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Regulatory decision making in the presence of uncertainty in the context of the disposal of long lived radioactive wastes

Third report of the Working Group on Principles and Criteria for Radioactive Waste Disposal

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FOREWORD

Plans for disposing of radioactive wastes have raised a number of unique and mostly philosophical problems, mainly due to the very long time-scales which have to be considered. While there is general agreement on disposal concepts and on many aspects of a safety philosophy, consensus on a number of issues remains to be achieved.

To assist in promoting discussion amongst international experts and in developing consensus, the IAEA established a subgroup under the International Radioactive Waste Management Advisory Committee (INWAC). The subgroup started its work in 1991 as the "INWAC Subgroup on Principles and Criteria for Radioactive Waste Disposal". With the reorganization in 1995 of IAEA senior advisory committees in the nuclear safety area, the title of the group was changed to "Working Group on Principles and Criteria for Radioactive Waste Disposal".

The working group is intended to provide an open forum for:

(1) the discussion and resolution of contentious issues, especially those with an international component, in the area of principles and criteria for safe disposal of waste;

(2) the review and analysis of new ideas and concepts in the subject area;

(3) establishing areas of consensus;

(4) the consideration of issues related to safety principles and criteria in the IAEA's Radioactive Waste Safety Standards (RADWASS) programme;

(5) the exchange of information on national safety criteria and policies for radioactive waste disposal.

This is the third report of the working group and it deals with the subject of regulatory decision making under conditions of uncertainty which is a matter of concern with respect to disposal of radioactive wastes underground.

The first and second reports were published in 1994 and 1996 under the titles "Safety Indicators in Different Time Frames for the Safety Assessment of Underground Radioactive Waste Repositories" (IAEA-TECDOC-767) and "Issues in Radioactive Waste Disposal" (IAEA-TECDOC-909), respectively.

The reports of the Working Group on Principles and Criteria for Radioactive Waste Disposal contain the developing views of experts within the international community and should be of use to those engaged in producing national and international standards and guidance in this area.

EDITORIAL NOTE

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1. INTRODUCTION

1.1. GENERAL

This TECDOC discusses an approach to handling uncertainties in the decision making process, consistent with the safety principles described in the RADWASS Safety Fundamentals [1] and with particular reference to the regulatory acceptance of a geological facility for the disposal of long lived radioactive waste. Many of the considerations discussed here may apply to any disposal facility, whether deep or shallow, whenever the lifetime of the radionuclides present would make it unreasonable to assume that institutional control of the site could be continued until decay has reduced the activity to levels considered safe.

At the outset, it is emphasized that a rigorous assessment of a radioactive waste disposal facility, so that its long term performance and level of radiological safety can be compared with the established standards, constitutes the backbone of the safety case for the facility. Such an assessment must be capable of withstanding scientific and technical peer review. The system which is to be assessed is liable to be complex, and any satisfactory assessment must take account of this complexity.

It is a general characteristic of waste disposal systems that their long term performance is subject to uncertainties. These uncertainties fall into two broad classes: those which can be quantified and as such expressed as part of the assessment results; and those which cannot, for instance because they represent divergence of informed view or because they are inherent to our abilities as human beings. In any case, exploration, analysis and discussion of the existing uncertainties would provide additional confidence in the ability of a disposal system to provide the required level of safety.

A clear distinction should be made between: (1) the uncertainty in predictions of actual outcomes; for example: dose or risks to individuals; and (2) the uncertainty in the case for safety, i.e. regulatory compliance. In general, one can be quite confident that the disposal system will be safe enough, even though the actual outcome may be quite uncertain. It is uncertainty affecting regulatory decision making that is the primary focus of this report.

The regulator is faced with uncertainty even when the results of a quantitative safety assessment demonstrate compliance with the appropriate standard. Therefore, even though demonstration of compliance by means of a quantitative assessment is necessary, recourse still has to be made to the use of judgement. Such judgement needs to take into account all relevant information and the use of a number of arguments to establish confidence that an adequate level of safety will be achieved. Thus, the main thesis of this report is that these circumstances should be properly considered in the definition of the standards and in establishing how to judge compliance.

To reiterate the foregoing ideas, a rigorous assessment, carried out by using methods which have been properly structured and justified scientifically and technically, is the core of the safety case for any disposal facility for long lived radioactive waste. However, difficult issues of judgement of compliance with the standards and communication are virtually impossible to avoid, because of the uncertainties and complexity associated with the case. This report explores ways in which these difficulties might be handled. The TECDOC also discusses briefly the need to communicate the basis of the safety case to various audiences.

1.2. UNCERTAINTY AND COMPLEXITY

Broadly, there are two main causes of uncertainty in the safety assessment of a geological disposal facility: firstly, incomplete knowledge of natural systems, such as the geological environment, owing to the inherent variability of the properties of these systems and the complexity of the processes taking place within them; and secondly, unpredictable aspects of human behaviour and of the evolution of the facility and its environment once institutional controls have come to an end.

Steps can and should be taken to estimate and potentially reduce uncertainty associated with the first of these causes to the extent practicable. The temporal and/or spatial variation of some properties of natural systems (for example groundwater flow, rock stresses, geochemical conditions, distribution of soil types, percolation of rain water) can be measured and to some extent quantified. Nevertheless, uncertainty will always persist. Additionally, attempts beyond a certain point to improve knowledge of the geological environment of a disposal facility may cause unacceptable disturbances to the behaviour of that environment and hence to the performance of the disposal system as a whole.

The analysis of the second cause of uncertainties should be approached in a different way, basically because it is neither possible nor even necessary to "predict" the future, that is, to provide a convincing set of arguments about the disposal system safety under all plausible circumstances expected in the future.

Some uncertainties, for example those associated with dosimetric data and the dose-risk factor, are common to all radiological assessments and are left implicit; there is no special reason to include them explicitly in the safety assessment of a disposal system. Other uncertainties may be eliminated from further consideration by making simple conservative assumptions based on reasoned arguments. To deal with future human behaviour, for example, assessments may be presented in terms of the impact on hypothetical groups of exposed individuals based on observed past and present human behaviour, justifying the particular groups chosen. Some uncertainties may be quantified and incorporated into numerical assessments of probability or risk. Quantification of other uncertainties may be inappropriate and they should be treated in a different way within the assessment methods. Sometimes one can explore the effect of some of the existing uncertainties by examining the sensitivity of the assessment results to variations in the hypothesis, approximations, assumptions and data.

Because of the limitations in our ability to completely understand the long term performance of disposal systems absolute assurance of safety, i.e. demonstrating unquestionable compliance with safety requirements, is not achievable (this fact should have an impact on how requirements are defined). For this reason, and because human judgement is a necessary and inevitable element of regulatory decision making in this as well as in other contexts, this TECDOC identifies *reasonable assurance* of safety as an appropriate goal for regulatory acceptance of a disposal facility. It discusses how this term is to be interpreted and explores some of the means by which it may be achieved.

Uncertainty is by no means a feature unique to the safety assessment of the disposal of long lived radioactive waste. Determining the regulatory acceptability of a facility proposed for this purpose is simply a particular example of technical decision making under conditions of uncertainty. Virtually all real-world decision making is characterized by uncertainty [2, 3].

Indeed, where there is no uncertainty, decision making may be regarded as trivial, since the facts and logic should speak for themselves. However, waste disposal presents some unusual problems in that the outcome cannot be tested or observed.

1.3. STRUCTURE OF THE REPORT

Section 2 of this report describes the concept of reasonable assurance as the goal for regulatory decision making under conditions of uncertainty and complexity, and discusses its nature. Section 3 discusses the role of the overall assessment of system safety, while Section 4 explores some of the necessary and desirable attributes of the process whereby reasonable assurance of safety may be gained.

2. REASONABLE ASSURANCE OF SAFETY

To proceed with the disposal of radioactive waste in a geological facility requires the confidence of many parties. The confidence of the regulators in the safety assessment is certainly a necessary condition to enable disposal to proceed, but it may not be sufficient. The regulatory body performs its role in order to protect the public. In practice, waste disposal is unlikely to be allowed to proceed unless the public has confidence in the regulatory process. Both the developers of a disposal facility and the regulators are therefore likely to be faced with the task of building in the public the required confidence that the facility is safe.

A critical issue is the level of assurance needed in demonstrating the safety of disposal systems. The nature of uncertainties in assessing the long term performance of waste disposal systems, identified in Section 1, and the conclusion that absolute assurance of safety cannot be achieved, lead to the realization that the concept of *reasonable assurance* should be used in demonstrating safety. Indeed, there appears to be no other standard of assurance that can be applied in reaching decisions on the safety of disposal of long lived radioactive waste.

If one accepts that the concept of reasonable assurance provides the only practical basis for demonstrating the safety of disposal systems, then this concept should be incorporated explicitly in safety standards (i.e. criteria) for waste disposal. For example, if safety criteria are expressed in terms of demonstrating absolute compliance with prescribed requirements, as is the case in existing standards in many countries, then such criteria should be accompanied by a statement similar to the following one, which is almost identical to a statement contained in the US standards and licensing criteria for disposal of spent fuel, high level waste, and transuranic waste in geological repositories [4, 5]:

> "While the safety criteria are generally expressed in terms of demonstrating compliance with prescribed requirements, it is not expected that complete assurance that they will be met can be provided. Proof of the future performance of engineered systems and the natural geological setting over time periods of thousands of years is not to be obtained in the ordinary sense of the word. For safety criteria that apply over long time periods in the future, there will inevitably be uncertainty in predicting performance of the disposal system and in comparing prediction results with criteria. For such long term safety criteria, what is required is reasonable assurance, based on the record before regulators and the public, that the criteria will be met, taking into account the nature of the uncertainties in predicting long term performance of the disposal system."

However, it should be noted that, in Ref. [4], the term "reasonable expectation" is used instead of reasonable assurance, although the two concepts essentially have the same meaning.

Another possibility would be to incorporate the term *reasonable assurance* directly into statements of the criteria themselves - for example a statement that reasonable assurance shall be provided that the risk from the disposal system to the most exposed hypothetical individuals will not exceed a specified value. Even with this approach, however, a statement on reasonable assurance similar to that given above should be presented in the standard itself. More generally, the concept of reasonable assurance in demonstrating compliance would apply to any safety criteria for the total disposal system or any subsystem, including qualitative as well as quantitative criteria.

If the safety case for a waste disposal facility is to meet a standard of reasonable assurance, the regulators have an obligation to the developer of the prospective facility and to the public to clarify what this means. The regulators need to have experience in performing safety assessments themselves to be in a position to understand the limitations and practicalities of such assessments. In the absence of precedents, however, the regulators are in no position to define in advance the level of demonstration, that the criteria are met, that they will ultimately find acceptable. This is inherent in the concept of reasonable assurance. Section 4 describes different ways to achieve reasonable assurance.

Nevertheless some requirements, although they may be hedged with caveats, should be specified by the regulators in advance since they will amount to general policy for acceptance or rejection of proposals for a waste disposal facility. These may include, for example, requirements on modelling, specification of acceptable data sets, and requirements for a quality assurance programme. Otherwise the regulatory process may suffer from a lack of credibility with proponents, the technical community, and other stakeholders, including politicians and the public.

Due to the iterative and judgemental nature of the process of deciding on the safety of disposal systems, it is unavoidable that, at the start of the safety assessment procedure, regulatory requirements for ensuring compliance will be incompletely defined. Furthermore, the decision process is not simply a matter of invoking technical arguments, because decisions will be made in a social and legal setting in which additional factors, which cannot be specified in advance, will be important. These include the possibility that basic safety criteria and other criteria for the performance of various components of a disposal system may change over time.

It would clearly be desirable for the applicant and the regulators to engage in a continuing dialogue from which the level of assurance to be required in demonstrations of compliance will emerge. Such a dialogue may result in changes in the methods and approaches used by the applicant and in the expectations of the regulators.

Although the concept of reasonable assurance is not new and, in fact, has been applied to reactor or chemical plant safety, there is a particular need to emphasize it in the context of radioactive waste disposal systems. This is because *judgement* can be seen as the single most important factor in performance assessments of disposal systems and demonstrations of compliance with safety criteria. The term *judgement* implies that, even though logic, reason, experience, expert scientific knowledge and understanding, experimental data, observation, peer review, etc., are all centrally involved in constructing the safety case, an important subjective element is also necessarily present, i.e. there is no purely objective approach to demonstration of compliance. In this context it may be necessary to specify somewhere that the objective of the safety case should be to provide reasonable assurance of safety.

For example, although complex calculations based on sophisticated mathematical models, including quantitative estimates of uncertainty in the calculations, can be performed, the probability of calculation results coinciding with reality is totally dependent on the validity of the judgements used in developing the conceptual models which provide the foundations for the mathematical models. This is not to say that such calculations should not be performed, but rather that the results need to be considered and interpreted in proper context as an aid to regulatory judgements, rather than as a substitute for such judgements.

An important goal of the regulatory process is to achieve a convergence of various views on the performance and safety of disposal systems, even though different approaches to reaching a conclusion are used. The primary importance of exercising judgement follows from the nature of uncertainties in long term performance of disposal systems identified in Section 1.

The notion that reasonable assurance of safety is the appropriate basis for demonstrating compliance of disposal systems with safety criteria implies that multiple lines of reasoning (i.e. a diversity of arguments), rather than a single approach, should be used in making the safety case. This is to support the necessary judgements and to provide sufficient confidence that the disposal system will provide proper protection. To this end, it is appropriate to examine the performance of the system using a variety of methods, bringing to bear as many arguments as possible to justify the expectation of satisfactory performance. Such arguments may, for instance, relate to the reasons for excluding certain failure mechanisms or processes, or to redundancy arguments, or to the justification of basic assumptions (for example that chemical conditions of the near field will be mainly reducing).

Thus, in developing the case for compliance with safety criteria, the applicant is likely to use as many lines of reasoning about the performance of disposal systems as are consistent with the available body of information. The importance of multiple lines of reasoning in achieving reasonable assurance of safety is discussed further in Section 4.1.

Although a precise interpretation of *reasonable assurance* cannot be provided in advance of a regulatory decision, its essence is to adopt a broad-ranging, rather than narrowly focused, perspective on the decision making process. A general approach to achieving reasonable assurance of safety can be suggested on the basis of present knowledge of disposal systems, methods for assessing their performance, and the nature of the regulatory process.

It should be remembered that decision making with respect to the implementation of a disposal system is an incremental process, and increasing levels of commitment, by developers and regulators, are needed at each major decision point on the way to full licensing. Consequently, assessments with different levels of sophistication will be required at each decision point and this fact should influence how reasonable assurance of safety is to be understood at each decision point.

3. ASSESSMENT OF SYSTEM SAFETY

The fundamental concern regarding the safety of a radioactive waste disposal system is its potential radiological impact on human beings and the environment. Any non-radiological impacts are likely to be less significant and are not the subject of this TECDOC. The expression of the radiological impact in terms of dose and/or risk benefits from decades of international development which has produced a substantial quantity of generally accepted scientific background.

The disposal system is generally composed of several parts (subsystems) both natural and man-made, which, in combination, are expected to provide adequate overall safety. This approach is known as the "multibarrier concept". Only by analysis of the total system, whereby each of the individual components of the system can be explored consistently and comprehensively, it is possible to determine which attributes of the overall system provide protection for a given contaminant and the level of performance that is attributed to any given subsystem, and hence the importance of uncertainty in the attributes of that subsystem.

This does not preclude the performance assessment being carried out at the component level but, if such is the case, the manner in which the overall system model is assembled needs to be described, including a discussion of how the different components interface with one another. It is important to have and to display an understanding of how individual components perform within the context of the overall system to be able to properly evaluate their performance.

There are two main broad methods for carrying out a performance assessment that includes quantitative uncertainty analysis: they are by means of deterministic and probabilistic approaches. When a deterministic approach is used, an attempt is usually made to overcome some of the uncertainties by applying bounding assumptions to models and data. Probabilistic assessments differ from deterministic ones, essentially, because they assign probability estimates, or probability density functions, to individual parameter values. In many cases the two approaches can be considered as complementary and both can be used, in combination, to improve the confidence in the assessment results.

An important aspect of a safety assessment for a waste disposal system is the choice of scenarios under which repository evolution is anticipated to take place. Scenarios are defined by the combination of features, events and processes (FEPs) that determine the predominant behaviour of the system. Formal procedures have been developed in a number of countries and reviewed by international organizations to ensure that all important FEPs have been considered. However, the most important element in the choice of FEPs and in the definition of scenarios is always expert judgement.

In some countries, performance assessment methods have been developed, where all relevant FEPs, their coupling, and their combined impact on the various components of the disposal system are analysed in an integrated manner. This approach, known as integrated performance assessment (IPA), works very effectively with probabilistic models, which allow the impact of system variability on the consequences of retained scenarios to be explored. The large number of runs usually carried out within IPAs is particularly suitable to a variety of statistical analyses on modelling outputs, such as: sensitivity analysis, importance analysis and the analysis of the impacts of different kinds of uncertainty. These issues are discussed further in Section 4.

In preparing a safety case for a disposal system for presentation to regulatory authorities, there is a need to focus on those scientific, technical and organizational aspects which bear most directly on regulatory decision making rather than to undertake an open-ended scientific exploration of the topic. In practice, however, questions raised or information requested by the regulatory authorities may trigger a wider exploration of a topic before resolution can be reached. This may be inevitable in the absence of a standard way of making a safety case.

4. AN APPROACH TO ACHIEVING REASONABLE ASSURANCE

This Section seeks to develop and describe a generally applicable and multi-faceted approach which, if followed, can help in judging whether reasonable assurance of the safety of waste disposal systems, despite the presence of uncertainty, has been achieved. While some aspects of the suggested approach are undoubtedly more important in making the case for safety than others, and their relative importance probably depends on the particular characteristics of a disposal site and disposal system, use of the different components in a complementary manner should provide a means of achieving reasonable assurance of safety.

It should be stressed that uncertainties in predicting the performance of disposal systems are likely to be, to a significant extent, unquantifiable. Nevertheless, their relevance regarding the assessment of repository safety can be highly variable and should be illustrated by sensitivity and importance analysis. In the end a valuable, and maybe sufficient, objective of uncertainty analysis, within a performance assessment, may well be to establish bounds on the significance of uncertainty for regulatory decision making.

4.1. MULTIPLE LINES OF REASONING (DIVERSITY OF ARGUMENTS)

There are many different methods which can be used to support arguments concerning the safe performance of a repository. Approaches include: analytical methods such as modelling, uncertainty, sensitivity and importance analysis; observations of natural systems and use of natural analogues; use of alternative conceptualizations - that is, alternative ways of describing, representing or thinking about, repository systems and processes; use of simplified assessment methods as well as those aimed at a more complete representation of the processes taking place; use of limit or bounding analyses and use of scoping analyses to complement those aimed at representing or indicating the most likely course of system evolution, etc.

Generally, conceptual models specify or represent the processes that are thought to be important. Thus the use of different conceptual models would seem to imply that different processes are considered important. By using different models, be they conceptual or different mathematical representations of the same concept, the importance of a given process to overall system performance can be identified. As noted, conceptualizations need to be consistent with data and observations.

It is important to consider whether the evidence gathered from field measurements could plausibly be interpreted in a manner significantly different from the one favoured (for example in relation to rock fracture patterns and groundwater flow), and whether this could lead to an alternative conceptual, and hence numerical, model. Although rock fracture patterns will in reality be unique, limitations on data gathering may prevent a unique interpretation of the data.

Generally, several different conceptualizations will produce similar qualities of statistical fit to the data and thus it may not be appropriate to assign a unique structure based solely on the "best" fit. However, other information may exist to constrain the range of possible interpretations.

Not all the approaches identified above will be applicable or useful in any given case. For example, if bounding analyses cannot show conformity with the quantitative criteria or if they do not encompass all the relevant processes, their usefulness will be limited. In particular, simple limit, bounding or scoping calculations are unlikely by themselves to be sufficient to bring the safety case to a successful conclusion.

It is desirable to use multiple approaches to provide a range of independent and complementary indicators of system performance intended to lead to an enhanced level of confidence or to reasonable assurance of long term safety. Such diversity of viewpoint should also help to address the differing needs of both technical and non-technical audiences. A constraint on this diversity is that alternative approaches should be reasonably consistent with the body of information relevant to disposal. Thus, while a degree of speculation may be appropriate to cover some uncertainties, the use of concepts which are clearly incompatible with this information is not reasonable. Nevertheless, some examination of concepts that obviously contradict the body of available evidence may be useful in sensitivity analyses or to illustrate the robustness of the safety case.

Overall, the range of approaches adopted should take full account of the information and evidence available, even though individual simplified approaches may not do so. There should also be overall consistency with general scientific and technical understanding.

4.2. USE OF JUDGEMENT

Computing tools, using mathematical models, can be used to perform calculations and to estimate uncertainties in the calculations. Nevertheless, in performance assessment, the range of applicability and the validity of mathematical models are limited by many factors, such as the mathematical realization, including approximations and computational techniques, the database used and the uncertainties in the concepts underlying them. It is important to understand and never lose sight of these limitations, which, however, in some cases, can be successfully compensated by the use of probabilistic techniques and/or conservative approximations and assumptions.

The integrated performance assessment of a disposal system is therefore much more than a purely mathematical exercise; it requires the use of models which should be well suited for their intended purpose. There is no possibility of empirically testing the total collection of hypotheses, assumptions and data that go into the performance assessment as a complete set. Hence, judgement is fundamental in concluding that compliance with safety standards has been achieved. Judgements and the issue of building confidence in them can be aided by a variety of means.

Concepts, assumptions, approximations and data sets can in many cases be tested individually or in groups and, where this is feasible, it is important that it is done so as to build confidence in the model results (see also Section 4.6, Validity of model outputs) and to provide a scientific basis for the informed judgement which must ultimately be made. It is the process of modelling and not the model as such, that is critical in achieving required level of confidence.

A central means of building confidence in modelling outputs produced in performance assessments is comparison with empirical observations from a wide variety of sources (for example: field observations and tests, laboratory experiments, engineering demonstrations and natural analogues). Empirical testing of assumptions and data, where practicable, can bound uncertainties and enhance confidence in the judgements made. Obviously, in circumstances where particular assumptions are identified to be of critical significance, it is especially important to ensure that they are reasonable and as fully justified as possible.

Other means of building confidence in modelling results include: comparison of studies carried out by different groups and assessment of differences and similarities between conceptualizations, assumptions, approximations, etc.; and sensitivity analyses providing insights into the importance of features and processes included in the model, and also into the importance of those excluded. Application of these various means should reduce the incidence of unjustified assumptions and approximations, biases and prejudices, misjudgements and mistakes.

Acceptance of a set of assumptions and approximations involves judgement at the individual level and also to some degree at the societal level which may have concerns unique to a given culture that need to be addressed. Given this, models, assumptions, approximations, and methods need to be systematically documented so that they can be subjected to review and verification.

4.3. GENERIC APPROACHES

4.3.1. Overall safety of disposal

General studies, based on geological knowledge and on the observation of natural analogues, have supported the basic idea that risks to humans from geological disposal should be very low and, thus, that disposal in suitable geological environments has the potential to be adequately safe. The basic assumption is that the isolation capability of a carefully sited repository should be capable of isolating waste from the surface just as various toxic materials that occur in the earth's crust have been isolated. Investigations of natural analogues such as Cigar Lake and Oklo, which show that natural containment of uranium and other actinides over geological time periods has occurred [6], lend support to this assumption.

In addition, simple calculations of radiotoxicity variations as a function of time show when various forms of radioactive waste will decay to toxicity levels equivalent to, or lower than, those of natural mineral deposits. Although the activity levels of natural deposits may not be related to regulatory standards for radioactive waste disposal, such studies may be very useful for communicating with non-specialist scientific audiences. They may also help to provide a broad overall context and perspective for detailed technical studies.

It is obvious that simple, generic studies of the type described above cannot answer all safety related questions or describe the performance of particular facilities at specific sites. However, in conjunction with scoping and bounding analyses, such studies can help define the constraint boundaries within which the possible variation of different parameters in repository performance assessments needs to be considered.

4.3.2. Desirable repository conditions

Assessments that focus on site and concept specific features and processes are undeniably necessary, but there are also considerable benefits to be gained from broadly based generic process-oriented assessments to identify more general systems characteristics that help ensure safety [7–10]. Such assessments may be viewed in one way as a special type of sensitivity analysis since they highlight some of the features and processes that are important to the safety of the overall system. They allow further work to focus on these critical areas. Through choice of repository design and siting which incorporate generically desirable characteristics, one may gain margins which help to achieve reasonable assurance of overall safety.

For example, low groundwater flow and reducing geochemical conditions are generally beneficial in all media and for all concepts. Depending on the specific circumstances, highly permeable features surrounding the block of host rock which accommodates the repository could reduce the hydraulic gradient across the disposal zone, and could reduce the influence of surface topography and closely spaced near-surface vertical fracturing. Similarly, the presence of reducing substances such as compounds of iron, sulphur, carbon and manganese can help maintain reducing conditions.

Nevertheless, site and concept specific assessments and their intercomparisons are also necessary for examining general system characteristics that help ensure safety. By being more realistic than generic studies, they can identify not only characteristics that are important, but also limitations in the ability to accommodate various features in disposal system designs. In addition, they can enable coupling mechanisms between design features and site features to be explored. In the end, generically desirable characteristics are without substance unless they exist at a real disposal site or can be introduced as an engineering option.

The use of generic assessments (i.e., non site specific) is essential to understand the overall relationships in a system and the relative sensitivity of the various elements. A good generic study is an essential part of a good site specific assessment. However, the direct use of generic assessments to show compliance with criteria for a site is limited. If the site concerned does not possess the relevant characteristics in the conjunction of circumstances that make them generically favourable, such assessments are inappropriate and potentially misleading. However, even when dealing with a particular design and site specific assessment, it may still be worthwhile pursuing generic assessments in the background in order to help steer the site specific work.

In pursuit of the same objective, a site and concept specific performance assessment could contain within it a site specific overview assessment which focuses on the fundamentals of repository performance so as to identify the critical safety related features. Such an assessment would serve to highlight those features of the specific site and design that contribute to achieving safety with a high degree of assurance.

4.4. WELL STRUCTURED METHODS OF ASSESSMENT

Radioactive waste repositories contain many natural and engineered components. The number and diversity of events and processes which might affect them over long periods are large and their sequencing difficult to establish. Thus it is necessary to use well structured methods to help ensure that all relevant events or processes have been properly considered (completeness) and that the basis for the judgements is clear and documented.

The internationally used approach is to carry out an integrated performance assessment (see Section 3) and to compare the results with the criteria established by national regulatory authorities. Given that part of the regulatory requirement is to undertake comparisons with criteria for the disposal system as a whole, such an approach is practically inevitable. Virtues of the approach are that it should help ensure credibility and completeness of the assessment. A central component of the assessment is the establishment of models to properly represent the processes judged to be important in determining repository performance.

A modular and possibly hierarchical approach to the construction of models is desirable. Such an approach assists clarity of thought and purpose on the part of the modellers and greatly assists transparency of presentation of the modelling approach to others. A modular approach is supportive of the multiple barrier concept inherent to the repository physical description, because the separate modules (subsystem models) simulating parts of the system will often correspond to or encompass identifiable barriers. By the same token, such an approach can make an important contribution to establishing quality assurance for the model including an audit trail so that, for example, it is made much easier to revisit the model later.

If properly applied, a modular approach is of value in focusing attention on the interfaces between the individual parts of the overall model which seek to model different but interacting phenomena. Interfaces need to take due account of interactions and coupling mechanisms (for example: thermal, mechanical and hydraulic coupling mechanisms) between disposal system components and subsystems. Outputs of one module should be suitably matched to input requirements of another, in recognition that there can be feedback between modules.

A modular structure for the overall performance assessment model can also help by grouping data and modelling assumptions for consideration as coherent subsets. Analyses of the sensitivity of an output to particular assumptions, items of data and inputs are facilitated, as are analyses of the importance of these parameters to the output taking into account their likely range of variation. In addition, individual subunits of the overall model can be switched out and alternative modelling representations switched in as desired (taking due account of interactions and coupling mechanisms) to explore the consequences of such changes.

There are basically two different and possibly complementary approaches to perform an integrated performance assessment for a disposal system, depending on how basic modelling is approached: (1) the so-called "total system modelling", and (2) the one based on the "aggregation of subsystem models". Each of them may prove to have advantages and disadvantages in terms of methods, but neither one can be advocated as better representing the disposal system being assessed or better supporting the safety case.

The assessments should be conducted in a formalized and well documented way, following a set of well established steps which form the assessment methodology.

A rigid structure or excessive formalization can itself be limiting, however, if the result is that the structure drives the assessment and excludes the use of other lines of reasoning, as discussed in Section 4.1. An example is the use of probabilistic methods as the central element of a performance assessment. This is entirely appropriate as long as it does not preclude the use of other methods, for example deterministic techniques or non-quantitative methods. A formalized process is generally believed to be beneficial to identify and document the features, events and processes that are important for a given performance assessment. In identifying these FEPs the overall disposal system must be specified.

In achieving reasonable assurance of the safety of a waste disposal system, it is of central importance to establish models which provide the necessary confidence and which can be used to explore the properties of the system. As noted earlier, numerical or mathematical models are ultimately derived from conceptual models which seek to represent the processes judged to be important in repository performance.

Coupling mechanisms may be evaluated using detailed models which are not incorporated into the model used for analysis of the overall system. Such detailed models may be used for a variety of purposes, for example to explore individual processes, features, components and subsystems, and to develop and test approximate representations to be used in larger coupled models.

While a decision on choice of structure needs eventually to be made, an analysis of possible choices should first be conducted to explore the effect of alternative structures and to see, in particular, whether the choice affects the results of the assessment.

4.5. ROBUSTNESS OF DESIGN AND ASSESSMENT

The actual long term performance of the isolation barriers ultimately controls the level of safety achieved in a disposal system. However, this performance is not known at the time when decisions and judgements must be made. The only basis for decisions is the expectation of safety contained in the performance assessment.

4.5.1. Robust design

As noted previously, the uncertainty associated with the long term performance of containment and isolation barriers can be large. Thus it cannot be assumed that a specific barrier will necessarily function as expected. It is generally agreed that disposal systems for long lived waste should employ multiple barriers to ensure the required isolation. In this way, overall system safety depends on a series of barriers, and performance can remain robust even if one barrier fails to function as expected. This expectation is enhanced by incorporating some degree of robustness into the facility design and the assessment itself.

Within the multibarrier concept each barrier has a role to play and the system composed of all barriers must provide a high degree of assurance that safety will be achieved. For most radionuclides there is redundancy in the sense that more than one barrier may be effective in ensuring their retention. Comparing the performance of the overall disposal system with one or more of the barriers removed is helpful in assessing the degree of redundancy provided by the overall system and building confidence in system performance. This may be accomplished either qualitatively or quantitatively, in each case paying due attention to whether the barriers are sufficiently independent.

Several different mechanisms may be important in the performance of a given barrier such as the geosphere; for example, the geosphere may provide hydrogeological containment, based on the absence of groundwater or on very low groundwater flow within the host rock, and chemical retention, owing to various chemical and physico-chemical retardation processes including, for example, sorption. Each of these may make an important contribution to overall safety.

Even if hydrogeological containment were to decrease in the future, it does not necessarily follow that the chemical and physico-chemical containment processes would be affected. On the other hand, it is also possible for coupling to occur between components of a multiple barrier system or between different processes within a single barrier. Thus, geochemical conditions may be affected by hydrogeological changes. Claims of independence need to be critically examined and justified in each case. One of the roles of an integrated system model is to take coupling mechanisms into account and examine their importance.

Repository designs should incorporate, as far as practical, some degree of conservativeness to accommodate the unavoidable uncertainties; this may imply making use of designs and materials which are known to be resistant to a broader range of conditions than are reasonably expected. These design options are all intended to provide reasonable assurance by increasing margins of safety. Some repository design concepts are inherently less sensitive than others to variations in the conditions they may experience. Regarding choice of materials, emphasis should be given to materials which are stable over a wide range of temperature, chemical state (pH, Eh and ionic strength) and level of stress. As a conservative measure, the thickness of materials used could also be made greater than necessary to meet basic performance specifications. If possible, robustness may be enhanced through the choice of a particularly thick layer of host rock or by placing the repository at a greater depth. Robust designs are generally more costly, however, and thus some balance will need to be struck between the increased cost and the possible increase in expected safety.

4.5.2. Robust assessment

Where possible, performance assessment of a disposal system should be robust, i.e. tolerant to uncertainty. An assessment demonstrating conformity with the regulatory requirements while being manifestly conservative would be regarded as robust. This is perhaps the simplest way of achieving a robust assessment, but it may not be possible and other approaches could also be pursued. In this respect identification of uncertainties, careful documentation of their potential impacts and presentation of good reasons why they are not critical to safety appear to be of the greatest importance.

Performance assessments should seek to achieve insensitivity to the characteristics of the modelling approach (such as the assumed boundary conditions, the way element grids are assigned, the dimensionality of a model, the scale of the assessment). In addition, they should employ representations and techniques which, as far as practicable, are simple and understandable, while being technically fit for purpose and well-established in their individual disciplines. A variety of approaches should also be used, as noted in Section 4.1. Considerable effort should be spent to ensure that the level of robustness of the assessment is directly linked to the level of importance of the assessed process or feature to the safety case.

Some natural systems are easier than others to characterize and assess. For example, when the host rock consists of a relatively uniform medium, such as clay or salt, it is easier to characterize than crystalline rock, which is usually intersected by a complex and spatially varying system of fractures. Furthermore, where relatively robust engineered features exist, a more robust assessment for a given level of effort tends also to follow. Thus, in some cases, the need for robust assessments may influence the choice of host medium and repository engineered features, even if there are other reasons which favour alternatives.

Robustness can also be interpreted as meaning that the assessment, including all modelling activities, can withstand scientific scrutiny. Thus, processes that are considered to be important need to be included in one way or another, and the approximations and methods of modelling these processes need to be justified and documented. The same requirement applies to the exclusion of what are considered to be unimportant processes. Determining what processes are important and which are not, and justifying the choice, is one of the central objectives of a FEP analysis.

While a robust assessment is a desirable characteristic, it is not an essential one for every component of the repository or for every line of reasoning. The significance placed on a particular assessment of a given subsystem should in part reflect the robustness of that assessment. It should also, however, reflect the relevance of the assessed subsystem to overall safety and the amount of independent support arising separately from other lines of reasoning (see Section 4.1).

4.5.3. Sensitivity and importance analysis

Sensitivity and importance analysis is a useful tool in achieving reasonable assurance of safety in the face of uncertainty, and can be applied at all levels of a safety assessment and to all levels of system performance, including components and processes contributing to system performance, data, models and methods, assumptions and uncertainty itself.

The use of sensitivity and importance analysis in a safety assessment for a waste disposal system is a major means of dealing with uncertainty and making the case for safety. Indeed, sensitivity and importance analysis is of concern only where there is uncertainty. Such an analysis provides a method for distinguishing between assumptions that significantly influence model outputs (i.e. conclusions from any line of reasoning) and assumptions that have little influence on model outputs even though they may be highly uncertain.

Sensitivity analysis is essentially an investigation of effects on the output of any model (i.e. the consequences of any line of reasoning about system performance) of uncertainties associated with the model inputs and the modelling itself (i.e. assumptions inherent in any line of reasoning). Within the context of a mathematical model, for example, sensitivity analysis explores the effect that changes in input parameters or assumptions internal to the model have on the model output. Importance analysis is based on sensitivity analysis but seeks also to take into account the likely range of variation of input parameters and model assumptions in such a way that their absolute or relative importance to the model output can be evaluated.

In specific relation to numerical models for assessing the performance of disposal systems, sensitivity and importance analysis can be considered with respect to uncertainties in input data for models, assumptions internal to different parts of the model, assumptions about how the different parts of the model interface with one another and uncertainties related to the long term evolution of the disposal systems. In making the case for reasonable assurance of safety, all these types of uncertainty should be investigated by sensitivity and/or importance analysis.

More generally, the sensitivity and importance of any line of reasoning used in making the safety case, including those that are only qualitative, should be explored. Sensitivity and importance analyses are valuable not only for determining the significance of various uncertainties in any particular line of reasoning, but also in judging which are the most robust lines of reasoning in the overall process of gaining reasonable assurance of safety. Some examination of concepts that are incompatible with the body of available evidence may be useful in sensitivity analyses or to illustrate the robustness of the design.

4.6. VALIDITY OF MODEL OUTPUTS (CONFIDENCE FOR DECISION MAKING)

As already stated, modelling is an important component of any performance assessment for a repository for long lived waste. The models used should be appropriate for their purpose within the assessment context. That is, the key issue is to develop confidence in the models for regulatory decision making.

As far as possible, modelling outputs should be shown to be valid, that is to correspond to empirical data obtained in a real world situation. It goes without saying that validation of modelling outputs would help in building confidence in the assessment results and in providing reasonable assurance of safety. On the other hand when modelling outputs represent the hypothetical consequences, in a remote future, of radionuclide release from a deep repository, it is obvious that their validation is not possible, in the sense that empirical observation of events that have not yet taken place is inconceivable.

Nevertheless, it may be possible to compare modelling outputs with observations, regarding the behaviour of certain components of the repository system; for example data sets obtained with *in situ* experiments, with the study of natural analogues or with measurements performed during site characterization and during the repository operational phase may allow the validation of simulations of the thermo-mechanical, or chemo-mineralogical response of the near-field barriers or the hydrogeological evolution in the host rock surrounding the repository.

Models used in performance assessment can be tested and updated not only on the basis of comparisons of their outputs with empirical data, but also on the basis of peer review, inter-code comparisons, comparisons with other performance assessments, results of experiments carried out to test specific aspects of conceptual and numerical models, comparisons with cases for which analytical solutions exist, etc.

In conclusion, validation should be regarded as a process of building confidence and not as an end result. The process is to be seen as an iterative and progressive one. Uncertainties and areas of particular sensitivity in the models are used to steer the systematic collection of data, and the overall model is systematically reviewed, adjusted and where necessary revised in the light of the data collected. Major changes to a model may be needed if it is found not to represent adequately some process important to the safety case or if it is excessively conservative. Area by area, a judgement will eventually have to be made about when it is sensible to stop the process of data collection and model testing.

4.7. USE OF DIFFERENT INDICATORS AND ROLE OF QUANTITATIVE ESTIMATES

4.7.1. Use of different indicators

Criteria for judging the level of safety of radioactive waste disposal systems have been developed over the last several decades. There is reasonable consensus among the international community on the basis for these criteria within the well-established system of radiological protection.

So far, however, little experience has been gained in applying these criteria to actual disposal systems; consequently, there is an international debate on the most appropriate nature and form of the criteria to be used, taking into account the uncertainties involved.

Emerging from the debate is the increasing conviction that the combined use of a variety of indicators would be advantageous in addressing the issue of reasonable assurance in the different time frames involved and in supporting the safety case for any particular repository concept. Indicators including risk, dose, radionuclide concentration, transit time, toxicity indices, fluxes at different points within the system, and barrier performance have all been identified as potentially relevant. Different types of indicators and their utility are discussed in [11].

Dose and risk are the indicators generally seen as most fundamental, as they seek directly to describe the radiological impact of a disposal system (see, for example [12]), and these are the ones that have been incorporated into most national standards to date. There are, however, certain problems in applying them, including, for non-technical audiences, difficulties of understanding, especially in the case of risk. In the USA, environmental standards applicable to the Waste Isolation Pilot Plant (WIPP) for the disposal of transuranic waste are expressed in terms of release limits as a measure of containment [4].

Application of a variety of different indicators may be particularly useful in terms of qualitative discussion and confidence building. Indicators such as concentration, flux and container corrosion rate are more easily conceptualized than dose or risk and in this sense can be regarded as "more direct". They may therefore be useful, particularly in discussions with non-specialists, provided their safety relevance can be established.

However, such indicators have their limitations. An important limitation is the current absence of suitable standards, with which to compare the assessment results. The definition of standards that could be used with alternative indicators is a matter presently receiving increased attention.

It is also important not to lose sight of the fact that the fundamental concern regarding the safety of a radioactive waste disposal system is its radiological impact on human beings and the environment, no matter how difficult this may be to evaluate. Indicators that do not directly relate to this concern therefore need to be interpreted in more fundamental terms in order to establish their safety relevance and this interpretation is subject to considerable debate.

4.7.2. Role of quantitative estimates

An obvious output from assessments consists of numerical results providing an indication of disposal system performance. The utility of individual numerical indicators will vary greatly and, given the large uncertainties, considerable caution is needed to avoid any suggestion or expectation that any given indicator of disposal system performance can be an accurate estimate of future reality. Such an indicator typically provides only an estimate of what might happen under certain assumed conditions. If the assumed conditions are chosen to be conservative, the indicator provides a reasonable upper bound on the possible consequences. The numerical result will be sensitive to the type of indicator chosen, the type of model used for the estimate and the nature of the data required (i.e. it is subject to considerable uncertainty).

Nonetheless, properly derived quantitative estimates provide the important basis for comparing system performance with criteria. If the regulatory requirements include a need to demonstrate conformity with a particular numerical standard, then plainly a quantitative assessment is indispensable. Such an assessment may show that the quantity estimated (for example dose or risk) lies so far below the regulatory standard that there can be little doubt that the standard is met, even though there may be great uncertainty associated with the assessment.

Alternatively, uncertainty associated with the assessment may significantly restrict one's assurance that the numerical standard is met. In this case, other arguments about the safety of the disposal system assume greater significance.

Uncertainty needs to be dealt with and considered in performance assessment. Indeed one role of performance assessment is to identify how uncertainty affects estimates of performance and to identify critical FEPs so that uncertainty in performance related to these FEPs can be dealt with, for example by design changes or by improving the knowledge of the FEPs.

Quantitative estimates also provide a basis for comparing the relative levels of safety achieved by different parts of the disposal system. Numerical indicators should not be quoted in isolation, but should be complemented by other indicators, so as to achieve a safety case based on multiple lines of reasoning (see Section 4.1), and by discussions and reasoned arguments aimed at putting the numbers in their proper overall context.

Numerical and analytical methods leading to quantitative estimates are central to safety and performance assessments. Such analyses provide insights to system performance. But it is important to recognize that reasonable assurance is achieved by integrating the various ways of assessing the system including both quantitative and non-quantitative elements. This is, essentially, a judgemental process.

4.8. ITERATIVE APPROACH TO ASSESSMENT

The development of methodologies for assessing the long term performance of radioactive waste disposal systems has been evolving over the last two decades with a milestone being reached when the emphasis was reoriented from the component level to a more integrated view of the disposal system as a whole.

In assessments performed in the past, detailed data from real systems were scarce. The situation is presently evolving and a number of performance assessments are now available that make use of data from site specific investigations. The trend towards more specific assessments is expected to continue in the future, in view of the progress being made in several national programmes on the investigation of sites for geological disposal facilities.

In general, it will not be sufficient to perform a single safety assessment at the start of a project to develop a waste disposal facility. Rather, with the objective of ensuring that the assessment is continuously adapted to the project's status and needs and with the ultimate goal of achieving reasonable assurance of safety, as appropriate for the type of decision and compromise needed at any step in the process, an iterative approach should be adopted. At each iteration, any assumption made in previous assessments would be subject to critical review as soon as new information became available. This process should include models and data, and should be applied at all assessment levels, from the single component to the integrated system. The availability of new data should lead to consideration of whether alternative conceptual models should be brought into play, as discussed in Section 4.1. This process would also be of value in giving guidance to the site characterization programme as well as to the research and development efforts.

Such an iteration may affect only a single component of the disposal system, or it may extend to the fundamental conceptualization of the system as a whole. It may affect the way in which individual components are themselves considered and/or their role in the hierarchical structure of the model adopted for the performance assessment of the system.

The iterative approach should be applied both to generic models used to support modelling at a specific site and to site specific assessments. It should be applied in the interaction established between the applicant and the regulators within the regulatory procedure during the whole process leading to construction, operation and closure of the disposal facility. An interactive approach should serve to continuously improve confidence in the performance assessment results.

4.9. SIMPLICITY

The aim of the assessment is not to predict the actual performance of the disposal system, which, anyway, would be an impossible objective, but rather to reach reasonable assurance that it will provide an adequate level of safety. The complexity of the models should be consistent with the assessment objective and compatible with the data which is available or can be obtained.

Many national regulations specify a numerical target based on risk or dose. To demonstrate conformity with such an indicator requires the use of quantitative models. In general, the simpler the model the better, as long as it can account for the important processes and whenever adding complexity does not provide relevant additional information. However, too much simplification may lead to a model which is incapable of demonstrating conformity with the given numerical criteria. As soon as a model is defined for use in quantitative analysis, its ability to represent the important processes begins to be tested.

To simplify the description of a complex system clearly carries a risk of missing essential features or processes, and may result in the need to assign a larger variability to particular parameters than a more complex model would require. Nevertheless, determined attempts to simplify are extremely valuable, because they force a clarification of what the critical features or processes may be and, if they succeed, are very helpful to communication and genuine understanding of the safety case.

The justification for the assumptions and approximations which have been made to develop a simple model of a complex system may itself not be a simple matter, and may be difficult to explain to the non-specialist. Furthermore, the range of validity of a simple model may be limited and, outside this range, different assumptions and approximations may be needed.

Examination of a range of several simplified conceptual approaches may assist in determining which processes are critical. The adoption of simplified approaches can be used in tandem with more mechanistic approaches such as a probabilistic analysis using a total system model. Both types of approach have their strengths and weaknesses in terms of identifying factors of importance and errors in conceptualization.

It is likely that, for an overall system assessment, both simple and complex methods will be needed. They should be regarded as complementary. Good examples of simple approaches are the so-called "limit approach", useful in screening analyses, and the use of natural analogues. The basic elements of the limit approach involve scoping and bounding calculations using a wide variety of simple and, as far as possible, independent methods aimed at determining the basic trends in the processes (increase or decrease in safety), the sensitivity of these trends (proportional or higher order) and the rough order of magnitude of the effect. In this way, the importance of major elements can be assessed and some priority given to those which are most central to ensuring safety. Natural analogues can be useful in a variety of ways, for example: to show that particular components can indeed remain effective over extended periods of time; to improve the understanding of certain processes and of what controls the important ones; to assist in the development of conceptual models; and, in particularly favourable cases, to permit model testing.

An important application of simple approaches such as the limit approach or the use of natural analogues is thus likely to be to constrain the range of possibilities which need to be examined using more detailed techniques. They also have a role in supporting, explaining and illustrating the concepts, models, assumptions and data used in integrated assessments, and in clarifying and explaining the results of such assessments and how the components of the disposal system function individually and collectively to provide safety.

Among the dangers of simple approaches are that they can lead to gross over- (or under-) estimates of consequences. Inappropriate use in a presentation to non-specialists could lead to the audience concluding that a disposal system is unsafe because, according to the approach presented, it does not comply with safety criteria.

Generally, understanding at the level of the overall system can be achieved by using integrated assessment methods with the addition of qualitative arguments and, possibly, information derived from natural analogue studies. At the more detailed subsystem and component level, understanding is usually helped by experiments, field measurements, simplified and more detailed modelling, and natural analogues.

Good understanding of a disposal system for the purposes of regulatory decision making is not inherent to either simple or complex methods. Both can be wrong or can mislead and both can be correct and provide useful information. One benefit of complex assessments may often be to confirm the conclusions from the preliminary simplified assessments. In practice, it may be necessary to go one step in complexity beyond what would appear to be required in order to show that the representation is indeed sufficiently detailed. A general observation is that, as knowledge increases, complexity usually increases as well, until enough knowledge is gained to enable some unified simplification which contains considerable knowledge and insight. Achieving such a unified simplification is important for providing a reasonable assurance of safety; it is desirable for the applicant to be able to explain the case for safety in simple terms.

Most people sense intuitively that a good simple method is more likely to convey the essence of some concern than is a very complex one. Simplified analyses are usually useful for illustrating and describing concepts, for explaining the results of more complex analyses, for studying specific factors and processes that are part of the overall system, etc. This is not to say that regulatory authorities would be satisfied with a safety case which does not sufficiently explore the complexities of the disposal system concerned.

A safety assessment which includes the detail necessary to explore the complexity of the disposal system to the satisfaction of regulators, however, will almost certainly be too complicated for a general audience. By and large, communication with non-technical audiences requires that simple means of expression be used. Thus, a complex analysis will need to be explained in simpler terms for effective public presentation.

4.10. QUALITY ASSURANCE AND PEER REVIEW

4.10.1. Quality assurance

Quality assurance is essential for demonstrating that the waste disposal system and the associated performance and safety assessment are fit for purpose. One aspect of demonstrating fitness for purpose is a specific evaluation of the system and the assessment so that a suitable judgement can be made. It is a matter of definition as to whether the conduct of such an evaluation is regarded as part of quality assurance.

Quality assurance is concerned with ensuring that tasks are specified and carried out properly, and with documenting what has been done so that it can be audited. It has a role at every level of the work associated with the development of a safety case for a radioactive waste disposal facility. This includes all activities associated with characterizing a site, and developing and operating the facility itself, which can affect the safety case, as well as supporting activities such as research, technical investigations and performance assessments. A quality assurance programme needs to be produced early in a project and to be reviewed by the regulatory authorities. An acceptable quality assurance programme will provide for the systematic documentation, planning, management and control of all relevant activities. It needs to be flexible enough, however, to allow for changes in the future direction of those activities which are at a developmental stage. It will be subject to regular audit. It is important that the quality assurance programme of a performance assessment activity is reviewed periodically to ensure that the additional burden placed on the work programme does not interfere with timely development and does not cause excessive cost.

Proper quality assurance arrangements in all waste management activities, including performance assessment, are to be regarded as an indispensable requirement for achieving reasonable assurance of safety.

4.10.2. Peer review

Although peer review could be regarded as part of quality assurance, it may be more appropriate to consider it separately because of its own special characteristics. Peer review is brought to bear on areas of the work where an independent technical appraisal is judged to confer significant added value.

An independent appraisal has a role at a variety of levels, including those of data collection, understanding the system and its conceptualization, numerical model construction, application of data and models, interpreting model results in terms of performance indicators, and achieving reasonable assurance of overall safety.

The value of peer review lies in two main areas. The first is to provide independent technical support for the judgements made and the decisions reached; this is of value not only technically but also for the sake of presentation, in that it is useful to be able to state that it has been possible to convince independent experts of the soundness of the work. The second, which is more narrowly technical, is the value of bringing a diversity of views to bear which may yield new insights into the problem. Such new insights may not, of course, be favourable in terms of making the judgements and decisions easier and advancing the time at which it is possible to bring the work to conclusion.

There are also potential problems associated with peer review. One is the enhanced risk of being drawn back into a conventional stance on some topic in order to achieve consensus, when the conventional stance ought to be challenged or overturned. Another is the perception that the value added by the review is greater than it actually is. Technical peers usually belong to the same specialist community as the authors of the work and therefore achieving a sufficient degree of independence in the review may constitute a problem. Furthermore, unless the reviewers have a clear specification against which to work (which itself may contain hidden dangers of misdirection), they may in practice undertake a less thorough review than assumed by those requesting the review.

Despite such potential difficulties, peer review is to be regarded as an important requirement for work to achieve scientific and technical respectability. Being a methodological issue as well as a matter of transparency, it contributes to building confidence in methods, models, judgements and decisions. Peer review is thus beneficial to both the technical parties (proponents and regulators) and the non-technical stakeholders.

4.11. ECONOMIC, SOCIAL, ENVIRONMENTAL AND ETHICAL ISSUES

The main thrust of arguments for disposal of radioactive waste in a geological repository is likely to lie with technical lines of reasoning to justify the safety of the disposal system. The uncertainty discussed so far is essentially relative to the technical case; however, economic, social, environmental and ethical lines of reasoning may be felt to add a different kind of uncertainty. In addition, consideration of economic, social and ethical aspects may also be needed in discussions with certain audiences to justify the practice of disposal in a given manner in comparison with alternative actions [1, 13, 14]. For example, alternatives to early disposal of the waste are extended storage with delayed disposal and indefinite storage. Each of these alternatives is technically feasible and in each case an argument could be mounted (which might or might not be acceptable to the regulatory authorities) that the approach would provide reasonable assurance of safety.

Assuming that reasonable assurance of safety could be achieved for all options, in economic terms, it would be appropriate to show the cost/benefit position for early geological disposal in respect to the other alternatives, for a given level of safety. In social, environmental and ethical terms, arguments might be mounted to support early disposal of the waste by invoking the safety principles of radioactive waste management *(protection of future generations* and *burdens on future generations)* [1] and the principle of *sustainable development*, which may be defined as "development that meets the needs of the present without compromising the ability of future generations to meet their own needs" [13]. Relevant supporting principles are:

- Decisions should be based on the *best possible scientific information* and analysis of risks;

- Where there is uncertainty and potentially serious risks exist, *precautionary* action may be necessary;

- Ecological impacts must be considered, particularly where resources are *non-renewable* or effects may be *irreversible*;

- *Awareness of cost implications* should be brought home directly to the people responsible — the *polluter pays* principle.

However, it is not within the scope of this TECDOC to explore such economic, social, environmental and ethical lines of reasoning, but simply to identify that they may need to be developed in conjunction with the technical ones.

4.12. ACCEPTABILTY TO DIFFERENT AUDIENCES

While the primary role in the acceptance process falls to the regulatory authorities, there may be other audiences involved in decision making and all of them need to be considered accordingly.

The different audiences involved may have different understandings of when reasonable assurance has been reached and they may also need different messages and arguments to convince them. One reason for this, among others, may be the different ways in which radiological risk is perceived by technical and non-technical people, which creates a real communication problem that still has to be overcome.

The need to communicate with different audiences arises in part from the desirability of engaging the applicant, the regulatory body, and various stakeholders in a continuing dialogue from which the level of assurance to be required in demonstrations of compliance will emerge. Such a dialogue may result in changes in the methods and approaches used by the applicant and in the expectations of the regulators. The agreement of the technical parties involved in the review of the assessment that it is soundly based and that it provides reasonable assurance may contribute to gaining the acceptance of the non-technical stakeholders.

Overall, the safety assessment must be as complete and rigorous as needed to allow for a proper high quality evaluation by the regulator. In addition, since it needs to provide a basis for satisfying a wide range of interested parties, it has to comply with apparently contradictory requirements, such as:

- Simplicity versus complexity.
- Comprehensiveness versus understandability.
- Following a variety of approaches versus choosing the one believed to be optimal.
- Technical versus socio-political orientation.

For both regulators and proponents, communicating at a technical level with an audience consisting of lay members of the public probably cannot go much beyond presenting simplified qualitative and semi-quantitative arguments. The so-called "limit approach" and the use of natural analogues are good examples of simple approaches that could be used for presenting the case to some of the different audiences involved.

Communicating at a socio-political level is likely to require dealing with issues such as: fear of particular hazards (for example ionizing radiation) and of particular consequences (for example cancer induction and genetic malformations); belief in the value or otherwise of the activity (for example nuclear energy and/or waste disposal); trust in the messages from the industry; and confidence in the regulatory system.

Owing to the need to instil confidence in the regulatory system, it is important to explain to the public the approaches the regulatory authorities will adopt, and the criteria they will apply, in assessing the safety of the disposal system and in allowing the disposal of radioactive waste to proceed.

On the other hand, it should be realized that for a complex system, it is inevitable that the details of a thorough analysis could only be understood through careful and time-consuming study. The capability to follow the rationale of the argument and to understand the modelling work, with their scientific justifications, requires an investment in time and effort which people without a direct professional interest in the subject are unlikely to be willing to make. By and large, audiences should accept this as a matter of common sense and may even regard it as a positive point that so much technical effort is being expended to put the safety case on a proper scientific footing.

The *principles* on which the safety assessment is based need to be robust and readily communicable to a wide range of audiences. Qualitative arguments can and should be presented to explain the results of assessments and how and why a given system can be expected to provide protection of human health and the environment.

Not only may it be helpful to present different material to different audiences, but it may also be important to present the same material in a different way. For example, a technical audience is likely to accept with equanimity a presentation which takes as its starting point the assumption that one or more barriers to the escape of radionuclides have failed, as a basis for exploring the performance of, and hence gaining confidence in, the rest of the disposal system. However, a non-technical audience, being unused to this type of approach, might receive the message from such a presentation that the barriers assumed to fail cannot be trusted and hence that there is cause for concern.

The needs of the various audiences are sufficiently different to ensure that they cannot be met with a common document. All documents, regardless of the audience, need to be consistent. The safety case prepared for the regulatory organization is likely to be too complex and lengthy for use with non-specialist audiences. Nevertheless, members of the public need to have access to the full detail of the assessments, should they want it. No public perception must be allowed to develop of a "divided culture" approach: "You are not telling us what you are telling them."

5. CONCLUSIONS

In the performance and safety assessments produced in support of an application for the disposal of radioactive waste in a deep geological repository, the focus is on predictive modelling and those scientific and technical aspects which most directly bear on regulatory requirements. However, difficult issues of judgement and communication are virtually impossible to avoid, because of the uncertainties and complexity associated with the case. This report has explored ways in which these difficulties might be handled in the decision making process.

The group which has produced this report believes that it should not be regarded as the last word on the subject of regulatory decision making under conditions of uncertainty, which is a rapidly evolving topic and a matter of considerable current concern. Rather, the report invites debate and further contributions. It has, however, sought to establish the following key points:

- A rigorous assessment, based on methods which have been justified scientifically and technically and which include quantitative as well as qualitative arguments, is the backbone of any safety case for a disposal facility for long lived radioactive waste.

- Regulatory decision making can only go forward on the basis of *reasonable assurance* of safety. This may be viewed as equivalent to building confidence in the eventual decision. Furthermore, the manner in which regulatory requirements are formulated needs to take account of the concept of reasonable assurance.

- In reaching a regulatory decision, judgements are likely to be based on multiple lines of reasoning, i.e. a diversity of arguments. No individual line of reasoning will necessarily be sufficient, and it is likely that both simple and complex approaches will be needed.

- A positive conclusion about the safety of the disposal system, i.e. that reasonable assurance of safety has been achieved, will depend on a number of factors, including: the choice of robust options for repository design; the development of a well-structured and robust assessment; and the capability to build confidence in the validity of modelling outputs for decision making. To date risk and dose have been used as the principle indicators of safety, but other indicators are also identified as potentially applicable to address the issue of reasonable assurance in the different time frames involved.

- There is a need for the approach adopted to address, and be understood by, multiple audiences. In particular:

  - It is desirable to engage the applicant, the regulatory body, and other stakeholders in a continuing dialogue from which the level of assurance to be required in demonstrations of compliance will emerge. Such a dialogue may result in changes in the methods and approaches used by the applicant and in the expectations of the regulators.
  - The principles on which the safety assessment is based need to be robust and readily communicable to a wide range of audiences. Qualitative arguments, as well as quantitative ones, should be presented to explain the results of assessments and how and why a given disposal system can be expected to provide protection of human health and the environment.

As a corollary, delaying a decision to advance in the process to finally dispose of radioactive waste in a geological facility on the grounds of incomplete knowledge may be inappropriate, because alternatives can only be interim solutions and irreducible uncertainties will naturally always remain.

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