository development.

Depending on the approach to uncertainty analyses, sensitivity analysis might also indicate which parameters have to be included in the uncertainty analysis.

One important advantage of a stepwise implementation process for a radioactive waste repository is that safety assessments are carried out iteratively and discussed with the regulator and the public. The outcome of the assessment of uncertainties and especially the sensitivity analysis is thus available at an early stage of the process to guide subsequent stages.

Some important aspects related to deterministic and probabilistic techniques for sensitivity analysis are the following:

- One approach is to vary single input parameters while fixing the rest of the parameter set, thus obtaining information about sensitivities to individual parameters. The results may be expressed either by a direct comparison of consequence values or by calculating numerical derivatives. By consecutively or simultaneously varying several input parameters, the neighbourhood of a point in multi-dimensional parameter space can be explored in this way. In broad terms, the advantages and limitations of these approaches are similar to those of deterministic uncertainty analyses (cf. 3.3.2). While making it possible to explore and understand particular but broadly defined situations of the repository system, they fail to address the whole parameter space in order to detect potentially important but still unknown FEP combinations.

- This possibility is provided for to a certain degree by a probabilistic approach. Global / probabilistic sensitivity analyses allow the study of simultaneous variation of several input parameter values over a wide range of values. Methods for generating samples and / or methods for deriving sensitivity measures can be deployed to determine which combinations of input parameters require further study. While there are established methods for identifying linear or non-linear monotonic dependencies in the context of a probabilistic approach, the issue of non-monotonic dependence is less well explored and the performance of the methods suggested for addressing them is not always satisfying.

The insights available through the different techniques are often quite similar. The choice of technique is likely to depend on which methods are used more generally for the uncertainty analysis (e.g. a comprehensive study of the propagation of uncertainty through the performance analysis).

Sensitivity analyses should not necessarily be limited to the investigation of the effects on highly aggregated indicators such as dose and risk, because such an investigation could be dominated by uncertainties with little relevance to safety, e.g. biosphere parameters. It may also be appropriate to study the effects on less aggregated performance indicators which are more directly related to safety functions (e.g. fluxes from one system component to another).

The Group is of the opinion that the implementer should identify important uncertainties by means of sensitivity analyses in order to demonstrate system understanding and to inform R&D in a stepwise process.

3.7 "What if?" scenarios

In general, "what if" scenarios are not designed to demonstrate or bound any realistic future evolution of the repository system, but rather to explore or illustrate certain properties of the system, e.g. properties of the barriers, or its robustness to hypothetical disruptive events (see section 3.9.1 below). To examine the properties of a barrier, it may be instructive to assume parameter values, or other properties of the remaining system, that influence the barrier being studied in an extreme way. Such an exploration may still be instructive, even if such extreme conditions can be conclusively shown not to hold true or can be avoided by design.

"What if" scenarios may help to provide multiple lines of reasoning and hence build confidence in the safety case (see section 3.10 below).

3.8 Deliberate introduction of uncertainties

Sometimes the specific technical methods applied in investigation, in model development, or in analysis, do not make full use of the technical knowledge available, leading to uncertainties that in principle could be avoided. Where this is done deliberately the motivation is usually simplification, so as to make the work more tractable or comprehensible. For example, integrated calculational models are often simplified to a significant degree. Such simplification amounts to the deliberate introduction of uncertainties. These uncertainties need to be recorded and reasons provided why it is acceptable to introduce them. Such claimed reasons might include either that the uncertainties are unimportant or that they introduce a conservative bias. The validity of any such claimed reasons needs to be demonstrated.

3.9 Specific aspects of scenario building

3.9.1 Disruptive events

The effects of disruptive events on a disposal system may be explored using "what if" scenarios (section 3.7). Such an exploration may help with confidence building (section 3.10), provided it is put properly in context.

With certain possible exceptions (e.g. human intrusion), disruptive events are to be regarded as hypothetical, i.e. beyond the design basis for a properly-sited repository system. Thus, in general, there is no requirement to demonstrate a prescribed level of protection given such an event. Accordingly, while it may be of interest to calculate the consequences in terms of a measure such as dose or risk, this would not usually be given great weight in the safety case.

Modelling disruptive events enables their effects to be better understood. Establishing what kind and what level of disruptive event could lead to severe, widespread or long-lasting consequences may be useful for repository design purposes. Understanding the direct effects of disruptive events, e.g. damage to barriers, may feed into repository design optimisation, such that the design is made more robust against such events.

It may be of value to establish what level of disruptive event of a particular kind (e.g. a seismic event) would still leave the repository system with sufficient isolation capability, and to assess the associated likelihood of such an event. This amounts to exploration of "cliff-edge" effects.

3.9.2 Human Actions

General

A range of future human actions can be envisaged having the potential to breach the natural or engineered barriers or significantly impair the performance of the system. These may be deliberate, i.e. taken with knowledge of the location, purpose and hazardous nature of the facility, or inadvertent because the location or purpose is unknown. The view has usually been taken that it is not necessary to undertake quantitative risk assessments of deliberate human actions, since the responsibility for these actions and their consequences should be regarded as a matter for the people taking them (NEA 1994). It has been assumed that such actions would not be taken without due regard to the safety implications and the economic and environmental values of the time.

The developer may advance arguments to justify a very low probability of inadvertent actions affecting the disposal system for a period following closure by reference to the proposed post-closure management plans. However, in the longer term, institutional controls cannot be relied upon and the developer will be expected to assess the consequences of possible future human actions. Although the developer may also provide a view on the likelihood of such actions, such a view will be highly speculative and thus may be of little value. **For this reason, an exploration of future human actions, including human intrusion, needs to be based on a stylised approach in which one or more scenarios are generated making arbitrary assumptions. Any assessment of the likelihood of such scenarios will also be arbitrary.**

Human intrusion

Typical assumptions for human intrusion include the postulate that the level of technology relating to the intrusion capability is the same as it is at the present day. This might be regarded as inconsistent with the implied assumption that the location or purpose of the repository is unknown. Such an inconsistency is conservative. Whether or not it is excessively conservative is a matter for judgement.

Among the scenarios postulated, taking due account of the regional context, may be: (a) drilling for water into the radioactive plume from the repository; (b) exploratory drilling into the repository or into the plume with the extraction of cores; (c) the operation of a mine near the repository; or (d) direct physical human intrusion into the repository.

The potential consequences by way of radiation exposure are of two different types:

1) Immediate consequences for the intruders themselves;

2) Deferred consequences for other exposed groups of people and for the wider environment, associated mainly with the transfer of radionuclides by water in a configuration whereby the containment barriers have been partly bypassed.

Regarding the immediate consequences for the intruders themselves, the doses received could be high and would be difficult to reduce through modification of the repository design. Given direct intrusion into the repository, these high consequences are closely linked to the selected strategy of "concentration and containment". Comparison of such doses with a regulatory limit is unlikely to be appropriate. However, it may well be appropriate to seek to minimise the likelihood of intrusion through selecting a site that is not rich in natural resources and/or through the depth at which the repository is constructed. Differing views have historically been taken about the value of markers at the surface, one school of opinion believing that suitable markers could discourage intrusion, with another school believing that any markers could excite curiosity.

The consequences of intrusion on people other than the intruders and on the wider environment are likely to be much less severe. Intrusion may lead only to a limited disturbance of the repository, with a somewhat altered evolution scenario. The release of activity may affect only a fraction of the repository, with the radiological consequences being assessed within the general framework of altered evolution scenarios.

Human intrusion scenarios share many characteristics with scenarios involving other disruptive events (see section 3.9.1). **Thus, understanding the direct effects of human intrusion (e.g. damage to, and bypassing of, barriers) may feed into repository design optimisation, such that the design is made more robust against such events. However, care needs to be taken to ensure that this aspect of repository design optimisation is not unduly dependent on the particular stylised assumptions made.**

3.9.3 Climate change

The potential for climate change needs to be taken into account in the siting, design and safety case for a repository. Possible climate change may be induced by natural processes, by human activities, or by a combination of the two. There is considerable uncertainty regarding the speed, the amount and even the direction of possible climate change. Thus, a range of possibilities needs to be considered. Climate change in which human activities make a significant contribution is likely to occur more rapidly than climate change as a result only of natural processes. However, major climate change as a result of natural processes alone can occur on a timescale of the order of 10,000 years, which is within the timescale of the safety case for a repository.

The potential consequences of climate change include changes in rainfall patterns, which can affect watercourses and aquifers, changes in sea level, erosion including coastal erosion, glacial cycling and tectonic movements. Many aspects of climate change can be built into normal evolution scenarios, but it may be appropriate to explore the more extreme possibilities through “what if?” scenarios in a manner similar to the approach for disruptive events (see section 3.9.1).

Because of the great uncertainty associated with climate change, it is difficult to associate meaningful numerical probabilities with postulated changes. Expert judgement might be of some help, but its value may be limited because of the problems of data relevance and the weakness of current climate models. For this reason, it may be broadly appropriate to make conservative assumptions in modelling climate change in the safety case for a repository.

A repository site that has been stable in its geological and hydrogeological properties over timescales long compared to the applicable timescale of the projected safety case is greatly to be preferred over a site where this is not the case. Considerable comfort in both a qualitative and a quantitative sense can thus be gained from site investigations showing that these properties have changed little over long timescales. (This remark also applies to the disruptive events discussed in section 3.9.1.)

3.10 Confidence building

Stages

Dealing with uncertainties is central to confidence building. Confidence building may be seen as a multi-stage process. The first stage is for the developer or operator of the disposal facility to build his own confidence in the safety analysis, since he will succeed in convincing no-one else unless he has first convinced himself. Hence the developer must be questioning of himself. He needs to become confident that he has properly understood the uncertainties associated with the safety analysis.

The second stage is for the developer to build the confidence of the regulator. This will be done through a series of technical submissions which the regulator will attempt to challenge, usually leading to a technical dialogue. Both the developer and the regulator may undertake or commission additional technical work to support their positions. Fundamentally, the dialogue is technical, although there may also be discussion of presentational issues.

The third stage concerns building the confidence of groups and members of the public more widely. This needs to be undertaken by the developer and the regulator together. The developer explains his safety analysis in terms understandable to a non-specialist audience, while the regulator explains how he has challenged it, how and to what extent he has come to be satisfied, and what questions and reservations remain. This stage involves some risk of a perceived loss of regulatory independence, but this may be regarded as a risk that can be managed. The confidence of external groups and members of the public is gained through a process of dialogue, in which all parties to the dialogue are entitled to make their points and to ask questions to which they can expect to receive answers. Some external groups may gain confidence through technical dialogue but, for most people in the wider audience, confidence will primarily be gained through building trust in the developer and the regulator.

Although confidence building as described above is a multi-stage process, these stages are not sequential but, rather, there will be an enormous overlap between them. This is because, for a geological disposal facility, the initial safety analysis will be in outline only and will develop progressively over a period of years or possibly decades as more information becomes available.

Methods

As stated above, both technical and non-technical confidence building are necessary. Each of these has its own requirements, which interface and to some extent overlap. Confidence building must be carried out in a continuing flow of information some of which, in the nature of things, will be favourable to the safety analysis and some unfavourable.

It will be difficult to build confidence in an audience unless the audience has at least some understanding of the technical arguments. Once interest has been engaged, all audiences will want to know what the technical arguments mean. Hence simplified versions of the arguments that illuminate the meaning are essential. Such simplified versions may also be helpful to the developer and regulator themselves in coming to grips with the safety analysis. False simplifications that give a misleading impression must, however, be carefully avoided.

Another method of confidence building is to approach the topic from different angles, "multiple lines of reasoning". If these different approaches lead to similar conclusions, people's confidence should be built. Such remarks apply both to the dialogue between the developer and the regulator, and to the dialogue with external groups and the public.

In some cases, uncertainties that are important following one line of reasoning may be much less important following another line. Care must be taken, however, that it is not simply that the uncertainties are obscured. For example, uncertainties regarding future human actions are likely to apply whatever the line of reasoning.

Care must also be taken to avoid false confidence building. In a dialogue it is possible for a consensus to emerge that suppresses uncertainties. People gain confidence simply because others share their view. For this reason it is important for both the developer and the regulator to work to maintain an honest view of the uncertainties associated with the safety analysis. Apart from being dishonest, confidence that is oversold can more readily be undermined.

Confidence and trust

Trust is needed in both the developer and the regulator in order to build sufficient public confidence in the repository development process. It is in the regulator's interest to ensure that the public gains confidence in the developer as well as in the regulator. Equally, it is in the developer's interest to ensure that the public gains confidence in the regulator as well as in the developer.

One aspect of building trust is to ensure that the public gains a proper understanding of the relationship between the developer and the regulator. Thus, the public needs to be brought to understand that criticism by the regulator of the developer's work is not intended to discredit the developer, but rather is a process of iterative peer review to ensure that the developer's work is brought to an appropriately high standard.

It is the task of the developer and the regulator not only to build confidence in the repository development process but also to maintain it. If confidence, once established, is subsequently lost, it is much more difficult to rebuild it, especially if that confidence is largely built on trust in the developer and the regulator.

4 Issues of compliance with protection objectives

A clear distinction needs to be made between protection objectives and the indicators used to demonstrate that these objectives are fulfilled. Protection objectives are expressed in general terms, and can be agreed internationally, while national regulations often provide standards and criteria relating to specific indicators (for example, dose or risk) expressed as targets, constraints, or limits, which may differ from country to country.

IAEA Safety Requirements document WS-R-4, *Geological Disposal of Radioactive Waste*, (IAEA 2005a) states the following as the objective for the protection of human health in the post-closure period:

"Geological disposal facilities are to be sited, designed, constructed, operated and closed so that protection in the post-closure period is optimized, social and economic factors being taken into account, and a reasonable assurance is provided that doses or risks to members of the public in the long term will not exceed the dose or risk level that was used as a design constraint."

This section of the present document does not attempt a comprehensive discussion of issues of compliance with protection objectives in the presence of uncertainties. Instead, the Group has identified a number of issues which it regards as important, and on which there is substantial agreement among its members. These are set out below.

First, a group of four issues associated with the assessment of compliance is discussed. These are: standards and criteria, and how they should be understood; aggregation of results for comparison with criteria; the specific issue of biosphere modelling and its implications for the comparison of assessment results with criteria; and cut-off timescales and the evolving role of different compliance measures.

Then, three somewhat separate and disparate issues are discussed, namely: non-radiation protection objectives; protecting non human biota; and optimisation.

4.1 Assessment of compliance

4.1.1 Standards and criteria

Standards and criteria are needed for judging the acceptability of the post-closure safety case for a radioactive waste repository. For situations where exposure is certain, the radiological protection standards are usually expressed in terms of received dose. If the exposure is uncertain, the standards can still be based on the potential dose, but consideration of the associated uncertainty becomes necessary. Alternatively a risk-based standard may be applied, which by a combination accounts for both the doses and their associated uncertainties. Instead of referring to dose or risk, the standard could also refer to other quantities such as environmental concentrations or fluxes of radionuclides.

Adoption of a standard implies a value judgement as to what constitutes an acceptable level of the quantity specified in the standard. A dose to an individual may be judged acceptable, for example, if it constitutes only a limited perturbation to the dose received from natural background radiation. Also, it may be judged acceptable by equating it to a level of risk which studies show that, in another context, the individual would take on without concern.

The post-closure safety case for a repository is characterised by the presence of uncertainties. This means that all doses assessed in the safety case are potential doses, i.e., they are not certain to be received. Where uncertainties can be quantified it is possible, at least in principle, to build them numerically into the safety case and to express the standards against which the safety case is judged in terms of potential doses also. Potential doses are equivalent to risks, in which one factor in the risk results from the probability that the dose will be received and another factor results from the dose itself. Risk standards could be expressed in terms of aggregated or disaggregated risks, or some combination of the two. Here, aggregation refers to combining contributions to risk from various sources in order to obtain the total risk.

Some countries have adopted risk standards against which to judge the post-closure safety case for a repository, while others have adopted dose standards.

Whether or not a risk standard has been adopted, the issue remains that many uncertainties in the post-closure safety case cannot reliably be quantified. Hence, there is a major difficulty in incorporating these uncertainties into a model that delivers a result that can be compared with a numerical standard, either relating to risk or dose.

The modelling approach adopted in practice includes many stylised elements (e.g. in relation to the biosphere or future human actions), which seek to err on the side of conservatism without giving a false picture. Stylisation is a way of bypassing unquantifiable uncertainties. Stylisation needs to be avoided, however, for those components of the repository system where avoidance is possible. For example, it would usually be inappropriate to adopt a stylised approach for modelling the performance of an important barrier, for then the safety case would provide no information about the capabilities of the barrier.

Given the degree of stylisation in models that address the post-closure performance of a repository system, and given the extent of the uncertainties that cannot reliably be quantified, the Group recognises that assessments of dose or risk to humans as part of the post-closure safety case can only be regarded as broadly conservative indicators of impact rather than anything more definite or concrete. The standards and criteria against which these assessments are judged need to be understood in this light.

4.1.2 Aggregation of results

The aggregation of results from the safety assessment of a repository system needs to be taken to the level at which the results can be compared to standards and criteria. In general, there is a desire to keep standards simple and transparent. This means that results must ultimately be presented in a highly aggregated way.

Unfortunately, aggregation of results implies serious loss of detail. Relevant details are, for example, which modes of evolution of the repository system are the most probable, which modes make the largest contributions to the results (expressed, for instance, in terms of dose or risk), which uncertainties are important for their effect on the results and how the important uncertainties have been treated.

In practice, a proper understanding of the safety case can only be obtained by skilful disaggregation of the results into the key strands. In this light, a comparison of aggregated results with a simple numerical standard can be seen as just one step in the total process. On the one hand, if the aggregated results are non-compliant with the standard, then disaggregation is appropriate to explore why they are non-compliant and whether this represents a true deficiency of the repository system, or whether it is an artefact of how the safety case has been constructed. On the other hand, if the aggregated results appear to be compliant with the standard, then disaggregation is equally appropriate to test the strength of the underlying safety approach and its treatment of uncertainties.

The principal dialogue between the regulators and the developer about the safety case will in practice be at various levels of disaggregation. Any third-party stakeholder who wishes to obtain a reasonable understanding of the safety case will also have to approach it in this way.

The Group recognises that an exposition of the safety case that simply compares the aggregated results of the assessment with the safety standard is unlikely to convey the insights necessary to provide confidence in the results.

4.1.3 Biosphere assessment

In order to evaluate the radiological impact of a repository system on humans and non-human biota, so that the safety of the system can be evaluated against radiological protection standards such as dose or risk, a model of the biosphere is required. The characteristics of the biosphere in the future are, however, elusive since they are potentially shaped not only by natural processes but also by human beings. In effect, there are great uncertainties associated with the future biosphere and how humans will interact with it.

The widely accepted way of dealing with these uncertainties is to adopt a stylised approach which makes generally conservative assumptions. Thus, future exposed groups of people living in the vicinity of the repository are usually assumed to take all or most of their food and drinking water from local sources. This tends towards assuming that local populations in the far future will be hunter-gatherers or subsistence farmers, and diverges sharply from how most modern humans in developed societies actually behave. A good example of such a stylised approach is provided by the IAEA BIOMASS (BIOsphere Modelling and ASSessment) project (IAEA 2003b). It is based on:

- The definition of a reference biosphere;
- The definition of critical and other hypothetical exposure groups on the basis of suitable conservative assumptions;
- An estimate of individual dose or risk to a member of a representative group using a modelling approach appropriate for these assumptions.

The use of a stylised approach for modelling the biosphere may be defended on the basis that neither the choice of repository site nor the design of the repository would greatly affect the uncertainties concerned. It should be the case that optimisation of the repository is not significantly dependent on the biosphere model.

The Group considers that a stylised approach should be adopted for modelling the biosphere since, as a result of uncertainties, assessments of dose or risk to humans as part of the post-closure safety case for a repository can only be regarded as broadly conservative indicators of impact rather than anything more definite or concrete.

4.1.4 Cut-off timescales and evolving role of different compliance measures

There is no definite limit on the time for which a geological disposal facility remains hazardous. Thus, the protection objectives remain valid without limit in time. There is, however, a limitation on timeframes for which useful numerical assessments, whether of dose or risk or other quantities, can be made. This does not necessarily imply that protection objectives are no longer met at later times.

The regulators may or may not prescribe a definite cut-off in time for the safety assessment of a repository system. If the regulators do not prescribe such a time cut-off, the timescales over which assessment results should be presented are matters for the developer to consider and justify as adequate for the wastes and repository system concerned.

If no time cut-off is prescribed, the developer would be expected to provide a suitable safety assessment for a time period that extends beyond the estimated time of maximum release from the repository into the accessible environment. Arguments need to be presented supporting the estimate of the time of maximum release and the period of time chosen for assessment. The developer would be expected to use high quality arguments taking explicit account of uncertainties and showing appropriate compliance with standards and criteria. An important component of these arguments is likely to be the demonstration of a stable evolution of the geological barrier.

The Group recognises that, at times longer than those for which the conditions of the engineered and geological barriers can be modelled or reasonably assumed, a formal demonstration of compliance with radiological protection objectives becomes virtually meaningless against the background of uncertainties. If an appreciable potential hazard remains at such times, the developer may need to fall back on more general lines of reasoning to support an argument of continuing safety. Scoping calculations or qualitative arguments based on comparisons with ambient levels of radioactivity in the environment may be used to indicate the continuing level of safety.

4.2 Non radiation objectives

Radioactive waste may also contain chemotoxic substances. Unlike radioactivity, chemotoxicity (depending on its nature) may not diminish with time. The non radiation safety of a radioactive waste repository potentially needs to be considered. Depending on the structure of the national regulatory system, regulatory control of chemotoxic aspects may accomplished in conjunction with radiological aspects or in separation.

Where chemical hazards are not regulated under nuclear or radiological protection legislation, their assessment may not be a required part of the safety assessments under that legislation. This should not mean that the chemical hazard is ignored. It should rather mean that the necessary safety assessment and regulatory control take place under another legislative regime and possibly by a different regulatory organisation. Where separate regulatory organisations are involved, they should liaise closely.

Uncertainties in the evolution of a repository system potentially apply equally to the radiological hazard and the chemical hazard.

4.3 Protecting non human biota

The statement was made in ICRP 60 (ICRP 1991, paragraph 16) that “The Commission believes that the standard of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk. Occasionally, individual members of non-human species might be harmed, but not to the extent of endangering whole species or creating imbalance between species.”

Thus, the ICRP 60 position was not to ignore the effects of ionising radiation on non-human species, but rather to take the position that such effects are limited to a sufficient extent by ensuring that humans are protected.

ICRP is currently consulting/has recently consulted [closing date for comments, 15 September 2006] on a successor document to ICRP 60. It reaffirms that the belief stated in ICRP 60 is likely to be the case in general terms under planned exposure situations. ICRP also now believes, however, that a framework needs to be developed to put the protection of non-human species on a more scientific basic. The consultation draft states that, for human radiological protection, ICRP’s approach has been greatly assisted by the creation of an entity called Reference Man (now called Reference Person). ICRP considers that a similar approach would be of value as a basis for developing further recommendations for the protection of other species. It is therefore developing a small set of Reference Animals and Plants, plus their relevant data bases, for a few types of organisms that are typical of the major environments. Such entities will form the basis of a more structured approach to understanding the relationships between exposures and dose, dose and effects, and the potential consequences of such effects.

ICRP states that, for human beings, it has been convenient to consider the effects of radiation as being of a non-stochastic (causing tissue damage) or of a stochastic nature. For non-human species, however, other ways of considering radiation effects are likely to prove to be more useful such as those that cause early mortality, or morbidity, or reduced reproductive success, irrespective of the stochastic or non-stochastic nature of the underlying causes.

ICRP recognises that the framework it is now developing for non-human species needs to complement and not compromise the radiation protection system that has been developed for human beings, and that this framework also needs to complement those measures that are being developed for the protection of the environment from other potential hazards.

IAEA and the European Union are also active in the area of protecting non-human biota. In particular, the European Commission under its 5th Framework Programme sponsored the FASSET project to develop a basic framework for conducting radiological assessments for non-human biota. Under its current 6th Framework Programme the EC is sponsoring the ERICA project (www.erica-project.org). The objective of ERICA is to provide an integrated approach to scientific, managerial and societal issues concerned with the environmental effects of contaminants emitting ionising radiation, with emphasis on biota and ecosystems. Although only organisations in EU member states are directly participating in the ERICA project, various non-EU countries are members of its End-Users Group.

For a deep geological disposal system, there is no reason why human beings should even be present in the vicinity at certain periods in the far future. Hence, it would seem important to include, among the regulatory acceptance criteria for the safety analysis, criteria that specifically address the impacts of the disposal system on the surface environment for non-human biota and ecosystems. It would seem appropriate to base such criteria at least in part in the forthcoming recommendations of ICRP and the outcome of the ERICA project.

The ERICA project is actively considering uncertainties associated with the assessment tools it is developing. In general, it is hoped to be able to envelop these uncertainties using a conservative approach. Even with these conservatisms, it is not likely that the protection of non-human species will be more challenging to the design and safety case of facilities in general, and of repositories in particular, than the protection of humans.

4.4 Optimisation

The view is taken that, in the present document, it is not worth exploring any detailed differences there may be in meaning between the different terms commonly used to express optimisation, i.e. ALARA, BAT, etc. Optimisation is taken simply to mean "doing the best you can" in a given set of circumstances.

All optimisation is constrained optimisation and, before trying to optimise, it is essential to try to establish what the constraints are in the particular circumstances of concern. In practice, there is often some iteration between the optimisation process and establishing the constraints, partly because not all constraints provide hard boundaries. Some are soft constraints and may yield somewhat to pressure. For example, cost might be viewed as a constraint but, if a large improvement in optimisation terms can be achieved by straying only a short distance beyond what was initially perceived to be a cost constraint barrier, then the cost barrier might yield a little. Also, some constraints may not initially be apparent, but may only emerge over a period of time.

Some issues involved in establishing the constraint boundaries on optimisation are as follows:

- What are you trying to optimise? For a repository, this could be risks, or doses, or release of radionuclides over some period of time, which may be specified or unspecified. Whom or what are you trying to protect? Is this only human beings, or does it also include non-human species and ecosystems? If so, to what standard are you trying to protect these? Are you trying to optimise only in relation to the radiotoxic properties of substances released from the disposal system, or also for the chemotoxic properties? Are you striving for optimal robustness (e.g. regarding external disturbances, or inexact values of parameter values), consistent with a given level of radiological protection? Are you concerned only about post-closure safety, or also about safety during the operational life of the facility?

- What constraints are there on the design and construction of the repository? Is there a cost constraint? Presumably there will be a constraint on where it is located. Are there externally imposed constraints such as requirements for retrievability and monitoring and/or a political decision on closure?

- Are you trying to optimise only the repository or, rather, the repository in some broader context? The broader context could include, for example, when and at what rate wastes will arise, the need for and lifetime of waste stores, the need to minimise operator doses in handling the waste and any reworking required, and issues of transport, regional development and employment.

Optimisation is also to be seen as a progressive process. Decisions are taken at various stages and later decisions are constrained by the earlier decisions that were taken and how they were implemented. Decisions when taken need to be recorded, together with the reasons for taking them and why they were regarded as optimum at the time.

Optimisation decisions will inevitably be taken in the presence of uncertainties. These uncertainties will change to some extent over time. Some will reduce; the more intractable ones will probably remain relatively fixed in their characteristics; and, no doubt, new ones will emerge.

In order to take optimisation decisions that will be perceived subsequently to be sound ones, it is necessary to have as clear an understanding as possible at any given stage in the process of decision-making as to where the main uncertainties lie and how they are likely to change while decisions that will have a significant effect can still be made.

Optimisation in the presence of uncertainties is different in an important way from optimisation against a fixed requirement. If a repository were to be optimised only against a normal evolution scenario, it would be left potentially vulnerable against other, less likely, scenarios. Optimisation in the presence of uncertainties needs to take some account of the whole range of possible evolutions of the repository system. Thus, for any possible evolution considered to be within the scope of the safety case, the performance of the repository system needs to be shown to be at least adequate. Such possible evolutions would include those involving some disruptive events, e.g. human intrusion. The effect of these considerations is potentially to make the design of the repository less than optimum when considered purely against a normal evolution scenario.

Large uncertainties are, in particular, associated with extreme events and processes that might affect the safety case for a repository. While it is important that these uncertainties are taken into account in optimisation, they and the extreme events to which they relate should not be allowed unduly to distort the design of the repository and the safety case. Inevitably, avoidance of undue distortion will largely be a matter of judgement.

Because optimisation has to take many different factors into account and also because of the uncertainties, optimisation decisions cannot in general be made in a rigorous manner but, instead, usually involve a significant element of judgement. Optimisation of a repository design can be viewed as a form of multiple criteria decision-making.

5 Summary

Within a European Pilot Study on “The Regulatory Review of the Safety Case for Geological Disposal of Radioactive Waste”, a case study has been carried out on the issue of uncertainties and their management in the context of achieving and assessing post-closure safety of geological disposal of radioactive waste. The case study focused on the handling of uncertainties in the context of the different elements of a safety case: safety strategy, safety assessment and assessment of compliance.

As is known, the regulatory frameworks differ considerably between countries. The group concerned with the case study (i.e. the authors of this document) nevertheless observed that regulatory practice differs to much less an extent. **This is evidenced by the statements typed in bold face which provide views and conclusions shared by the authors.** In particular, the following issues were addressed:

Safety Strategy. Conscious accounting for uncertainties and analysis of their possible consequences is a required part of any safety assessment for a radioactive waste repository. Within a stepwise approach to repository development, this includes providing a register of uncertainties and a clear process for managing them and drawing conclusions about how they can be avoided, mitigated or reduced. The ways in which a stepwise process is implemented in regulations vary from country to country, and so do the requirements concerning the involvement of regulators and licensing authorities at decision points. The group is however of the opinion that it is important to keep regulatory and licensing authorities and their technical support organisations informed about the state of development at each step and to involve them in the major decisions (e.g. about the repository concept or about R&D priorities) to be made, no matter whether or not there is a formal requirement for doing so.

Assessment strategy. Regarding the effects of uncertainties on the safety assessment, emphasis is placed on those elements of the assessment which are not yet fully included within guidance provided by international organisations such as IAEA or NEA, namely:

- The strategy of scenarios and its important role in a) structuring the safety case and the review of the safety case, b) capturing uncertainties effectively and efficiently, and thus c) identifying the need for further work to avoid, mitigate or reduce uncertainties and to evaluate their effect. By this means, the link between safety assessment and safety strategy is maintained. Deterministic and probabilistic approaches both have a role to play in the strategy of scenarios.

- The contribution to be made by best estimate, conservative and pessimistic approaches for determining models and parameters, depending on the part of the repository system, the scenario and the time frame being considered. Within the framework of the stepwise approach, the regulator is advised to clarify at each decision point his expectations on the relative importance of these different approaches.

Assessment of compliance in the presence of uncertainty. The approach for compliance assessment differs considerably depending on the country. But whatever the standards, the issue remains that many uncertainties in the post-closure safety case cannot reliably be quantified. Calculated future doses or risks can only be regarded as broadly conservative indicators rather than anything more definite or concrete and, accordingly, additional arguments may effectively contribute to the confidence in safety. Thus, the post-closure safety case will need to be based on multiple lines of evidence. It is considered that at times longer than those for which the conditions of the engineered and geological barriers can be modelled or reasonably assumed, a formal demonstration of compliance with radiological protection objectives becomes meaningless against the background of uncertainties. Accordingly, the developer may need to fall back on more general lines of reasoning.

The group also dealt with other topics connected with the subject of uncertainties, including sensitivity studies, human actions, expert judgement, confidence building and optimisation.

6 References

AECL (1994): The Disposal of Canada's Nuclear Fuel Waste: Postclosure Assessment of a Reference System, Atomic Energy of Canada Limited, AECL-10717, COG-93-7

CNWRA (1993): Expert elicitation of future climate in the Yucca Mountain vicinity, Center for Nuclear Waste Regulatory Analyses, CNWRA 93-016, San Antonio

DOE/HMIP (1992): Dry Run 3: A Trial Assessment of Underground Disposal of Radioactive Wastes Based on Probabilistic Risk Analysis, Overview, Department of Environment: Her Majesty's Inspectorate of Pollution, DoE/HMIP/RR/92.039

DOE (1998): Viability Assessment of a Repository at Yucca Mountain – Volume 3 – Total System Performance Assessment, Department of Energy (U.S.), DOE/RW-0508/V4

EC (2002): Testing of Safety and Performance Indicators (SPIN), Final Report, European Commission, EUR 19965 EN, Nuclear science and technology, Luxembourg

HORA, S (1993): Formal elicitation of expert judgements, in « Conservation and Retrieval of Information », Final Report of the Nordic Nuclear Safety research Project KAN-1.3, NKS 1993: 596

IAEA (2003a): Safety indicators for the safety assessment of radioactive waste disposal, International Atomic Energy Agency, IAEA TECDOC Series No. 1372, Vienna, http://www-pub.iaea.org/MTCD/publications/PDF/te_1372_web.pdf

IAEA (2003b): "Reference Biospheres" for solid radioactive waste disposal. Report of BIOMASS Theme 1 of the BIOsphere Modelling and ASSessment (BIOMASS) Programme, International Atomic Energy Agency, IAEA-BIOMASS-6, Vienna (2003b), http://www-pub.iaea.org/MTCD/publications/PDF/Biomass6_web.pdf

IAEA (2005a): Safety Requirements, Geological Disposal of Radioactive Waste, International Atomic Energy Agency, IAEA Safety Series WS-R-4, Vienna, http://www-pub.iaea.org/MTCD/publications/PDF/Pub1231_web.pdf

IAEA (2005b): Natural Activity Concentrations and Fluxes as Indicators for the Safety Assessment of Radioactive Waste Disposal, International Atomic Energy Agency, IAEA

TECDOC Series No. 1464, Vienna,
http://www-pub.iaea.org/MTCD/publications/PDF/te_1464_web.pdf

ICRP (1991): 1990 Recommendations of the International Commission on Radiological Protection, Annals of the ICRP, Publication 60, Pergamon Press, Oxford and New York

ICRP (2000): Radiation Protection Recommendations as Applied to the Disposal of Long-lived Solid Radioactive Waste, International Commission On Radiological Protection, Annals of the ICRP, Publication 81, Pergamon Press, Oxford and New York

NEA (1994): Safety Assessment of Radioactive Waste Repositories: Future Human Actions at Disposal Sites, Nuclear Energy Agency, OECD, Paris

NEA (1999): Confidence in the long term safety of Deep Geological Repositories. Its Development and Communication, Nuclear Energy Agency, OECD, Paris

NEA (2004): Post-closure Safety Case for Geological Repositories. Nature and Purpose, Nuclear Energy Agency, OECD, Paris

NEA (2005): Management of Uncertainty in Safety Cases: The Role of Risk, Nuclear Energy Agency, OECD, Paris

SANDIA (1991): TSPA 1991: An Initial Total-System Performance Assessment for Yucca Mountain, SANDIA National Laboratories, SAN91-2795, Albuquerque, Livermore

THOMPSON, B.G.J. (1989): The Time Dimension in Risk Analysis: Examples from Recent Work in the United Kingdom. In: SALTELLI et al. (eds.): Risk Analysis Nuclear Waste Management, pp. 231-262

THOMPSON, B.G.J., SAGAR, B. (1993): The development and application of integrated procedures for post-closure assessment, based upon Monte-Carlo simulation: the probabilistic system assessment (PSA) approach, Reliability Engineering and System Safety 42, 125-160

THOMPSON, B.G.J. (1999): The Role of Performance Assessment in the Regulation of Underground Disposal of Radioactive Wastes: An International Perspective, Risk Analysis, Vol. 19, No. 5