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Regulating the Long-term Safety of Geological Disposal

Towards a Common Understanding
of the Main Objectives and Bases of Safety Criteria

NEA No. 6182

NUCLEAR ENERGY AGENCY
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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FOREWORD

The Long-term Safety Criteria (LTSC) initiative was launched in 2004 by the Regulators' Forum of the NEA Radioactive Waste Management Committee (RWMC) to investigate the criteria used in member countries to regulate the disposal of long-lived, high-level radioactive waste. The work was carried out through a series of working group meetings, topical sessions at RWMC meetings and a workshop held in Paris in November 2006. During these gatherings, participants, speakers and authors addressed a broad range of issues related to establishing long-term criteria and determining relevant compliance. Other NEA committees – notably the Committee on Nuclear Regulatory Activities (CNRA), the Committee on Radiation Protection and Public Health (CRPPH) and the Nuclear Law Committee (NLC) – also had the opportunity to provide comments during the course of this work. The scope of the initiative did not include an attempt to harmonise different regulatory criteria, but was based on the premise that it is important to understand the origins and bases of these differences.

This report summarises the work of the LTSC initiative as of the end of 2006, with the aim to help foster a common understanding of the objectives and issues related to long-term regulatory criteria for radioactive waste disposal. It is hoped that the report may also contribute to clearer communication and public understanding of regulatory criteria, and provide important and useful guidance to national programmes that are developing or refining these criteria.

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EXECUTIVE SUMMARY

The Long-Term Safety Criteria (LTSC) working group established by the NEA RWMC Regulators' Forum, has found significant differences among the criteria used in various member countries, with a range of up to two orders of magnitude in the reference numerical values. Because the standards used in all countries are well below levels at which actual effects of radiological exposure can be observed, either directly or statistically, the observed variability in the regulatory criteria does not translate to a meaningful difference in the level of radiological impacts, and there is no suggestion that the existing criteria in any NEA member country are in any way inadequate from the point of view of radiological safety, and no reason to call into question the conclusions of the RWMC 1995 Collective Opinion on geological disposal.

The criteria differ not only in their numerical value, but also with respect to the time frame over which they are envisioned to apply and in the way they are applied. Overall, these differences appear to reflect different expectations regarding the desired level of confidence in safety, differing cultural attitudes towards the questions of establishing and interpreting safety-related targets, criteria and margins of safety, as well as different approaches to demonstration of regulatory compliance in the far future.

The study has found that, in addition to the protection criteria and the methods of demonstrating compliance, the bases for setting the criteria appear to vary as well from country to country. To investigate further the reasons for these differences, the group focused on a number of underlying issues, including: the meaning of "safety" and the lack of a common definition of this term; the challenge of communicating the import of regulatory criteria to the general public; and the means by which fairness to future generations should be provided.

The study observes that regulatory policies and decision making are not solely based on technical matters. In addition, they must take into account expectations of civil society, international experience, ethical considerations and practical needs of implementers. There is a wide diversity of decision-making processes and frameworks among countries, and an equally wide diversity of regulatory processes and systems. In light of this diversity, as well as the diversity in cultural approaches to safety and protection and to ethical issues, variability of the criteria used in regulation and in decision making is to be expected.

The work to date concludes that the observed diversity of criteria is essentially grounded in societal differences. The quantitative differences have no significant consequences in terms of radiological impact. Besides it should be borne in mind that the calculated doses and risks that are measured against these criteria are only indicators of performance and that protection requirements related to complementary measures such as optimisation and the application of "best available techniques not entailing excessive costs" are equally important. The work to date has identified many leads for further investigation, among them the need to study ethical issues in more depth; the need to improve participatory techniques to be applied to long-term projects characterised by stepwise decision making; and the need for better understanding of fundamental safety objectives underlying the criteria that are currently applied. A deeper investigation of these issues could help explain choices of criteria, could help illustrate that the safety assessment process itself is more important than the calculated dose and risk numbers it produces and could play an essential role in informing the normal development of national policy, objectives, regulations and guidance.

INTRODUCTION

The RWMC Regulators' Forum considers that, while it may not be necessary or desirable to harmonise different regulatory criteria, it is important that we understand their origins and bases. The work carried out under the Long-Term Safety Criteria (LTSC) initiative seeks to contribute to this understanding. Developing such a common understanding will make comparisons of regulatory approaches, at the IAEA Joint Convention review meetings and elsewhere, more meaningful and useful. It is also felt that discussions leading to a common understanding can contribute to clearer communication and public understanding of regulatory criteria, and can provide important guidance to national programmes that are developing or refining these criteria.

The present document provides background information on issues identified by the LTSC initiative and incorporates the discussions at its final workshop held at the end of 2006. The document thus represents a status report on the LTSC initiative, incorporating not only the original group's findings, but also the comments received from RWMC members, external reviewers, a review of the literature and extensive discussions in topical sessions and at the workshop of the end of 2006. It is hoped that it will serve both as a starting point for further discussion and as a benchmark for the state of progress to date.

The next section reviews the activities of the LTSC and places them in the international context since the NEA Cordoba workshop of 1997 [1]. The remainder of this report focuses then on two broad questions:

- The interaction between policy issues and technical regulation.
- Fundamental issues in regulatory decision making for the long-term safety of geological disposal.

A section is devoted to each question, respectively. A final section presents the overall conclusions.

In addition, readers interested in examining specific aspects in more depth are directed to the Appendices following the main body of the report. These include tabulations of national regulatory structures (Appendix 1) and criteria (Appendix 2); a more detailed discussion of the differences found and documented in Appendices 2 and 3; a series of topical discussions intended to stimulate discussion (Appendices 4-7). Appendix 8 contains a description of parallel work done in the RWMC Integration Group on the Safety Case (IGSC) on timescale issues primarily from an implementation (rather than a regulatory) viewpoint. Appendix 9 is a summary of the November 2006 workshop outcomes subdivided into six broad areas, each one representing the expression of the participants' viewpoints on the relevant practical issues and challenges facing the international community.

CONTEXT AND OVERVIEW OF THE INITIATIVE

Geologic disposal

Internationally, underground disposal of certain long-lived radioactive wastes such as spent fuel and high-level radioactive waste is so far the most widely accepted approach to ensure confidence about the long-term protection of future society. The disposal concept, and its safety and ethical considerations, have been debated in national legislatures; in state, provincial and local discussions; by individuals; in peer reviewed literature; and by scientific bodies (for example, the National Academy of Science in the United States, the National Evaluation Committee in France, the Committee on Radioactive Waste Management in the United Kingdom and KASAM in Sweden.) This demonstrates a general consensus on the disposal option, achieved through a broad societal process.

The underground disposal concept relies on the capabilities of both engineered barriers and the geologic setting to ensure that spent fuel and high-level radioactive waste are isolated from humans for the time of greatest hazard. This concept anticipates that any releases are small relative to the overall inventory of waste as well as in absolute terms; and that these proportionately small releases move very slowly, resulting in negligible incremental impacts on public health and safety. The placement of these wastes deep underground, in a robust engineered system matched to a suitable geologic setting, is thus felt to afford appropriate protection for this and future generations [2].

As stated in the most recent international advisory standard on the subject [3], "The aim of geological disposal is not to provide a guarantee of absolute and complete containment and isolation of the waste over all time but to ensure that any levels of radionuclides eventually reaching the biosphere are such that possible radiological impacts in the future are acceptably low." Nevertheless, the level and time frame of protection that is demanded – and can be provided – by a geological disposal system is unprecedented when compared to other practicable options including those in common use for many non-radioactive hazardous wastes.

Defining regulatory criteria

Implementation of the geological disposal concept requires, on the national level, a strategy that provides decision makers with the means to develop a sufficient level of confidence in the level of long-term protection ultimately achieved.

A number of countries have established regulatory criteria already, and others are now discussing what constitutes a proper regulatory test and suitable time frame for judging the safety of long-term disposal. National strategies are based upon the respective culture, value system, and priorities of each nation. The government and legislators in each nation develop regulatory systems that define the elements of each nation's strategy including guidance about a suitable geologic setting and a suitable engineered system. It is axiomatic that physical evidence, even when it can be related to a long-term geologic history, cannot alone provide definitive answers about any disposal system's ability to isolate wastes over hundreds of thousands of years into the future; regulators must nevertheless make decisions reaching far into the future based on the information available. Therefore, each regulatory programme seeks to define reasonable tests of repository performance, using protection criteria and approaches to safety consistent with the culture, values and expectations of the citizens of the country concerned.

NEA initiatives dealing with regulatory criteria and the long term

In 1997, an international workshop was held in Cordoba, Spain, on "Regulating the Long-Term Safety of Radioactive Waste Disposal." It was organised by three NEA committees (CNRA, CRPPH and RWMC) and hosted jointly by CSN and ENRESA. The two main sessions of this workshop addressed the topics of "Making a Safety Case" and "Judging the Safety Case: Compliance Requirements." The conclusions were summarised under the headings of:

- Criteria development and clarification.
- Performance assessment issues.
- The regulatory process.

These conclusions included reference to the need for clearer guidance on basic dose/risk targets, limits and indicators, and on the meaning of risk in the context of safety assessment and regulation. They also included reference to multiple lines of reasoning and multi-factor approaches, as well as the need for guidance on the approach to protection of the environment as such. Other references were made to issues such as confidence building in the context of performance assessment for long time-scales, and to the development of a step-wise approach to regulation and a structured interface between implementer, regulator, policy maker and the general public. The overall conclusions were considered by the appropriate NEA committees and incorporated into the NEA programmes of work.

Subsequently, under the auspices of the NEA Radioactive Waste Management Committee, two initiatives were undertaken to study and compare the ways in which a suitable level of confidence is attained in different countries. One of these is the timescales initiative (Appendix 8) of the Integration Group on the Safety Case (IGSC), which focused on the technical issues associated with safety demonstrations over the long timescales involved. The other is the RWMC Regulators Forum's Long-Term Safety Criteria initiative (LTSC). The initial main objective of this initiative was to review long-term protection criteria and issues in NEA countries and collate the findings to determine if it might be possible to support a collective opinion that all countries' regulations aim at, and provide, similar levels of protection. The initiative evolved towards providing the groundwork for better understanding the bases of current long-term safety regulation and their applicability. Although the timescales and LTSC initiatives dealt with different aspects of the demonstration of safety, there is considerable overlap and convergence of the results that they achieved.

The long-term safety criteria initiative

When the Regulators' Forum of the RWMC was formed in 1999, one of its first tasks was to review the arrangements in member countries for regulation of radioactive waste management. This work resulted in a comparative study of regulatory structures in member countries [4] (Appendix 1). One part of the work leading to this comparative study was a review of the long-term radiological protection criteria for disposal of long-lived waste, and an examination of their consistency amongst countries.

After this initial comparison, which revealed a broad range of differing criteria and practices, an initiative on long-term safety criteria was undertaken, and a group was formed to examine this question in more detail. This group included representation from the RWMC Forum on Stakeholder Confidence and the IGSC as well as from the Regulators' Forum. The objective of this initiative has been to provide a forum for discussion and study of the criteria used by various member countries. The goal has been to understand the basis for similarities and differences in their derivation and in the principles they represent. The purpose has never been to achieve harmonisation of all criteria, which are expected to vary in order to reflect national cultures, values, and technical differences among programmes.

While regulatory criteria for long-term safety normally address several aspects related to safety and protection, the focus of the group's work was initially on radiological dose and radiological risk criteria, because these are fairly readily quantified and compared. The initial results of the LTSC group's work are documented in Appendices 2 and 3. The group found significant numerical differences among the criteria, ranging over roughly two orders of magnitude. The numerical criteria differ not only in their magnitude, but also with respect to the time frame over which they are envisioned to apply. Because criteria used in all countries are well below levels at which actual effects of radiological exposure can be observed, either directly or statistically, this variability in the regulatory criteria does not translate to a meaningful difference in the level of radiological impacts. There is no suggestion that the existing criteria in any member country are in any way inadequate from the point of view of radiological safety, and no reason to call into question the conclusions of the "RWMC 1995 Collective Opinion" on geological disposal [2]. Instead, the differences appear to reflect differences in the ways numerical criteria are applied, different expectations regarding the desired level of confidence in safety, differing cultural attitudes towards the questions of establishing and interpreting safety-related targets, criteria and margins of safety, and different approaches for demonstration of compliance in the far future.

The LTSC group found that not only did the radioprotection criteria and the methods of demonstrating compliance differ from country to country, but the bases for setting the criteria appeared to vary as well. In fact, the differences may even reflect differences in the fundamental concepts of safety and protection (Appendices 3 and 5). The regulatory criteria for the long term in different countries were found to be based variously on:

1. Acceptability of levels of risk.
2. Comparison with numerical radiological protection criteria used for current practices.
3. Comparison with existing levels of natural radiation.
4. A combination of these.

This disparity in the foundations for criteria leads to a conclusion that the proper basis for meaningful comparison is not simply the numerical criteria *per se*; it also includes the philosophy underpinning decisions on what is considered an acceptable level of consequences, now and in the future. One can reasonably expect this philosophy to differ between countries and cultures; one should expect, therefore, that criteria based on differing approaches and principles would, likewise, differ. The observed discrepancy is also affected by the various methods and scenarios by which safety must be evaluated.

The subsequent work within the LTSC initiative focused on a number of underlying issues, including: the lack of a common definition of safety, both within and outside the field of radioactive waste management; the challenge of communicating the import of regulatory criteria to the general public; and the means by which fairness to future generations should be provided. This work is reported Appendices 4-7 dating from March 2006. A workshop was then planned and held in November 2006, at which the work of the Regulators' Forum and the LTSC group as well as related work at the IAEA, ICRP and NEA (including the IGSC's timescales initiative) were discussed and a comparison was made between the current situation and that which prevailed in 1997 (Appendix 9).

The continuing evolution of regulatory criteria

The issues considered by the LTSC group are largely similar to those identified in the 1997 Cordoba workshop [1]. However, the context in which this work is carried out and also the way in which disposal projects are generally regarded are in a state of change.

At one time disposal was viewed as if it were a relatively short-lived action to be completed by the present generation, whose goal was simply to provide a facility that could safely contain radioactive waste without any further action or intervention by future generations. Increasingly, however, the implementation of a disposal project has come to be viewed as an extended (and in certain countries, a reversible) process, taking several decades or generations. This changing vision involves not only the concept of protection of future generations, but incorporates as well an assumption of their involvement in the process and a need to preserve their ability to exercise choice (Appendix 7). This gradual shift in the complexity of the approach also has implications for the regulatory criteria used to judge the acceptability of disposal projects, as is reflected in the evolution of international guidance on this subject (see Table 1). This evolution is also one of the factors underlying the variation among national criteria as observed in Appendices 2 and 3.

THE INTERACTION BETWEEN POLICY ISSUES AND TECHNICAL REGULATION

Defining the regulator

Technical regulation of a disposal facility is one aspect of decision making on whether to construct the facility [5] (Appendix 1). This in turn depends upon decisions on disposal strategy for radioactive waste, decisions which themselves take place within broader decision making on energy policy. In addition, the institution(s) that carry out the various regulatory functions (setting standards, issuing licences and verifying compliance with regulatory criteria and licence conditions) are themselves embedded within a broader institutional (governmental and societal) framework, which may involve multiple levels of government as well as multiple agencies and institutions. Both the policy-making context and the institutional context differ from one country to another, making it difficult to define the regulatory role in a fashion that will be recognised and understood in the same way in different countries. The goal of the LTSC initiative has been to better understand processes, institutional frameworks so as to make comparisons more fruitful. In order to do so, however, it is useful to try to adopt a common model as a basis, even though that model may differ in many respects from existing national institutional and procedural contexts.

Broad policy decisions such as whether to adopt nuclear energy as a source of electricity, or whether to adopt a strategy of disposal or of extended storage for radioactive wastes, are taken at a higher level than that of the technical regulator. It is the broad policy decisions that define the framework within which the regulations operate.

Decisions on acceptable levels of risk or on how safe are safe enough may sometimes also operate at a higher level than that of the technical regulator. For example, regulations regarding the import and export of radioactive materials, or on matters such as clearance and release, are often based not only on technical radiation protection principles but also give significant weight to societal preferences. Thus, we may consider that the elaboration of the fundamental obligations of current generations to future generations is a higher level policy decision, which sets the objectives that must be met when defining regulatory criteria for protection.

However, the definition of roles and responsibilities in such matters is often complex. The regulatory organisation may, for example, be one of the main national repositories of individual and corporate expertise in radiation protection matters, and may have a predominant role, at least *de facto,* in making some of these decisions. The regulator may also act as a technical expert or advisor to government even on higher level matters such as waste management strategy.

Even within what is usually regarded as the technical regulatory ambit, the partitioning of roles and responsibilities among the organisations involved also differs greatly between different jurisdictions. For example, in some countries the regulation of wastes and the regulation of the practices giving rise to those wastes are separated while in others they are combined. In some countries the regulatory roles of development and promulgation of regulations and criteria, of issuing licences or permits, and of verifying and enforcing compliance are combined in one organisation, while in others these roles are separated. In some cases, some of these roles may even be the responsibility of different levels of government.

For all of these reasons, it is difficult to map an idealised (or even a "typical") model of the regulatory process onto reality, and the mapping may be very different in different societies. In particular, it is almost impossible in the international context to draw clean agreed-upon boundaries between what is considered to be a national policy question and what is considered to be a purely regulatory matter.

Factors which influence the choice of regulatory criteria, including radiation protection criteria, extend well outside the regulatory function as it is sometimes defined [5]. As a result, a number of the issues which arose during the LTSC initiative have led into areas which are often considered to be outside the responsibility of the technical regulator. The discussion needs then to be informed by input from persons with outside expertise. There is no clear definition of where these limits should be placed. It is proposed, however, that a broad and inclusive definition of the regulatory function is more helpful to the present work than a narrow definition which leaves critical questions unaddressed. Therefore, in what follows the term "regulator" is used in a very broad sense, in order to include the key issues which enter into the selection of regulatory criteria for decision making, at both the policy and the technical regulatory level.

The choice of regulatory criteria and their evolution

The interaction between broader policy issues and the technical safety requirements can be seen in the development of these requirements over time. One of the most striking aspects from the point of view of long-term criteria for disposal has been the gradual *evolution of the international principles and criteria* upon which the requirements are based (Table 1). These include the introduction of protection of the environment, the consideration of social and economic factors, and the concept of reasonable assurance. There has also been a shift in the expression of applicable ethical principles, from the prevention of future burden to intergenerational equity to the language of sustainable development and knowledge management and transfer.

While considering the underlying reasons for the differences that were observed between national criteria for long-term management of radioactive waste, the LTSC group's investigations led into a discussion of such matters as:

- The role of the regulator (Appendix 4).
- The meaning of safety and protection (Appendix 5).
- Building confidence in decision making (Appendix 6).
- Ethical considerations (Appendix 7).

As a result of discussions in the presence of experts in ethics and social sciences, the group concluded that one of the outstanding issues may be the elaboration of a common understanding on several aspects, including the obligations of current generations to future generations with respect to long-lived wastes (Appendix 9). Once these obligations are understood, it is important to clarify which are capable of being discharged by current generations and which must be transferred to subsequent generations. Based on an understanding of how these ethical obligations are interpreted, we can thus derive a common understanding of the fundamental objectives through which these principles can be implemented. This, in turn, would lead to an improved understanding of the similarities and differences in technical requirements for protection in the long term**,** including such issues as the use of cut-offs in time for some technical criteria; the use of criteria which vary with timescales; and the relative importance of dose and risk criteria vs. other criteria based either on the performance of a repository in containing wastes or directly upon design-related requirements, including requirements relating to the use of best available techniques (BAT); and so on.

Table 1. **The evolution of regulatory principles and criteria**[1]

IAEA Safety Series 99 (1989)	**Safety Fundamental 111-F (1995)**	**Joint Convention (1997)**	**IAEA WS-R-4 (2006)**
Responsibility to future generations: based on minimisation of burden, assurance of safety, independence of safety from institutional control. Radiological criteria: dose and risk upper bounds.	Protection of future generations: no undue burden and inter-generational equity (principles 4 and 5). Protection of the environment in addition to human safety.	Protection of future generations: to ensure effective measures for the protection of individual, society and environment, expressed in terms of sustainability principle. Criteria: based on intergenerational equity, avoiding actions that impose "reasonably predictable impacts", and undue burdens.	Protection in the post-closure period is optimised, social and economic factors being taken into account, and a reasonable assurance is provided that doses or risks will not exceed the dose or risk level that was used as a design constraint. Criteria: based on intergenerational equity. Recognition that doses for times farther into the future can only be estimated; uncertainties at very long timescales may dominate and care needs to be exercised in using the criteria at very long times.
The latest IAEA Safety Fundamentals, SF-1 (2006), restate the principle of protection as follows: "people and the environment, present and future, must be protected against radiation risk". Regarding radioactive waste, it maintains the principle of avoiding undue burdens to future generations and introduces the "obligation of seeking and applying safe, practicable and environmentally acceptable solutions for its long-term management".			

1. The table focuses on IAEA guidance, similar evolution could be observed in ICRP guidance.

FUNDAMENTAL ISSUES IN REGULATORY DECISION MAKING FOR THE LONG-TERM SAFETY OF DISPOSAL

Obligation to future generations: ethical, technical and practical considerations

Decisions taken now and in the near future regarding the management of long-lived wastes have implications for the risks to which generations far in the future may be exposed. There is thus an ethical dimension to the issue of the levels of protection to require or aim for as a function of time. This ethical dimension is in turn reflected in the fundamental objectives as variously stated in References 6-8.

The Joint Convention [7] is a particularly important source for these fundamental safety-related objectives, since most OECD/NEA member countries are also Contracting Parties under the Convention and have moral and legal obligations to meet its requirements.

The relevant objective as stated in Article 1(ii) of the Joint Convention is to ensure that "… individuals, society and the environment are protected from harmful effects of ionising radiation, now and in the future, in such a way that the needs and aspirations of the present generation are met without compromising the ability of future generations to meet their needs and aspirations". The corresponding requirement on Contracting Parties is stated in Articles 4(vi) and 11(vi), namely to "… take the appropriate steps to… strive to avoid actions that impose reasonably predictable impacts on future generations greater than those permitted for the current generation". The Convention contains a glossary of terms, but several important ones are left undefined, such as "harmful effects", "needs and aspirations", "reasonably predicted impacts" and "future generations". Differences in interpretation of these terms – as well as others, such as the term "safety" – lead to differences in regulatory criteria.

More concrete advice on the setting of radiological protection criteria for disposal can be found in a number of international documents [3,6,8]. Generally speaking, these documents recommend that the same criteria should be used as are applied for radiation protection from current practices. These documents also recognise, however, that such criteria cannot be applied in the same way for the distant future as they are for current practices and that care needs to be exercised.

- The IAEA Safety Requirements document [3] states that "It is recognised that radiation doses to individuals in the future can only be estimated and that the uncertainties associated with these estimates will increase for times farther into the future. Care needs to be exercised in using the criteria beyond the time where the uncertainties become so large that the criteria may no longer serve as a reasonable basis for decision making."
- ICRP-81 [8], paragraph 86, elaborates on this: "Demonstration of compliance with the radiological criteria is not as simple as a straightforward comparison of calculated dose or risk with the constraints, but requires a certain latitude of judgement. Neither should estimated transgression of a constraint necessarily oblige rejection, nor should numerical compliance alone compel acceptance of a waste disposal system. The dose or risk constraints should increasingly be considered as reference values for the time periods farther into the future, and additional arguments should be duly recognised when judging compliance."

Both documents allow a certain latitude in the setting, interpretation and application of the radiological criteria that are to be used for very long timescales, leading to notable differences in regulatory criteria from country to country. It should be noted that the fundamental objective of radiological protection and other criteria is not the absolute prevention of harm; it is the reduction of the potential for harm to acceptable levels. This is consistent with the wording used in the Joint Convention and with the advice in the IAEA and ICRP documents to exercise care and apply judgement.

Regulatory requirements must also be practicable, i.e. it must be possible to decide and demonstrate whether or not they are met. To be credible and meet societal expectations, this decision should be transparent. We must make clear the distinction between our duties towards future generations, which may be expressed in terms of fundamental goals such as not doing harm, and our ability to guarantee the achievement of those duties, especially when the latter is measured by evaluating the results of calculations of the outcomes of events and processes presumed to occur in the distant future.

In light of these considerations, then, those who seek to establish requirements must find practicable means to apply the standard of reasonable assurance of compliance in the distant future. This is typically done using today's standards or other reference values as targets or indicators. With respect to dose and risk, these reference values are often used as indicators against which calculations of outcomes based on stylised future scenarios are measured. This is also the case with respect to some other performance indicators, such as calculations of the repository's performance in isolating waste from the environment over long periods of time. In addition to such indicators of future performance, another category of requirements relates directly to today's design requirements (among them the use of "best available techniques" or BAT, as described in the European Commission's Integrated Pollution Prevention and Control Directive of 1996) [9]. All of these represent different means of establishing criteria to be used for decision making today that will result in acceptable levels of protection in the future. A discussion of the topics of safety and protection is presented in Appendix 5.

A related issue is how regulatory programmes can assure that protection will not, in time, be undercut by unanticipated intrusion by future generations. For as long as practicable, steps should be taken to ensure that knowledge of the location and hazards associated with underground disposal sites are retained, and subsequent generations receive sufficient information to protect themselves and their successors from the consequences of intrusion, whether unintended or deliberate. The Forum on Stakeholder Confidence, for example, is exploring how controls could be preserved by individual accountability and commitment passed on from generation to generation in local communities. Although such cultural approaches can not provide a demonstrable and technically based assurance, they can provide additional defences beyond technical measures that we contemplate today [10]. The role these cultural approaches play during the policy-making and decision-making processes varies from country to country.

The criteria for very long time frames

Several time frames can be identified that are relevant to the setting of criteria for disposal projects. These range from societally relevant time frames of at most several generations or a few hundred years, to the much longer time frames relevant to large-scale geological (e.g. tectonic) changes, with the time frames over which safety assessments are considered to be meaningful and relevant generally lying somewhere in between these two extremes. National programmes which have already established such criteria have generally found it possible to make cautious, but reasonable assumptions to extend the use of radiological limits already applied to contemporary activities for several thousands of years. The greater challenge lies in setting criteria for very long time frames, extending to a million year and beyond, for which safety analyses must account for high uncertainty and for which the understanding of the needs and impacts on future generations become increasingly speculative. As noted in Appendix 8, the limits to the predictability of the repository and its environment need to be acknowledged in safety cases. Argumentation for safety in the very long term is likely to require a consideration of ethical principles, since the criteria established for safety in the long term must relate on the one hand to our responsibility to establish the level of protection of the environment in the very remote future and, on the other hand, to our ability to face up to the task.

Several ways to apply judgement in the use of criteria for long term safety have been discussed and considered in national programmes and internationally, for example:

1. Restrict application of radiological protection principles to timescales over which radiological impacts can reasonably accurately be predicted.
2. Interpret "future generations" to mean only a limited number of generations, in keeping with common current practices for non-radioactive hazardous wastes in many countries.
3. Interpret the acceptability of levels of impacts differently over different timescales, whether on ethical grounds [11-13] (Appendix 7) or on technical grounds (e.g. increasing levels of uncertainty in modelling assumptions over time).
4. Noting that, in general, regulatory requirements also reflect other societal and technical objectives, beyond radiological safety (for example, ICRP-81 recommends that technical and managerial principles be applied in addition to radiological criteria), allow for changes in the relative weighting or application of various types of criteria over different timescales.
5. Allow the variability with time of the degree of assurance of compliance with the criteria.

The first two options may be implemented in the form of regulatory requirements that need to be met for only a limited time period (cut-offs). For example, it may be considered that safety assessments need be compared against numerical criteria for limited timescales only, such as for the first one thousand, or ten thousands or a million years, say. Safety assessment beyond that period may still be required, but whether it is done by numerical modelling and calculations, by arguments not involving such calculations, or both, it would be considered qualitative information and not measured, for acceptability, against numerical criteria.

The next two options might lead to the use of differing criteria (or at least the differing use of criteria) over different timescales. That is, the criteria used for comparison may be relaxed at longer timescales to reflect increased uncertainty over their applicability, whether for technically-based and/or for ethically-based reasons. In some countries, even if the criteria remain the same over different timescales they may be regarded as firm limits to acceptability for shorter time-scales, but serve only as targets for longer time frames.

The fifth option might lead to a situation in which the criteria do not change, but the "burden of proof" of compliance is different at different timescales. For example, the level of conservatism in assumptions and models and/or the requirements for validation of calculation techniques may be less strict on longer timescales than in calculations for the nearer future.

Various combinations of these options have been applied in different member countries (Appendix 2). These different approaches represent varying attempts to deal with the difficulties posed by the very long timescales under consideration, resulting from different philosophical approaches and assumptions in different cultures. While harmonisation across national boundaries is not the goal, the current variability will likely cause difficulties in achieving stakeholder acceptance if it is not properly explained.

Of equal importance to the choice of numerical criteria are choices as to how compliance with those criteria is demonstrated. Most obviously, there is the difference between the use of a criterion as a "hard" limit vs. as a "soft" target. Perhaps just as significant is the relative importance given to the conflicting goals of: (i) reflecting as accurately as possible the events and processes leading to the calculated outcome of the safety assessment (e.g. a "design-centred" approach) vs. (ii) assuring to as high a level of confidence as possible that the actual exposures to humans resulting from the existence of the repository will not exceed the calculated values (e.g. a "bounding" approach). In addition, during the performance of consequence assessments a wide range of judgements have to be made about choices of parameters and models. Sources of uncertainty include differences in the conditions assumed as part of calculation scenarios; uncertainties related to the completeness of the description of the engineered system; variations in parameters related to the behaviour of the host rock; uncertainties related to the calculation models used; and uncertainties related to the choice of modelling parameters. Different approaches to managing these uncertainties can have significant effects on the outcomes of calculations. Only rarely are these approaches completely quantified; more often, they are considered to lie within the realm of professional judgement. Differences of this kind between national approaches can be substantial, reflecting differing national attitudes towards risk, "safety factors" and the desired degree of assurance of safety.

In addition to the numerical dose and risk criteria, most if not all regulators also take into account a variety of other factors ("complementary indicators"). These may include performance indicators related to the ability of the repository to contain and isolate wastes, such as calculated concentrations and fluxes of radionuclides within the host rock. They may also include criteria related to geological characteristics of proposed sites, as well as to the engineered features of the design. One problem in comparing such indicators is the practical one of finding and agreeing upon reference values for many of them, particularly when one considers the wide variety of possible geological settings in different countries.

One approach useful for evaluating complementary indicators is that of optimization. Focusing on dose and risk indicators may lead one to think of optimisation as acting on the calculated dose and risk numbers, but in fact optimisation may be applied to other parameters, either to outputs of calculations (performance measures) or directly to design parameters. Related to the latter application are requirements for the use of best available techniques (BAT), which include both the technology and the way the installation is designed, constructed, operated, maintained and decommissioned [9]. The importance of optimisation and BAT relative to direct calculations of dose and risk varies with the time scale under consideration. Questions remain open on how to deal with unavoidable qualitative judgements in these areas, how to weight these methods relative to quantitative dose and risk calculations, and how to present optimisation and BAT arguments as part of safety cases.

Underlying all of these approaches are several fundamental ethical questions. These relate to such issues as our obligations to future generations, our varying ability to carry out those obligations at remote times, and the balance between protecting other generations' safety and allowing them flexibility to undertake their desired actions. Similarly, at a fundamental level, the design of a repository involves not only limitation of risks but also their redistribution, both spatially and temporally. This raises issues of fairness, among them the issue of balancing real (conventional as well as radiological) risks to workers involved in constructing, operating and maintaining a repository prior to closure versus the hypothetical risks to future generations or the preservation of their ability to make choices as represented in requirements for step-wise development and reversibility. There are no easy black-and-white answers on these issues, but discussion of them may shed light on the criteria we use to make decisions and on the reasons for differences among programmes and countries.

Regardless of their origins or underlying assumptions, the resulting variation in the ways in which numerical criteria are set and used in order to demonstrate the achievement of fundamental safety goals makes it difficult to compare different national approaches. It is hoped that further discussion of the issues raised in this document will facilitate comparisons and the development of a common understanding.

CONCLUSIONS

The initial main objective of the LTSC initiative was to review long term protection criteria and issues in NEA countries and collate the findings to determine if it might be possible to support a collective opinion that all countries' regulations aim at, and provide, similar levels of protection. The group found significant differences among the current numerical criteria, ranging over roughly two orders of magnitude. Because criteria used in all countries are well below levels at which effects of radiological exposure can be observed, either directly or statistically, this variability in the regulatory criteria does not translate to a meaningful difference in the level of radiological impacts, and there is no suggestion that the existing criteria in any NEA member country are in any way inadequate from the point of view of radiological safety, and no reason to call into question the conclusions of the RWMC 1995 Collective Opinion on geological disposal.

The criteria differ not only in their magnitude, but also with respect to the time frame over which they are envisioned to apply and in the way they are applied. Overall, these differences appear to reflect different expectations regarding the desired level of confidence in safety, differing cultural attitudes towards the questions of establishing and interpreting safety-related targets, criteria and margins of safety, as well as different approaches towards demonstrating regulatory compliance in the far future.

In the course of the work, the LTSC group found that not only did the protection criteria and the methods of demonstrating compliance differ from country to country, but the bases for setting the criteria appeared to vary as well. The initial idea of a "collective opinion" evolved to one of fostering a common understanding of the bases for regulation that countries have formulated or are adopting. The LTSC group's investigations identified then a number of important contributing factors to national differences, among them the complexity and non-uniformity of the regulatory decision-making process across nations, a lack of established consensus on how to characterise and measure protection in the distant future, not fully worked out fundamental ethical issues related to the nature of current society's obligations to the future, and, reflecting all of this, international guidance that has been evolving with time and still is in the process of evolution.

The focus of the LTSC group's work has not been on the technical support for criteria – the work of the ICRP and IAEA on this is well developed and accepted to be of a high technical quality – but rather on the development and application of these criteria in the regulatory process. The discussions during the group meetings, topical sessions and workshop covered a broad range of areas – societal, ethical and technical – related to regulation for the long-term safety of radioactive waste disposal. The participation of persons with a wide variety of backgrounds and expertise other than technical was productive and useful, and should be continued.

Some issues – such as ethical considerations and questions of social acceptance – may be outside the normal realm of regulatory bodies. Nonetheless, such issues can, and frequently do, influence the choice and interpretation of protection criteria for radioactive waste, and are discussed in this context. It is expected that the common understanding that is envisaged as the outcome of this initiative might take into account current thinking with respect to intergenerational equity that recognises that, as the possibility for verification and intervention is no longer available and the time frame becomes longer and longer, our ability to guarantee that specific limits will be met to an acceptable level of confidence will diminish because of increasing uncertainties. These uncertainties exist not only in the physical and engineering models, but also and perhaps more significantly, in our ability to predict and influence the behaviour, needs and aspirations of future generations far removed from ours.

Overall, three main conclusions arise from the study:

- There exists important variation in numerical criteria for long-term disposal safety in NEA countries. The quantitative differences, however, have no significant consequences in terms of radiological impact. Besides, it should be borne in mind that the calculated doses and risks that are measured against these criteria are only indicators of performance and protection requirements related to complementary measures such as optimisation and the application of "best available techniques not entailing excessive costs" are equally important.
- There is important variation in the bases for criteria and the ways they are used in order to demonstrate the achievement of fundamental safety goals. This variation is grounded in societal differences and makes it difficult to compare different national approaches.
- Developing a common understanding of obligations to future generations and of how to implement these obligations in regulatory criteria for long-lived radioactive waste would make comparisons of regulatory approaches within national and international contexts, including at IAEA Joint Convention review meetings, more meaningful and useful.

Several other observations may also be drawn from the group's work:

- There are many parties involved in addressing safety, including regulators, policy makers, implementers and affected communities. Social and ethical dimensions of safety affect regulatory criteria as well as other stages of policy setting and implementation. As a result, regulatory policies and decision making are not solely based on technical matters. They take into account expectations of civil society, international experience, ethical considerations and practical needs of implementers.
- There is a wide diversity of decision-making processes and frameworks among countries, and consequently an equally wide diversity of regulatory processes and systems. In the light of this diversity, as well as the diversity in cultural approaches to safety and protection and to ethical issues, it is understood that variability of the criteria used in regulation and in decision making is to be expected.
- While there is agreement on the need to provide a high level of protection in the long term, the fact that there cannot be ongoing active control to assure safety poses difficulties for regulators.
- There is agreement that calculations of dose and risk in the future are illustrations of possible system behaviour rather than predictions of outcomes, and there is consensus that, in the long term, numerical criteria for radioactive waste disposal should be considered as references or indicators, addressing the ultimate safety objectives, rather than as absolute limits in a legal context.
- There is continued and increasing recognition of the importance of the role of safety functions of the repository system, and of performance indicators related to those functions. Performance indicators other than dose and risk, the use of multiple lines of reasoning, the application of constrained optimisation and demonstration of the use of best available techniques can all contribute to regulatory decision making. There is

considerable variability in how these complementary indicators are applied, and in how their relative importance and utility is seen to change with time scale. This is an area where continued discussion and exchange of views could be enlightening.

- Ethical issues are important, especially in view of the very long timescales involved and the impossibility of providing continued institutional controls over those timescales. The design and implementation of a repository involves balancing of risks and responsibilities between generations. The obligations of the present generation toward the future are complex, involving not only issues of safety and protection but also of freedom of choice and of the accompanying burden of responsibility, and of the need to transfer knowledge and resources. Our capacity to deliver these obligations diminishes with distance in time, which complicates the setting of criteria to be used today in order to demonstrate that obligations to the future will be met. There is no ethical absolute, and no generally agreed consensus on these long-term ethical issues. Each country needs to balance its own objectives within its own social and institutional context.
- There is agreement that decision making and the criteria and methods on which it is based need to be clear and transparent. Societal considerations are involved in discussions of tolerance of risk, and there is a need to provide a role for society and affected communities to participate in discussions of safety.
- Together with the need for transparency and inclusion there is an accompanying obligation on both regulators and implementers not to over-simplify, not to promise or require the undeliverable, and to use language which is neither imprecise nor obscuring. Doing so is made more difficult when there is a lack of clarity about terminology and about the underlying objectives.
- The increasing importance of stepwise decision making, and of reversibility and retrievability, are changing the nature of repository design to a process that may itself span several generations. This poses difficulties for the regulatory decision-making process, and for the ability to maintain transparency.
- There is a need to continue to improve methods for participatory decision making, especially in the context of projects with extended durations. There is also a need to ensure the continued capacity of society to monitor, assess and adjust direction as developments warrant, and this capacity in turn depends upon the preservation of knowledge, skills and expertise.

These outcomes do not represent a departure from the conclusions of the 1997 Cordoba workshop. Rather, the LTSC group’s work can be seen as building upon and extending those conclusions in the light of international and national developments during the intervening decade. One of the conclusions of the Cordoba workshop was that international harmonisation makes sense at the level of the overall safety objectives, rather than at the level of detailed regulatory criteria. This remains true today. It would be useful to investigate these fundamentals further. A deeper investigation of these issues could help explain choices of criteria, could help illustrate that the safety assessment process itself is more important than the calculated dose and risk numbers it produces and could play an essential role in informing the normal development of national policy, objectives, regulations and guidance. Effective communication of our common safety objectives around the world could contribute to public understanding and acceptance as they participate in this practical implementation. The work of the LTSC to date has laid groundwork for further improvements in the collective understanding of these issues, and offers many leads for consideration and for future work.

Appendix 1

THE REGULATORY INFRASTRUCTURE IN NEA MEMBER COUNTRIES

The present Appendix consists of tables taken from *The Regulatory Function and Radioactive Waste Management. International Overview*, NEA No. 6041, Paris 2005, revised to reflect recent changes.

The tables make frequent use of acronyms. These are also provided in this Appendix at the end of the tables.

Regulatory Element/Activity	**Associated Bodies**		
	Belgium	**Canada**	**Finland**
Policy	Government	Government (NRCan).	Government
Primary legislation	Parliament	Parliament	Parliament
Secondary legislation	Government, FANC	Government, CNSC.	MTI
Advice to government	FANC	NRCan, CNSC (Secretariat)	MTI + STUK advisory bodies
Standards	NIRAS/ONDRAF (Waste packaging)	CNSC, ECan	STUK
Guidance		CNSC, ECan	STUK
Licensing (Disposal)	FANC, MINT	CNSC	Government (Parliament + municipality), STUK
Licensing (Health and safety)	FANC, MINT	CNSC	Government (Parliament + municipality)
Licensing (Spatial planning/development)	FANC, MINT	CNSC, ECan, CEAA, Provincial Govt.	Government (Parliament + municipality)
Inspection/Monitoring	FANC	CNSC	STUK
Enforcement	FANC	CNSC	STUK
Appeals		CNSC	
Public consultation	FANC, local authorities	CNSC, NRCan.	
R&D (Including industrial work)	NIRAS/ONDRAF, FANC, CEN/SCK, others	Industry, CNSC	Waste producers (small public co-ordinated programme) Posiva Oy, STUK, VTT
Cost estimation (Including industrial work)	NIRAS/ONDRAF	CNSC	SNWMF (MTI)
Transboundary shipment	FANC	CNSC (OIA)	
Safeguards		CNSC (OIA)	

Appendix 1. **The Regulatory Infrastructure in NEA Member Countries** (Cont'd)

Regulatory Element/Activity	**Associated Bodies**		
	France	**Germany**	**Hungary**
Policy	Government	Federal Government (BMU, BMBF, BMWA, BMF, BMVBW)	Government (Minister for HAEA, other Ministers)
Primary legislation	Parliament	Parliament	Parliament
Secondary legislation	Government (MoI, MoE, MoH)	BMU	Government (Orders by the Government and various ministers)
Advice to government	OPECST, CNE, ASN and Civil Service Departments	RSK, SSK, KTA, GRS	HAEA, Atomic Energy Coordination Council
Standards	ASN, DSND (Defence)	BMU (KTA)	Given in above Orders
Guidance	ASN, DSND (Defence)	BMU	Given in above Orders
Licensing (disposal)	Government (advised by ASN).	Länder licensing authorities	Parliament, SPHAMOS, HAEA + special authorities
Licensing (Health and safety)	Government (advised by ASN), local authorities	Länder licensing authorities	SPHAMOS, HAEA + special authorities
Licensing (Spatial planning/development)	Local authorities	Länder licensing authorities	Special authorities
Inspection/Monitoring	ASN, DSND (Defence)	Länder licensing authorities. BfS (final disposal)	SPHAMOS, HAEA + special authorities
Enforcement	ASN, DSND (Defence)	Länder licensing authorities	SPHAMOS, HAEA + special authorities
Appeals			Second instance of the regulatory body
Public consultation	Prefect (public enquiry) CNDP in some cases	BMU	Regulatory body for environment protection
R&D (including industrial work)	Waste producers, ANDRA, CEA, IRSN	BfS, BMU, BMBF, BMWA, Industry, GRS, BGR, DBE, GSF, Universities etc.	PURAM
Cost estimation (including industrial work)	Waste producers /Andra/ Administrative Authority	BfS, BMBF	PURAM (in agreement with HAEA and HEO) + approved by HAEA Minister
Transboundary shipment	ASN	Bundesausfuhramt	HAEA
Safeguards	DSND	BMWA	HAEA

Appendix 1. **The Regulatory Infrastructure in NEA Member Countries** (Cont'd)

Regulatory Element/Activity	**Associated Bodies**		
	Italy	**Japan**	**Korea, Rep. of**
Policy	Government (MoPA + other ministries)	Government (AEC)	Government
Primary legislation	Parliament.	Parliament (Diet)	Parliament
Secondary legislation	Government (Ministerial Decrees)	METI, MEXT	Government
Advice to government	TCNSHP, Expert Group (Disposal site select.)	NSC (Advises Prime Minister)	NSC (Advises MOST Minister)
Standards	(Adopted from EC Directive by Legislative Decrees)	METI, MEXT, MLIT	MOST/ KINS
Guidance	MoPA, ANPA	NSC	MOST/KINS
Licensing (Disposal)	MoPA (based on APAT judgements)	METI, MEXT	MOST
Licensing (Health and safety)	MoPA (based on APAT judgements.)	METI, MEXT	MOST, MOE
Licensing (Spatial planning/development)		MLIT	MOCIE, Local Community
Inspection/Monitoring	APAT	METI, MEXT	MOST/KINS
Enforcement	APAT	METI, MEXT	MOST/KINS
Appeals			
Public consultation		All regulatory bodies	Licensee
R&D (Including industrial work)	APAT, SOGIN	NUMO, JAEA, RWMC, CRIEPI	KINS, KAERI, KHNP
Cost estimation (*including* industrial work)	SOGIN	METI	MOCIE
Transboundary shipment	APAT	MLIT, METI	MOST
Safeguards	APAT	MEXT	MOST/KINAC

Appendix 1. **The Regulatory Infrastructure in NEA Member Countries** (Cont'd)

Regulatory Element/Activity	**Associated Bodies**		
	Norway	**Slovak Republic**	**Spain**
Policy	Government	Government	Government (MINECO, advised by ENRESA + MoE.)
Primary legislation	Parliament	Parliament	Parliament
Secondary legislation	Government (MoH)	All regulatory bodies	MINECO (advised by CSN)
Advice to government	NRPA	MH SR, MZ SR, UJD SR	CSN
Standards	NRPA	Given in Regulations	(Adopted from EC Directive by Decrees or Orders)
Guidance	NRPA	UJD SR	CSN
Licensing (Disposal)	Government, MoH (advised by NRPA)	Municipal Office (based on UJD SR + UVZ judgement)	MINECO (advised by CSN)
Licensing (Health and safety)	As above	As above	MINECO (advised by CSN)
Licensing (Spatial planning/development)		MZP SR, Municipal Office	MoE, MINECO, CSN
Inspection/Monitoring	NRPA	UJD SR, UVZ	CSN
Enforcement	NRPA	UJD SR, UVZ.	CSN
Appeals			
Public consultation	All regulatory bodies, mainly NRPA, IFE	All regulatory bodies.	CSN
R&D (Including industrial work)	IFE	VUJE, UJD SR, waste producers	CSN, ENRESA
Cost estimation (Including industrial work)	IFE, MoTI	MH SR	ENRESA
Transboundary shipment		UJD SR, MZ SR	CSN
Safeguards	NRPA, IFE	UJD SR	

Appendix 1. **The Regulatory Infrastructure in NEA Member Countries** (Cont'd)

Regulatory Element/Activity	**Associated Bodies**		
	Sweden	**Switzerland**	**United Kingdom**
Policy	Government	Federal Council (Federal government)	Government (DEFRA, SE, NAW, DoE(NI)
Primary legislation	Parliament	Parliament	Parliament, Scottish Parliament.
Secondary legislation	Government	Federal Council, UVEK, BFE	DEFRA,SE,NAW, DoE(NI)
Advice to government	KASAM, SKI, SSI	HSK, KSA, AGNEB	RWMAC, NUSAC, RCEP, COMARE, HPA/NRPB
Standards	SKI, SSI	HSK	EA, SEPA, DoE(NI), HSE. Nirex (waste packaging)
Guidance	SKI, SSI	HSK	EA, SEPA, DoE(NI), HSE
Licensing (Disposal)	Government on advice from e.g. SKI (nuclear facilities) and SSI, Environmental Court	Federal Council (conducted by BFE, reviewed. by HSK + KSA, in consultation with Cantons)	EA, SEPA, DoE(NI)
Licensing (Health and safety)	As above	Federal Council, (as above)	HSE(NII) on nuclear sites, HSE(FO) on non-nuclear sites
Licensing (Spatial planning/development)	County administrative boards	General licence issued by Federal Council, (as above), + approved by Parliament.	Local authorities, DEFRA, SE, NAW, DoE(NI)
Inspection/Monitoring	SSI, SKI (nuclear sites)	HSK	EA, SEPA, DoE(NI), HSE(NII) (nuclear sites)
Enforcement	SSI, SKI (nuclear sites)	HSK	EA, SEPA, DoE(NI), HSE(NII) (nuclear sites)
Appeals	Environmental Court		DEFRA, SE, NAW, DoE(NI)
Public consultation	SSI/SKI (jointly)	UVEK, BFE, HSK	All regulatory bodies
R&D (Including industrial work)	SKB (reviewed by SKI + SSI), SKI + SSI	PSI, universities (funded by Federal State + NAGRA)	EA, DEFRA, Nirex, Waste producers
Cost estimation (Including industrial work)	SKB/SKI/BNWF	NPP operators + NAGRA reviewed by HSK + FMC	Operators
Transboundary shipment	SKI, SSI	BFE reviewed by HSK	EA, SEPA, DoE(NI)
Safeguards	SKI	BFE	DTI

Appendix 1. **The Regulatory Infrastructure in NEA Member Countries** (Cont'd)

Regulatory Element/Activity	Associated Bodies
	United States
Policy	Federal government
Primary legislation	Congress
Secondary legislation	DoE, EPA, NRC
Advice to government	EPA, NRC, NWTRB, NAS
Standards	EPA, NRC
Guidance	NRC, EPA (for WIPP)
Licensing (Disposal)	NRC(NMSS), EPA (for WIPP), DOE (self-licensing in some cases)
Licensing (Health and safety)	NRC(NMSS), excluding operating power reactors and all other non-power reactors
Licensing (Spatial planning/development)	NRC, federal States.
Inspection/Monitoring	NRC(NMSS and OSTP), EPA (for WIPP)
Enforcement	NRC(NMSS), EPA (for WIPP)
Appeals	
Public consultation	NRC(OPA)
R&D (Including industrial work)	NRC(RES), NRC(NMSS) for HLW confirmatory research
Cost estimation (Including industrial work)	NRC
Transboundary shipment	NRC(NMSS), DoT
Safeguards	NRC(NSIR)

List of acronyms for Appendix 1

Belgium

CEN/SCK	Centre for Nuclear Energy
FANC	Federal Agency for Nuclear Control
MINT	Ministry of Interior, responsible for Radiation Protection and Nuclear Safety
NIRAS/ONDRAF	National Organisation for the Management of Radioactive Waste

Canada

CEAA	Canadian Environmental Assessment Agency
CNSC	Canadian Nuclear Safety Commission
CNSC (OIA)	CNSC Office of International Affairs
ECan	Environment Canada
NRCan	Natural Resources Canada

Finland

MTI	Ministry for Trade and Industry
SNWMF	State Nuclear Waste Management Fund
STUK	Radiation and Nuclear Safety Authority
VTT	Technical Research Centre of Finland
Posiva OY	Finnish Implementing Organisation for Spent Fuel Disposal

France

ANDRA	National Agency for Radioactive Waste Management
ASN	Autorité de sûreté nucléaire
CEA	Atomic Energy Commission
DSND	Delegate for Nuclear Safety and Radioprotection on Defence Sites
MoE	Ministry of Environment
MoH	Ministry of Health
MoI	Ministry of Industry
CNE	National Review Board
IRSN	Institute for Radioprotection and Nuclear Safety
OPECST	Parliamentary Office for Evaluation of Scientific and Technical Choices

Germany

BGR	Federal Institute for Geosciences and Natural Resources
BMBF	Federal Ministry of Education and Research
BMF	Federal Ministry of Finance
BMU	Federal Ministry of Environment, Nature Conservation and Nuclear Safety
BMWA	Federal Ministry of Economics and Labour
BMVBW	Federal Ministry of Transport, Building and Housing
BfS	Federal Office for Radiation Protection
DBE	German Company for Construction and Operation of Waste Repositories
GSF	National research centre for environment health
GRS	Gesellschaft für Anlagen- und Reaktorsicherheit mbH
KTA	Nuclear Safety Standards Commission
RSK	Reactor Safety Commission
SSK	Radiation Protection Commission

Hungary

AECC	Atomic Energy Co-ordination Council
HAEA	Hungarian Atomic Energy Authority
HEO	Hungarian Energy Office

Hungary (cont'd)

MoH	Ministry of Health, Social and Family Affairs
PURAM	Public Agency for Radioactive Waste Management
RBEP	Regulatory Body for Environmental Protection
SPHAMOS	State Public Health and Medical Officer's Service

Italy

APAT	National Agency for Environmental Protection and Technical Services
ANPA	National Association of Lawyers and Advocates
MoPA	Ministry of Productive Activities
SOGIN	Society for Management of Nuclear Installations
TCNSHP	Technical Commission for Nuclear Safety and Health Protection

Japan

AEC	Atomic Energy Commission
CRIEPI	Central Research Institute of Electric Power Industry
JAEA	Japan Atomic Energy Agency
METI	Ministry of Economy, Trade and Industry
MEXT	Ministry of Education, Culture, Sports, Science and Technology
MLIT	Ministry of Land, Infrastructure and Transport
NSC	Nuclear Safety Commission
NUMO	Nuclear Waste Management Organisation
RWMC	Radioactive Waste Management and Research Center

Korea, Republic of

NSC	Nuclear Safety Commission
MOST	Ministry of Science and Technology
KINS	Korea Institute of Nuclear Safety
MOE	Ministry of Environment
MOCIE	Ministry of Commerce, Industry and Energy
KAERI	Korea Atomic Energy Research Institute
KHNP	Radiation Health Research Institute
KINAC	Korea Institute of Nuclear Nonproliferation and Control

Norway

MoE	Ministry of Environment
MoH	Ministry of Health
NRPA	Norwegian Radiation Protection Authority
MoTI	Ministry of Trade and Industry
IFE	Institute for Energy Technology

Slovak Republic

MH SR	Ministry of Economy
MZ SR	Ministry of Health
UJD SR	Nuclear Regulatory Authority
UVZ	Public Health Authority
MZP SR	Ministry of Environment
VUJE	Engineering, Design and Research Organization

Spain

CSN	Nuclear Safety Council
ENRESA	Spanish National Company for Radioactive Waste
MITYC	Ministry of Industry, Tourism and Commerce
MINECO	Ministry of Economy and Property

Spain (Cont'd)

MoE	Ministry of Environment
CIEMAT	Research Centre for Technology, Energy, and the Environment

Sweden

BNWF	Board of the Nuclear Waste Fund
KASAM	Swedish National Council for Nuclear Waste
SKB	Swedish Nuclear Fuel and Waste Management Company
SKI	Swedish Nuclear Power Inspectorate
SSI	Swedish Radiation Protection Institute

Switzerland

AGNEB	Interdepartmental Working Group on Radioactive Waste Management
BFE	Federal Office of Energy
FMC	Finance Management Consulting
HSK	Swiss Federal Nuclear Safety Inspectorate
KSA	Swiss Federal Nuclear Safety Commission
PSI	Paul Scherrer Institute
NAGRA	National Co-operative for the Disposal of Radioactive Waste
NPP	Nuclear Power Plant
UVEK	Federal Department for Environment, Transport, Energy, and Communication

United Kingdom

COMARE	Committee for Medical Aspects of Radiation in the Environment
CoRWM	Committee on Radioactive Waste Management
Defra	Department for Environment, Food and Rural Affairs
DoE(NI)	Department for Environment (Northern Ireland)
DTI	Department for Trade and Industry
EA	Environment Agency (for England and Wales)
HPA	Health Protection Agency
HSE(NII)	Health and Safety Executive (Nuclear Installations Inspectorate)
HSE(FO)	Health and Safety Executive (Field Operations)
NAW	National Assembly for Wales
Nirex	UK national radioactive waste management organisation
NRPB	National Radiological Protection Board
NuSAC	Nuclear Safety Advisory Committee
RCEP	Royal Commission on Environmental Pollution
RWMAC	Radioactive Waste Management Advisory Committee
SE	Scottish Executive
SEPA	Scottish Environment Protection Agency

United States of America

DOE	Department of Energy
EPA	Environmental Protection Agency
NAS	National Academy of Sciences
NRC	Nuclear Regulatory Commission
NRC(NMSS)	NRC (Office of Nuclear Material Safety and Safeguards)
NRC(NSIR)	NRC (Office of Nuclear Security and Incident Response)
NRC(OPA)	NRC (Office of Public Affairs)
NRC(OSTP)	Office of State and Tribal Programs
NRC(RES)	NRC (Office of Nuclear Regulatory Research)
NWTRB	Nuclear Waste Technical Review Board
WIPP	Waste Isolation Pilot Plant (for defence TRU waste)

Appendix 2

NATIONAL DOSE AND RISK CRITERIA FOR DISPOSAL OF LONG-LIVED WASTE IN DIFFERENT COUNTRIES

Country	Target Limit of Impact (Most exposed individuals)	Other Limitations or Conditions
Belgium	Dose constraint: 0.1 to 0.3 mSv/yr. Risk constraint: 10^{-5}/yr. (Note: Working values in absence of regulatory values.)	Dose constraint relevant to high probability scenarios and risk constraint to lower probability scenarios.
Canada	Under development: Interim dose constraint of up to 0.3 mSv/yr for design optimisation as recommended by ICRP & IAEA.	Guidance on timescales, institutional control and other indicators is also under development. A public dose criterion of 1 mSv/yr is used for evaluation of human intrusion scenarios.
Czech Republic	Dose constraint: 0.25 mSv/yr	Disposal site should provide a natural barrier that assists in keeping the radiological impact to human and the environment within acceptable levels. Safety analysis are required for release scenarios that cannot be excluded.
Finland	Dose Limit: 0.1 mSv/yr for normal evolution. For unlikely events, impact assessed against risk equivalent to dose limit.	Release of radionuclides into human environment to be less than nuclide-specific constraints. Dose/risk constraint applies for several thousand years. RN release limitation applies for longer.
France	Dose Limit: 0.25 mSv/yr for normal evolution.	Dose limit applies for 10^4 yrs, and is a reference for later periods. Institutional monitoring assumed to prevent human intrusion before 500 yrs.
Germany	In order to provide adequate protection of man and the environment, the criteria define the individual dose as the main safety indicator for the post-closure phase. The analysis has to show that an individual dose limit of 0.3 mSv/a will not be exceeded. Currently, the Safety Criteria for the disposal of radioactive waste are being revised. The revised criteria will take into account recent international developments in waste disposal as well as concerning the structure, content and presentation of the post-closure Safety Case.	The Safety Criteria for underground disposal require proof that the site under consideration has favourable mechanical, technical and hydro-geological properties. Safety analysis required for all radionuclide release scenarios that cannot be completely excluded. Demonstration of safety required for period of one million years. Use of further indicators has been required in licensing procedures.
Hungary	Dose Limit: 0.1 mSv/yr. Risk Limit: 10^{-5}/yr, for impact of individual disruptive events.	The consequences of individual disruptive events shall be evaluated using probabilistic analysis.
Japan	(Under development)	
Korea Rep. of	Dose limit : 0.1 mSv/yr for normal evolution Risk limit : 10-^{6}/yr for probabilistic disruptive events	A public dose criterion of 1 mSv/yr is applied for human intrusion scenarios.
Netherlands	Dose Limit: 0.1 mSv/yr, (Optimisation goal: 0.04 mSv/yr), for normal evolution.	
Norway	(Not available)	

Approach to Handling of Probability or Uncertainty	References	Country
	SAFIR 2.	**Belgium**
Under development		**Canada**
10^{-6}/yr – scenarios with lower probability need not to be considered in the safety analysis	Decree: No. 307/2002 on radiation protection No. 215/1997 on sitting of nuclear facilities	**Czech Republic**
Unlikely events assessed quantitatively where practicable, otherwise by qualitative discussion. Deterministic, conservative analyses with assessment of implications of uncertainties.	Govt. Decision: 478/1999. Guide: YVL 8.4.	**Finland**
Random, unanticipated events subjected to case-by-case judgement, including glaciations after 50 000 years.	RFS III 2f	**France**
Safety case with uncertainty analyses (requirements during licensing procedures). Presumes knowledge of repository for 500 years, and no human intrusion before then. Targets for individual dose are defined for different classes of likelihood of occurrence. (Derived from natural background radiation variation.) This approach has been chosen, amongst other reasons, in order to avoid conceptual problems linked with the risk concept for long time frames.	Atomic Energy Act of December 23, 1959 (last Amendment April 22, 2002) Safety Criteria for the Final Disposal of Radioactive Wastes in a Mine; 1983,	**Germany**
In probabilistic analysis, events with likelihood of occurrence of less than 10^{-7} event/year may be neglected.	Decree: 47/2003 (VIII.8) E5ZCSM	**Hungary**
		Japan
Under development	MOST Notice 2005-17	**Korea Rep. of**
	1st Report, 2003, under Joint Convention on Waste/Spent Fuel.	**Netherlands**
		Norway

Appendix 2. **National Dose and Risk Criteria for Disposal of Long-lived Waste in Different Countries** (Cont'd)

Country	Target Limit of Impact (Most exposed individuals)	Other Limitations or Conditions
Slovakia	Under development – for radioactive waste that contains significant levels of radionuclides with half-lives greater than 30 years	Dose limit 0.1 mSv/yr. (normal evolution scenarios) and 1 mSv/yr. (intruder scenarios) – for low level and intermediate level radioactive waste with limited content of radionuclides with half-lives greater than 30 years.
Spain	Dose Limit: 0.1 mSv/yr. Risk Limit: 10^{-6}/yr. Under revision, according to the ICRP 81	Dose limit relevant to high probability scenarios and risk limit to lower probability scenarios. General criteria for site selection.
Sweden	Risk Limit: 10^{-6}/yr. (Dose/risk conversion factor of 0.073 Sv^{-1} to be used.)	Biodiversity and biological resources also to be protected against the effects of ionising radiation. Quantitative assessment, including collective dose, to be made for the first 1 000 yrs. For period beyond 1 000yrs, general consideration of various possible scenarios for evolution of the repository's properties, its environment and the biosphere (SSI). A safety assessment shall comprise as long time as barrier functions are required, but at least 10 000 years.
Switzerland	Dose Constraint: 0.1 mSv/yr. Risk Target: 10^{-6}/yr.	Dose constraint relevant to high probability scenarios and risk target to lower probability scenarios. (Valid for all time.) Complete containment for 1 000 years.
United Kingdom	Dose constraint: 0.3 mSv/yr. Risk target: <10^{-6}/yr. (Dose/risk conversion factor of 0.06 per Sv to be used for dose-rates less than 0.5 Sv/a)	Dose constraint applies to period before control is withdrawn. Risk target to longer periods. Required to show that radionuclide releases are unlikely to lead to significant increase in levels of radioactivity in the accessible environment.
USA (Yucca Mountain)[1]	Dose Limit (no human intrusion): 0.15 mSv/yr. (Equivalent to fatal cancer risk of $8.5*10^{-6}$/yr using conversion factor of 0.0575 cancers per Sv). Dose Limit (after human intrusion): 0.15 mSv/yr as result of a human intrusion at or before 10^4 yrs after	Detailed restrictions apply for 10^4 yrs to radionuclide concentrations in groundwater. Compliance with quantitative dose limit required for 10^4 yrs. Requirement to calculate peak dose if it occurs later, (up to 10^6 yrs, i.e. the assumed limit of geologic stability), but the quantitative standard does not apply beyond 10^4 yrs.
IAEA	Dose constraint: 0.3 mSv/yr. Risk constraint: 10^{-5}/yr.	

1. In 2005, certain changes were proposed to the Yucca Mountain standards at 40 CFR Part 197. These changes would extend the period over which a quantitative dose limit applies, out to the estimated time of geologic stability at Yucca Mountain, approximately 1 million years. The dose limits for the first 10 000 years after disposal would remain as shown in the table. The proposed rule would establish a new dose limit of 3.5 mSv/year for the period from 10 000 years to 1 million years for undisturbed performance and, separately, in the event of human intrusion. These limits would assure that any people living near Yucca Mountain up to 1 million years in the future would not receive total radiation doses that exceed natural background radiation levels in comparable geographic and geologic regions. The groundwater standard would not extend beyond 10 000 years. For more details on the proposed rule, visit: www.epa.gov/radiation/yucca. The changes have not yet been made final

Approach to Handling of Probability or Uncertainty	References	Country
	Decision of Chief Hygienist (1988)	**Slovakia**
	CSN Decision on the Proposal of the 1st General Radioactive Waste Plan, approved in 1997. CSN Report to Parliament, 2nd semester 1985. 1st Report, 2003, under Joint Convention on Waste/Spent Fuel.	**Spain**
Uncertainties in the description of the functions, scenarios, calculation models and calculation parameters used in the description as well as how variations in barrier properties have been handled in the safety assessment must be reported, including the reporting of a sensitivity analysis which shows how the uncertainties affect the description of barrier performance and the analysis of consequences to human health and the environment	SSI FS 1998:1 SSI FS 2005:5 SKI FS 2002:1	**Sweden**
For long-term dose calculations: − Reference biospheres. − Population with realistic habits. − Conservative assumptions.	HSK R-21	**Switzerland**
Presentation of information on risks to include desegregation of probability and consequences, where practicable.	Environment Agency "GRA" Document, 1997 (EA, SEPA, DoE(NI)).	**United Kingdom**
10^{-8}/yr cut off for consideration of events/scenarios. (Corresponds to ≈ 10^{-4}/10 000 yrs for post-closure period.)	40 CFR Part 197, as implemented in 10 CFR Part 63	**USA**
Multiple lines of reasoning, e.g., based on natural analogues and paleo-hydrological studies of site and host rock	Safety Requirements currently in draft.	**IAEA**

Appendix 3

DISCUSSION OF DIFFERENCES AMONG CRITERIA

Introduction

First, it should be noted that the scope of the following discussion is limited to radiological protection criteria used to evaluate proposals for geological disposal of high-level radioactive waste. The discussion does not attempt to address the question of consistency between criteria for high-level waste and criteria for very long-lived low level wastes such as mine and mill wastes. It also focuses solely on radiological hazards and on criteria for protection of humans (vs. protection of the environment).

Quoting from the summary of responses to the first question in the questionnaire on long-term protection criteria (NEA/RWM(2004)8/REV1), there seemed to be a "good degree of agreement" that there is "broad consistency" among the target levels for protecting future generations. The key word, however, is "broad". In the table of national criteria, the dose constraints listed vary from 0.1 mSv/a to 0.3 mSv/a, i.e. by a factor of three. While not all of the responses mention risk constraints, those that do are split almost equally between two values of risk: 10^{-5} per year and 10^{-6} per year. Applying a nominal radiological risk conversion factor in the range of 5×10^{-2} to 7×10^{-2} Sv^{-1}, we find that dose constraints of 0.1 to 0.3 mSv/a correspond to annual radiological risks between about 5×10^{-6} and 2×10^{-5}, so the entire range in the table (from a 10^{-6} per year risk constraint to an 0.3 mSv/a dose constraint) appears to cover a factor of roughly 20 between the highest and lowest values.[1]

In order to interpret this broad range, it will be useful to consider a number of topics, among them: terminology and interpretation; the bases for selection of criteria; and how conformity with the criterion is assessed. Having better understood how to interpret the information, we can then proceed to consider whether the differences are significant in terms of radiological protection.

Terminology and interpretation

First, it should be clear that for the most part we are not talking about regulatory limits but rather design constraints. By demonstrating that a repository design meets the constraints, we hope to ensure to a high level of confidence that no member of a future generation will be exposed to a dose in excess of present-day regulatory dose limits, or to a risk that would not be considered acceptable today. In some countries, criteria are expressed in the form of design targets rather than design constraints. Whereas a design constraint represents a fixed pass/fail criterion for licensing, a design target represents a goal for the design optimisation process.

In talking about risk criteria, we also need to distinguish between radiological risk, which is actually a conditional risk (conditional on the probability of the scenario giving rise to the exposure),

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1. Since this was written, the revised proposed regulations for the Yucca Mountain Project in the USA have been issued. If these proposals are adopted, the range spanned by national dose/risk criteria will be broadened further. See also Appendix 2.

and aggregate risk, which also includes directly in the calculation the probability of the scenario. For normal evolution and other high-probability scenarios, the probability of the exposure is considered to be 1 (or nearly so), and radiological risk and aggregate risk are the same. For example, for low-probability events such as human intrusion into a deep geological repository, if an aggregate risk constraint is used the predicted exposure may be allowed to exceed the normal dose constraint as long as the combined or aggregate risk does not exceed the overall risk constraint (risk aggregation).

Because people are often less willing to accept a high-consequence low probability outcome than a low-consequence high-probability outcome with the same calculated aggregate risk, a single risk criterion may not be appropriate for both situations. For example, risk constraints or targets to be applied to high-consequence events may be more stringent than the risk constraints or targets that would be applied to high-probability or normal evolution scenarios (risk aversion).

Some of the regulatory criteria include some degree of risk aggregation, risk aversion or both. However, most of the following discussion will focus on the criteria used for high-probability normal evolution scenarios. For these scenarios, radiological risk and aggregate risk are the same, and risk criteria and dose criteria can be compared directly to one another with the use of a constant radiological risk conversion factor.

Bases for selection of criteria

Part of the variation in criteria may be attributed to the use of different bases for criteria selection in different countries. Three such bases are: comparison with current radiological protection criteria for operational facilities; comparison with the variability of background radiation exposures; and comparison with generally accepted risk criteria developed without regard for the type of hazard. Of course, despite different philosophical underpinnings, all of these bases are interconnected, and many of the national criteria are justified by comparison with more than one basis, although with differing emphases in different countries.

One approach is the one followed in ICRP-81 and the draft IAEA Safety Requirements document DS-154.[2] This starts from the premise that the basic goal is that no person in the future should in the normal course of events receive a dose from the repository any higher than the dose that would be allowed from a nuclear facility today. The dose constraint recommended by the ICRP is 0.3 mSv/a or less. This is the same value as the recommended dose constraint for new practices, which is intended to account for the potential that doses may be received from multiple sources. Some countries have adopted the 0.3 mSv/a dose constraint directly. Some others apply an additional safety factor of two to three to account for additional uncertainties from various sources. This line of argument often results in dose constraints in the 0.1 mSv/a to 0.15 mSv/a range.

The ICRP also suggests a risk constraint of 10^{-5} per year as being an approximate equivalent to the 0.3 mSv/a dose constraint. In fact, however, using current values for the risk conversion factor the 0.3 mSv/a dose constraint corresponds to a risk constraint of roughly 2×10^{-5} per year, i.e. the two numbers actually differ by a factor of roughly two. There does not seem to be an obvious technical basis for this difference between the risks corresponding to the ICRP recommended dose and risk constraint values.

A second approach does not depend directly on the ICRP recommendations, but instead compares the additional radiological dose from the normal operation of the repository to the variability of natural background radiation. Since people do not ordinarily take variations in natural background into account when planning everyday activities, it is considered that an increase in dose in the vicinity of a

2. Now WS-R-4.

repository that is small compared to the normal variability should not be of concern in terms of radiological risk. Some countries that have adopted or are considering criteria established on this basis (e.g. Germany and Switzerland) have arrived at a dose criterion of around 0.1 mSv/a. The United States has also used variations in natural background levels as a basis for its proposed extension of the Yucca Mountain standards.

A somewhat different approach from the above two starts from the level of overall risk. A risk constraint of 10^{-6} per year for the aggregate risk from lower-probability scenarios has been suggested in a number of countries. The one in a million level is sometimes described as a societally acceptable value applicable to a wide variety of risks.

In some countries such as the United Kingdom, this numerical value of risk is used as a target for normal evolution scenarios. Using current risk conversion factors, this corresponds to a radiological exposure target of 0.015 mSv/a, which is considerably smaller than the constraint values that are arrived at on the basis of radiological protection arguments. In some other cases including the United States, a risk constraint of 10^{-5} per year is justified at least partly on grounds of consistency with arguments based on dose limits.

It is notable that risk constraints and targets are often rounded off to the nearest order of magnitude (10^{-5} or 10^{-6}). This is most obvious in the case of the ICRP suggested risk constraint, but appears to apply to other cases as well. In effect, we tend to specify risk criteria as if we were using a logarithmic scale with only one digit of precision, reflecting the fact that the numbers themselves are small.

By contrast, the numbers for the dose constraints are specified in units which are the same as those used for assessing compliance with regulatory limits, where relatively small differences can result in substantial consequences (such as enforcement actions). Thus, we may perceive the difference between 0.15 mSv/a and 0.25 mSv/a to be important. However if the numbers were converted to risks, it is possible that the corresponding difference between 1.1×10^{-5} and 1.8×10^{-5} per year would be felt to be less significant.

Assessment of conformity

There are several ways in which different interpretations of the assessment of conformity with design criteria can affect the outcome.

Design criteria can be used in different ways in the optimization process. If we think of optimization as a process that affects the design in a range between an upper limit which must not be exceeded (analogous to a 1 mSv/a dose limit for an operating facility) and a lower threshold below which further optimisation would not be considered justified (like a 10 μSv/a de minimis criterion), then we must decide what role the design criterion has: is it the upper limit or something else? In most cases dose and risk constraints are used as upper limits, but in some cases dose or risk criteria are used as risk targets rather than limits or constraints (e.g. the United Kingdom).

In performing consequence assessments, judgements have to be made about choices of parameters and models. Different approaches to assessing the degree of conservatism that is appropriate for such choices can have significant effects on the outcome of the calculation. Only rarely are these approaches quantified and written down; more often, they lie in the realm of professional judgement. The variability that results from these differences could in some cases be larger than the range of variation in the criteria themselves.

One means of dealing with this variability may involve formal uncertainty analysis to help determine and document the degree of conservatism. Even so, questions are likely to remain to be dealt with when it comes to comparing approaches (e.g. differences between 90% confidence intervals and 95%; one-sided and two-sided intervals; analyses where all parameters are included in the uncertainty analysis vs. analyses where some are left unchanged; etc.).

One interesting specific example of differences in assessment of conformity arose during the comparison of the bases for the criteria in a number of countries. This was the approach to the "critical group" concept. While most countries appear to use the ICRP critical group approach, some (e.g. the United States) do not, while others (e.g. Sweden) modify the approach relative to the original ICRP recommendations. The choice of the critical group and in particular the breadth of variation allowed across a critical group can have significant effects on the outcome of analyses. For example, a case where a regulatory risk constraint of 10^{-5} per year is used to assess the dose received by the most exposed individual could be effectively equivalent to a case where a regulatory risk constraint of 10^{-6} per year is used to assess the dose received by the average member of a critical group where that critical group is allowed to consist of individuals who receive doses within a factor of one hundred, i.e. doses which vary by a factor of about ten on both sides of the average dose.

Are the differences significant?

Overall, radiological protection for disposal involves two components: the setting of criteria (i.e. the definition of acceptable risk) and assessment of conformity with the criteria (i.e. the definition of reasonable assurance). With respect to the first, we are faced here with apparent differences in criteria that appear to range over a factor of twenty, at least partly as a result of differences between the fundamental bases which are considered most important (radiation protection-based arguments vs. pure risk arguments vs. comparisons with variability in the real world). However, these differences must be combined with the differences in the approach to assessment of conformity before we can arrive at a judgement about the comparative level of safety.

One approach towards comparison of safety is to continue to compare criteria and how conformity is assessed with a view to identifying and resolving differences. This may enable a more meaningful comparison than is possible today. Note that while a comparison of approaches to assessment will be less clear-cut than a comparison of criteria, it may be necessary before we can reach a conclusion on levels of safety.

Another approach might be to rely on peer reviews of actual post-closure safety assessments. If such peer reviews were an accepted part of the review process, we could use this as a means to assure ourselves that regardless of the specific criteria, the actual design optimisation and assessment process used has led to a design that would be judged acceptable regardless of which regulatory system was used to evaluate it.

Finally, we should ask ourselves whether the differences are significant, not so much numerically as in terms of actual safety. Annual risk increments of 10^{-6} to 10^{-5} to the critical group correspond to lifetime risk increments of a small fraction of a percent, as compared with cancer incidence from all causes of a few tens of percent. In other words, if a repository is designed and built to meet any of these design constraints it seems unlikely that the health and safety of the critical group, or even of the most exposed individual, would be affected sufficiently to be statistically detectable.

Comparison with variations in background, not only natural variations but also incidental variations due to human activities may be more helpful. Many risk-related decisions are routinely taken which have incidental radiological impacts, but these radiological impacts are often considered too small to take into account during decision making. If the predicted radiological impact of a proposed repository design is no larger than these other incidental and normally unconsidered radiological impacts, then it may be reasonable to conclude that the benefit to be gained by reducing the impacts any further needs to be weighed carefully against the costs. All human activities involve associated risks; before spending resources on reducing those risks, we ought to consider whether the net social cost of spending those resources for that purpose outweighs the gains that will be achieved by doing so. Ultimately, of course, this is a societal decision and not a regulatory one.

Appendix 4

DISCUSSION OF THE ROLE OF REGULATION

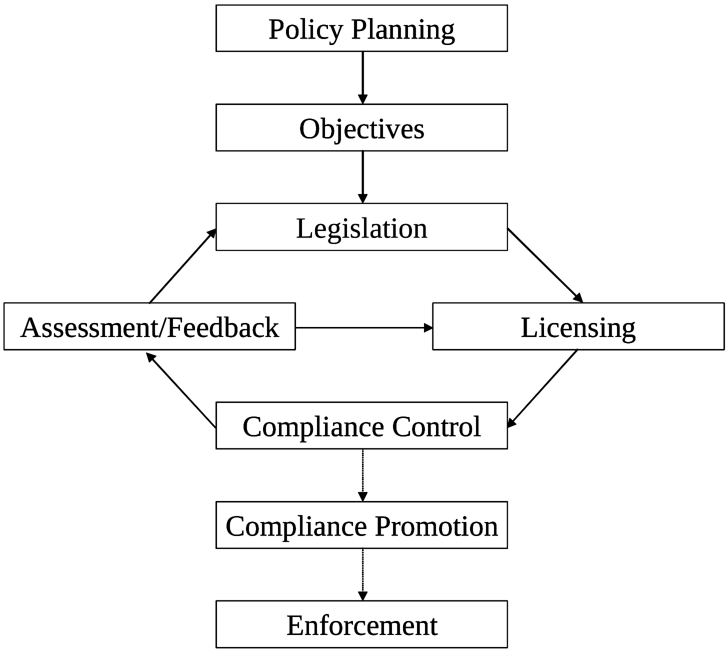
As in most forms of regulation, the regulatory control of radioactive waste management involves a number of identifiable elements and, usually, a number of bodies or institutions associated with their development and delivery. For example, in addition to safety assessments to be submitted and accepted by a technical regulatory body, there are often also requirements for Environmental Impact Assessments, for public hearings or other proceedings, and in many cases for decision making at the parliamentary or government level. The interrelationships between these various elements and bodies vary significantly between countries. Although many of these aspects may fall outside the remit of the regulator in some or all countries, it is felt that a broad and inclusive definition of the regulatory function is more helpful to the present discussion than a narrow definition which may leave critical questions unanswered. The description that follows is therefore necessarily a generalised one, from which individual national arrangements will differ in detail. The conclusions reached and recommendations for future actions must likewise be stated broadly, since their ultimate application may depend heavily on decision-making structures which are not the same in all countries.

Without attempting to account for detailed national differences in roles, responsibilities and processes, the elements generally associated with a regulatory process are conveniently depicted as a generalised cycle that embraces the principle of continuous improvement. Such a schematic "Regulatory Process" is shown at Figure 1 [5].

These elements generally start with recognition of a practice or situation that needs a system of regulatory control and with development of a policy for its implementation. The establishment of broad policy and essential objectives is then usually followed by creation of appropriate primary, enabling legislation together with secondary legislation involving regulations, rules, ordinances, decrees, arrêtés, etc. Except where these legal elements are judged to be sufficiently detailed, they are usually followed by publication of the standards to be achieved and by guidance on how these legal elements are to be implemented in practice. Examples of policy and requirements applying to the long term are reported in Box 1.

Consent to act within the bounds of legislation and regulations is generally by way of some formal, legal instrument, often described as a licence but also, variously, as a permit, authorisation or decree. This contains detailed terms and conditions and is issued to the person or company that is recognised legally as the operator of a process or activity subject to regulation. In some cases a licence may cover all aspects of regulation related to the regulated process or activity, from initial planning and development, through matters such as occupational health and safety of workers and accident prevention, to the final act of disposal. In other cases they may address such aspects separately, having regard, of course, to the interactions between them. Compliance with the terms and conditions of a licence is then checked by inspection and monitoring of the operator's activities. Cases of non-compliance are often dealt with by way of notices or requirements placed on the operator or by other inducements, which may be described collectively as compliance promotion. If necessary, non-compliance is subject to some form of enforcement action.

Figure 1. **The Regulatory Process**



Box 1. **The long-term in policy and requirements**

International Examples

Policy

Joint Convention [7], Article 1

"*The objectives of this Convention are:*

…

(ii) *to ensure that during all stages of spent fuel and radioactive waste management there are effective defences against potential hazards so that individuals, society and the environment are protected from harmful effects of ionizing radiation, now and in the future, in such a way that the needs and aspirations of the present generation are met without compromising the ability of future generations to meet their needs and aspirations;*"…

IAEA Safety Fundamentals [6], Principle 4

"Radioactive waste shall be managed in such a way that predicted impacts on the health of future generations will not be greater than relevant levels of impact that are acceptable today."

Requirements

Joint Convention [7], Articles 4 and 11

"… each Contracting Party shall take the appropriate steps to:

…

(vi) strive to avoid actions that impose reasonably predictable impacts on future generations greater than those permitted for the current generation;"

To complete the cycle there are also, in most cases, arrangements whereby the overall success of the regulatory system in meeting the policy objectives is reviewed. If necessary, corrective action is taken by way of feedback directly to the licensing stage, where detailed terms and conditions may be modified, or to the controlling legislation. In addition, compliance enforcement actions might also include some form of physical intervention for repair or recovery. This is true for regulation of elements of radioactive waste management such as transport, storage, effluent discharge and, perhaps, even for the disposal of short-lived waste. For these elements, therefore, continued assurance of safety rests on the continued presence of regulatory bodies and relevant means to deliver regulatory oversight.

The disposal of long-lived radioactive waste, however, is different from the above activities in that by design the impacts are unlikely to become apparent until far into the future, if at all. Therefore, regulatory follow up after granting of a disposal licence, in order to see that the desired long-term effects are being achieved, is effectively impossible over the full design life of the disposal system. This means that any long-term remedial action is unlikely, unless undertaken by future generations on their own initiative, and an important conventional component for assuring continued safety is unavailable to current regulatory bodies. The granting of a licence for definitive disposal of long-lived waste and closure of a repository involves the ultimate absence of the key element of active control, and therefore the objective is passive safety without the requirement for further intervention. It depends on the satisfactory assessment of disposal concepts that are designed to be safe, and actually involves an act of trust in the technology and the legal and regulatory systems, taken by the current generation on behalf of future generations.

It is thus seen that the meaning of "safety", and how it is assessed and controlled, depends to some extent on whether short or long term aspects of radioactive waste management are being addressed. The simple, technical measures of harm as used for operational systems (i.e. in the short term) lose their original significance for the long term, in that they cannot be directly measured, and they need to be replaced by concepts that generate trust in the whole system of regulatory delivery of safety and therefore confidence in the final judgement of whether adequate provision for safety has been achieved. Studies indicate that the concept of trust implies that something is being risked in expectation of gain (or limitation of loss). Limiting the potential for negative impacts can in some cases reduce the degree of trust that is needed in such situations by limiting the risk [14].

Besides controlling the physical factors that could produce unwanted consequences, decision-making process components can be designed to improve trust. These components may include involving in the decisions those who are affected, so that they gain more familiarity and control, and dividing major decisions into smaller steps, providing feedback after each step and allowing stakeholders to halt the procedure if they are not confident in the ultimate safety of disposal. Institutional factors also enter into the equation for generating trust, such as the role of the regulator and other decision-making bodies [15]. The practicability of the measures to be taken for assuring and explaining safety clearly plays a role as well.

In the case of long-term radioactive waste management, it can be observed that the objective was originally seen as being the health protection of the general public and workers against the dangers of ionising radiation. For some time, therefore, regulation was largely (although not totally) an exercise of radiation protection, according to objectives and standards that were usually traceable to the recommendations of the International Commission on Radiological Protection (ICRP). In more recent times, however, broader environmental, international, social and economic objectives have been recognised [8] with, for example, the setting of objectives, standards and guidelines for disposal site selection criteria, waste package requirements and monitoring criteria. Additionally, ICRP [8] insist that any analysis of radiological impact is insufficient by and in itself to authorise a geologic disposal facility, but that any such analysis should be complemented with statements or indication that sound technical and managerial principles were implemented, as well as with argumentation showing that due account was taken to reduce the likelihood and the impacts of human intrusion. This position is reflected also in recent NEA documents, whereby it is suggested that the safety case for disposal include a “confidence statement” [16-17], which indeed is no less than a justification that sound technical and managerial principles were implemented. There is a large variability among regulatory organisations in how these objectives and standards have been formulated [4]. In order to better understand the observed differences, it is important to gain a common understanding of some basic underlying principles, such as the nature of the obligations of today’s society towards future generations. These underlying principles involve issues which are beyond the normal regulatory remit, and thus success may require the involvement of constituencies other than regulators and proponents.

Appendix 5

DISCUSSION OF THE MEANING OF SAFETY AND PROTECTION

The role of the technical regulator is to assure to society that licensed projects and licensees (proponents and operators) will meet their commitments for safety. It is thus necessary for the regulator and society to agree on what is meant by safety.

Safety analysts (including the regulator) and the public need to take into account that safety is not assured simply by a numerical comparison against a single protection criterion. Safety depends on the context: the level of protection afforded the general public is greater than that provided for a nuclear worker who chooses to accept the slightly greater risk as a condition of employment; what is considered adequately safe in conditions of high economic stress or conflict is different from what is considered adequately safe in conditions of affluence or peace.

Recognition of this context-dependence can be found in cases where the regulatory requirement is “reasonable assurance” or “reasonable expectation” that a protection criterion is met, rather than absolute hard and fast compliance. By introducing the concept of reasonable expectation, these regulatory systems recognise that even at the technical level, acceptability is a matter of judgement within a context. This judgement takes into account the quality of the approach in terms of management and engineering, in addition to compliance with protection criteria.

This discussion document is primarily concerned with safety as understood technically. However, confidence in the disposal concept is based on more than just a consideration of technical safety, and must also take into account societal issues. Similarly, decision making is based on more than regulatory judgements, and on more than the outcomes of environmental impact assessments. Typically, the ultimate decision on whether to proceed with a disposal facility is not made by the technical safety authority alone (“the regulator” in the usually accepted sense), but by the national government. Thus, in addition to the essential technical criteria considered by the regulator, socio-political and socio-economic issues also play an important or dominant role in recognition of the different roles of science and technology, policy development and politics.

While this document does not attempt to deal comprehensively with such issues, it is impossible to cleanly separate technical from social issues, and indeed attempts to do so have proven to be counter-productive. Therefore, while the discussion may focus on technical measures of safety, there are close ties to social acceptability and to ethical issues which must not be ignored [18]. Technical safety and protection criteria and policies should not be defined without taking into account the spatial, temporal and social contexts in which they will be applied.

Safety, as understood technically, is an intrinsic property of the disposal system as implemented, i.e. the absence of physical harm resulting from the existence and operation of the system over a given period of time. In this document, we use the term “harm” to mean unacceptable impact. The significance and acceptability of impact vary with context. The term “system” represents all the arrangements that make it work, including technical and administrative measures (such as institutional controls). In deciding whether a system is safe, the characteristics of the system that enable it to avoid causing physical harm to humans and the environment are tested. Safety is not an outcome of analysis; analysis is merely one way of demonstrating that safety is achieved.

When it comes to physical harm, safety is more than just protection against radiological exposure. Not all regulatory bodies deal at the same time with radiological and non-radiological (e.g. chemotoxic) exposures, but even where they do not, other factors will enter into the final decision making, among them consistency of risk management from comparable hazards.

In more general terms, harm is an impact that is judged, within a social and temporal context, to be unacceptable. Criteria for defining acceptability normally involve value judgements and can change with the context. In order to judge whether an outcome involves harm, questions such as the following need to be asked: Who (or what) are the receptors (individuals, communities, the environment…)? What is the nature of the impacts (risks to health or to life; risks to economic well-being; foreclosing on future choices; irreversible or temporary)? How certain are the impacts to occur? Over what time period do they occur? What are the criteria for protection against those impacts? Do the receptors benefit in any way from the practice that gave rise to the wastes? Do they have any choice in the matter, or any control over the impacts? A judgement of harm – meaning unacceptable impact within a social and temporal context – may depend on the answers to any or all of these questions.

Different aspects of harm are relevant in different timescales. For example, in the near term socio-economic concerns may dominate. At long-timescales, there is so much uncertainty about our ability to predict the needs and aspirations of future societies that short-term socio-economic concerns may become irrelevant. Even when considering physical criteria, such as radiological doses to persons, the nature and relevance of the criteria may change with time, and ethical considerations of the present generation's responsibility to future generations become important.

In fact, it is not possible to guarantee the future acceptability of current decisions. This is one of the underlying reasons behind the adoption of various forms of optimisation requirements (ALARA, ALARP, BAT, BPM, and so on) – where we can reasonably do better than simply meet current criteria, it is often felt to be appropriate to require doing so, in at least some small part because of the possibility that what is currently found to be acceptable may at some future time be considered no longer to be acceptable. Indeed, in situations of very high uncertainty about the very long term, the only practicable means of assuring long-term safety may be simply the adoption of best currently available engineering and management techniques taking into account economic feasibility. Past and current practice in the disposal of non-radiological hazardous wastes appears to be an illustration of this approach.

Considerations such these have led the LTSC group to re-examine the reasons for the choice of the fundamental strategy of disposal, i.e. isolation of the wastes until the potential for causing harm is sufficiently reduced. A hypothetical regulatory approach which focused solely on radiological or risk criteria might lead one to believe that the fundamental goal was to achieve a prescribed level of radiological protection, and that isolation was simply the approach or method chosen to achieve that level. However, that would not necessarily be the case. The choice of isolation as opposed to dispersal of wastes may be motivated by considerations of spatial equity, collective impacts, and ethical concerns about pollution of the environment, and not by a comparison of radiological doses to maximally exposed individuals under the two strategies. Indeed, disposal represents a conscious choice by society to manage these wastes by concentrating and containing them, as opposed to selecting a "dilute and disperse" strategy. It should also be noted that the distinction between these two strategies depends on the time scale under consideration; on geologically long timescales, both strategies can be seen merely as different choices of how to redistribute risks in time and space, since neither strategy completely eliminates the intrinsic hazard and the potential for harm.

If, based on the above, we take the view that the fundamental strategy of disposal is to isolate the wastes from humans and the environment over a given time frame, it is necessary to have concrete criteria for measuring the success of a proposal in meeting this objective. From this point of view, we may regard calculations of radiological doses as numerical indicators or tests of the degree of success of the strategy. Indeed, both risk and dose calculations are dependent on very uncertain models of the biosphere and of the behaviour of future populations, which are independent of the behaviour of the repository system. If radiological and risk criteria are viewed in this light, as indicators, amongst others, rather than as primary objectives, the observed variability of regulatory criteria and regulatory approaches as well as the variability in choices of different criteria for different situations or different time-scales becomes more understandable and defensible. Indeed, variations in the use of such indicators between different cultural and regulatory milieus would not be unexpected.

In this context, it also needs to be recognised that limitation of doses potentially resulting from ingestion of radiotoxic substances that may be released from a repository into the environment is not the only protection goal. It is also necessary to protect persons, now and in the future, against direct exposure to ionising radiation from high-level wastes, since if persons were allowed to come into direct physical contact with these wastes, they could be exposed to unacceptably-high external irradiation doses even at times in the far distant future. In addition, it is necessary to protect the wastes against the possibility of theft or removal for nefarious purposes (i.e. safeguards and physical protection). Regulatory criteria and decision-making processes do, of course, take all of these safety goals into account. Therefore, calculations of doses via the ingestion pathway, while an important component of the regulatory approval process, are supplemented by other indicators of protection or performance related to the overall safety goal.

If the primary safety objective is isolation rather than, or in addition to, non-harmful radiological impacts, then other indicators of performance are also important. Depending upon the context, there may well be situations where indicators of other safety functions are more meaningful than calculated doses. Among such indicators may be demonstrations of compliance with design criteria unrelated to predicted outcomes (similar to those used in the design of conventional civil and mechanical structures). In the longer term, such containment design criteria could be supplemented by other criteria related to geologically-based barriers (long return pathways, long groundwater retention times, absorptive attenuation, comparisons to natural fluxes of radionuclides, etc.) Criteria of this type may be more widely understood than calculations of hypothetical doses to hypothetical critical individuals, although these calculations are nonetheless valuable illustrations of repository safety for a given scenario.

Safety also involves the concept of control: a hazard which is controlled is felt to be safer than one which is uncontrolled, even if there is no difference in the numerically calculated risk. To achieve confidence in future safety involves either establishing control (e.g. institutional control) or a high level of trust in the safety arrangements and the safety assessment. Trust in a safety function (e.g. containment) may be easier to establish than trust based on a numerical calculation whose result is below a specified criterion.

Appendix 6

DISCUSSION OF CONFIDENCE BUILDING

Many of the activities of today's societies will result in legacies that may have an impact on the safety of future generations. The requirement for assurance of safety over long time-scales requires a high degree of trust and confidence in the decisions that are to be made in the present and near future. Because of their continued potential impacts on future generations, these decisions involve a high degree of responsibility towards persons who have no chance to participate. Furthermore, in a democratic, pluralistic society acceptance of major projects requires confidence on the part not only of the technical community but also of the public at large.

To achieve the required degree of public confidence requires a high level of trust founded on three major pillars:

- Trust in the institutions involved in decision making.
- Trust in the decision-making process.
- Trust in the technical concept and the assessment of its ability to prevent or avoid harm.

Trust in the institutions

There are several bodies or institutions involved in decision making related to disposal of radioactive wastes, including the proponent, the regulator, advisory bodies, the public, and government acting in several roles: as policy maker, as decision maker, and in assuring institutional control and monitoring. The roles of each of these bodies need to be clearly defined and understood. Mixing of roles, or opaqueness about the roles, engenders mistrust, and should be avoided. There must also be confidence in the capability of each of the institutions to carry out the tasks before it.

With respect to the role of the regulator in particular, it is essential that independence from the proponent and from political interference can be demonstrated. There must be trust in the credibility, integrity and honesty of the staff, as well as of the regulatory body as an institution. A major contributor to establishing this trust is transparency and openness of the regulatory decision-making process.

It is also important that the regulator be seen to be competent and capable. The regulatory bodies must have sufficient funding and staffing to carry out their job, and they must be well-managed and maintain their focus on their mission, mandate and values so as to ensure that they carry out the responsibility that they have been entrusted with on behalf of the public. It is important that the regulator adhere to a code of conduct that assures non-confrontational and open dialogue with all interested parties. Internal quality procedures and external peer reviews are among the tools that help the regulator assure the public of its continued competence and capability as an institution.

Trust in the decision-making process

Just as the roles of the various institutions involved in decision making need to be well-defined, so also do the steps in the decision-making processes. The scope of each decision and the rules according to which the decision is to be made need to be clear and consistent. Lack of clarity in either of these elements will impair the trust in the decision-making process. Instability in the processes and criteria likewise leads to confusion and impairs trust.

The role of the public in the various decision-making steps is an important element in establishing trust. There must be opportunities for meaningful public input into and participation in the decision-making process.

An important element of decision-making processes that is receiving increasing recognition is the role of stepwise decision making. By allowing for monitoring of the results of each decision and providing feedback from this monitoring into the next step, the likelihood of an unacceptable final outcome can be reduced.

For a stepwise process to be truly meaningful there must be a possibility of reversal or modification of a decision made in a previous step if the outcome of its implementation does not meet criteria established for it. Similarly, monitoring is only meaningful if the results of the monitoring have the possibility of leading to appropriate adjustments.

A stepwise process allows for criteria that are tailored to each step, taking the particular safety context and timescales into account. It also permits the application of the concept of "reasonable assurance". By allowing for continuous improvement, for alternative outcomes of future decisions, and for modifications subsequent to observation of the outcomes of earlier decisions, a stepwise process reduces the reliance on strict assurance of compliance with protection criteria at each step. The use of multiple lines of argument and of multiple or parallel criteria is likewise facilitated by a stepwise process.

Trust in the technical concept and control measures

As regards the project itself, it should be based on sound science, subjected to rigorous and transparent analysis, and evaluated independently by regulators and by the public themselves, with the help of independent expert advisors. The criteria on which a project is judged will include not only protection criteria, but also other criteria such as passive safety, robustness, land use, retrievability, and ability to monitor and adjust accordingly.

The methods by which safety is assured and assessed need to be adequate, verified and transparently documented. In this regard, it is important to note that different analyses may be performed to serve different purposes: for example, bounding or limiting conservative analyses to demonstrate the robustness of the safety conclusions vs. best-estimate or design-centre analyses to demonstrate an understanding of expected system behaviour and of the dependence of this behaviour on various design features, natural processes, etc.

The development and assessment of a safety case depends on more than just calculations. Furthermore, the level of detail and contents of a safety case will probably vary from step to step of a stepwise process. While it is not likely that every step in the process, including the methods and criteria to be used, can be finalised with certainty at the beginning of a stepwise process that itself may last more than one generation, it is important for reasons of transparency to have a clear "road map" of the process even at the earliest steps.

Special consideration needs to be given to the role of institutional control in establishing confidence. This issue needs to be addressed early in the planning and consultation processes. On the one hand, the ability to control a system is an important component in establishing confidence in safety; on the other hand, our inability to assure that such control can and will be exerted by societies in the distant future leads to the conclusion that the system must be designed in such a way that it can assure an acceptable level of safety even in the absence of future control.

For relatively short timescales, during which there is reasonable confidence in the ability of existing institutions and governments to assure continuing control, institutional control measures, both active and passive, may form an important part of the safety case (as for example in the safety case for disposal of short-lived radioactive wastes). Indeed, the public acceptability of a project in the short term may depend critically upon the ability of the regulator or other institutions to exercise control and take corrective steps in the event of failure.

For much longer timescales, while the intent to continue monitoring, surveillance and control may play a role in establishing and increasing confidence, in the end it is not possible to make a convincing case that institutional controls will continue to provide protection (against intrusion, for example) into the indefinite future. Therefore the safety case for the long term needs to be able to demonstrate that even in the event of failure of the planned and presumed controls, the system as a whole continues to deliver an acceptable level of safety. It follows from this that the institutional control systems, including monitoring provisions, must be designed in such a way that their physical presence or absence does not have an adverse effect on safety, particularly after the monitoring systems are no longer in use and being maintained.

Appendix 7

DISCUSSION OF ETHICAL CONSIDERATIONS

Any consideration of long-term safety criteria for disposal of radioactive waste inevitably raises questions of intergenerational equity – waste is generated today, beneficiaries are today's consumers of energy, but the waste can potentially impact future generations for a very long time.

Historically, the approach to this issue has been exemplified by the IAEA Safety Fundamentals document [6], Principle 4: "Radioactive waste shall be managed in such a way that predicted impacts on the health of future generations will not be greater than relevant levels of impact that are acceptable today." This has been restated in various national documents.

This appears to correspond fairly closely to what has been called the "strong principle of justice" by KASAM [11]: "We have an obligation to use or consume natural resources in such a way that subsequent generations can be expected to achieve a quality of life equivalent to ours", and the "Sustainability Principle" by the US National Academy of Public Administration [12]: "No generation should deprive future generations of the opportunity for a quality of life comparable to its own."

Current thinking with respect to intergenerational equity recognises, however, that as the time frame becomes longer, our ability to guarantee that current limits will be met to an acceptable level of confidence diminishes because of uncertainties, not only in the physical and engineering models, but also (and perhaps more significantly) in our ability to predict and influence the behaviour, needs and aspirations of future generations several generations removed from us.

The KASAM report, for example, goes on to argue that the strong principle of justice is appropriate when dealing with generations in the relative near term (e.g. up to approximately 150 years). However, beyond that time, the KASAM report argues, our ability to predict and assess the factors that will be considered at that time to contribute to equivalent quality of life (as distinct from basic needs) diminishes; also, our direct ability to influence future actions diminishes to such an extent that continued application of the strong principle of justice becomes problematic.

During succeeding years (the KASAM suggestion is from 150-300 years), the KASAM report argues for the application of the "weak principle of justice", namely: "We have a moral obligation to exploit natural resources in such a manner that not only the present generation but also future generations can satisfy their basic needs." While we may not be able to influence the future and to predict adequately future expectations regarding quality of life, we can still make reasonable predictions of basic needs, and therefore have a responsibility to assure with a high degree of certainty that they are protected.

At some later time (KASAM suggests 300 years), the "minimal principle of justice" is called upon: "we have a moral obligation to exploit or consume natural resources in such a way that we do not jeopardise future generations' possibilities for life." This applies at times which are sufficiently remote that we no longer have complete confidence in our ability to predict how basic needs will be provided for, or how they might be impacted by present actions. Nevertheless, we must still ensure, as a minimum, that our actions today do not run the risk of endangering lives in the future.

It may also be considered that in addition to safety-related obligations towards future generations, the current generation also has obligations not to impair future generations' freedom of choice (which may be considered to be included among their aspirations). However, an obligation to preserve freedom of choice two or three generations from now may conflict both with obligations to protect basic safety of more distant generations, and with our immediate obligations to provide protection to the current and succeeding generations. It is thus necessary to achieve a balance between avoiding burdening future generations with the need to take decisions and actions to mitigate the effects of our decisions, versus providing those same future generations with the capability to take decisions and actions if they choose to do so. At the same time we must continue to take into account our more immediate obligations to current and intervening generations.

In this respect, the NAPA approach modifies the sustainability principle by the application of the "Chain of Obligation Principle": "Each generation's primary obligation is to provide for the needs of the living and succeeding generations. Near-term concrete hazards have priority over long-term hypothetical hazards." The impacts of our decisions on distant future generations are modified by the actions of intervening generations, and our obligations to these distant generations are thus less direct than those toward immediately succeeding generations. We may express this through the concept of a "rolling present" – each generation is primarily responsible to the immediately succeeding generations, and only secondarily to more distant generations, for whom it is the intervening generations that bear the greatest responsibility. This is particularly the case for projects like disposal whose implementation is expected to last several generations, and in which a stepwise decision-making approach may be followed, since it is clear in such a case that immediately succeeding generations must have the capability to take decisions and actions that will significantly modify the impacts of those taken today. As in the KASAM approach, this argues for the possibility of deviation from current-day standards in the long term, or in low-probability hazard scenarios. Nevertheless, any such deviation is constrained by the fundamental obligation stated in the "Trustee Principle": "Every generation has obligations as trustee to protect the interests of future generations."

The concept of the "rolling present" also takes into account the fact that in large measure, the best means we have of carrying out obligations to the distant future is through the intermediary of our more immediate successors. As individuals, our most effective means of meeting our obligations to our grandchildren is to ensure that our children have the resources and the value systems to themselves be good parents to their children. Likewise, as a society one of our major obligations with respect to disposal is to ensure, to the best of our ability, that succeeding generations have the technical knowledge, ability and resources to carry out their roles during the stepwise implementation of a disposal project. It is important that we do not put so much focus on the assessment of the safety of distant future generations that we lose sight of the overriding importance of this obligation to our more immediate successors.

The approach suggested by EKRA [13] to the question of obligations to future generations (see Box 1) presents a similar hierarchy of three principles, presented in the reverse order. A fundamental "safety" principle, similar to the KASAM "minimal principle of justice", would apply at all times. On timescales short enough that there is some present ability to ensure the stability of institutions and pass on knowledge, a stronger "fairness" principle would apply, and on the shortest timescales, this is supplemented by a yet stronger "acceptability" principle which is quite similar to the KASAM "strong principle of justice".

Discussion of intergenerational equity and of the sustainability principle is related to the subject of sustainable development. However, the discussion with respect to long-lived radioactive waste differs from typical sustainable development discussions in two important respects. The first is that in many countries, decisions on the course of action to deal with long-lived radioactive waste are separated from decisions on development of nuclear energy, and even where they are not, the current discussions on radioactive waste are taking place well after the decision to proceed with the development that created that waste. Regardless of the outcome of decisions on future development of nuclear energy, there is an obligation to deal with existing wastes. Nevertheless, when the context of the discussion does not include development, a significant aspect of the sustainable development paradigm is missing, and we can expect that there may be difficulties in applying the full paradigm.

Box 1. **An approach to the question of obligations to future generations**

EKRA [13]

A hierarchy of three ethical criteria, in decreasing order of the level of obligation imposed:

1. Safety of man and the environment:

Safety is necessary for an individual to be able to act, take decisions and make use of his/her freedom. Safety during the whole lifetime of the waste is paramount and should be addressed from today. Assuring safety should constitute as small a burden as possible on future generations.

2. Fairness:

There must be intra- and inter-generational equivalence of opportunities and protection. The timescales for radioactive waste management are so long, however, that they exceed the possibilities of our society in terms of passing-on know-how and in terms of stability of political and social institutions. When considering management concepts, a distinction has to be drawn amongst time periods, namely the period that is within grasp of current society and the period during which safety cannot be assured through human presence or intervention.

3. Individual and social acceptance:

At the time of construction and operation, the facility must be acceptable by the majority of the people, especially those in the siting zone. The facility should be designed in a way that it may be acceptable also to future generations. Individual and social acceptance plays a third role because by favouring, within decision making, the present or the immediate following generations, it infringes to some extent the principle of fairness across generations.

The second significant aspect that differs from most industrial practice is the consideration of very long timescales (paradoxically, considering that many other industrial hazards do not decay at all). Current practice in most industries, even when considering management of hazardous wastes that do not decay, appears to be confined to a very few generations, and does not normally consider the long timescales under discussion in the present document. While there appears to be a trend towards considering longer timescales in industries other than the nuclear industry, such considerations are not yet standard practice. For these reasons, while there may be useful insights to be brought to bear from other industries, we cannot expect many of the questions we are dealing with to have been resolved elsewhere.

Returning to currently adopted international standards for radioactive waste management, one of the objectives of the Joint Convention (Article 1) is “to ensure that during all stages of spent fuel and radioactive waste management there are effective defences against potential hazards so that individuals, society and the environment are protected from harmful effects of ionising radiation, now and in the future, in such a way that the needs and aspirations of the present generation are met without compromising the ability of future generations to meet their needs and aspirations”. The requirement not to compromise the ability of future generations to meet their needs and aspirations seems to combine the strong (aspirations) and weak (needs) principles of justice.

In practice, however, a requirement to protect the aspirations of future generations can be difficult to meet. Beyond a very few generations, it is difficult to predict what those aspirations will be. Thus, we may find it impossible to judge whether a calculated release from a repository hundreds of years from now would affect the ability of persons to meet their aspirations; the best we can do may be to judge whether or not it would affect their ability to meet their basic needs. At longer timescales, perhaps even a judgement related to basic needs could be questionable.

Expressed in terms of dose and risk, the weak principle of justice might perhaps equate to a statement that radioactive waste must be managed in such a way as to guarantee that its disposal or management will not threaten the health and safety of future generations, i.e. that the level of protection to be demonstrated is a level which will, to the extent of present-day knowledge, guarantee that observable negative health effects will be avoided.[1] The level to be assured is thus less onerous than the target levels based on operational radiation protection, or on very low risk (10^{-5} to 10^{-6}). These latter are orders of magnitude below levels at which impacts would be observable either directly on individuals or through epidemiological observations on populations.

Of course, the design goal for a waste repository in the long term may be the same as in the short term; the strong principle of justice or sustainability principle is a desirable goal to strive for even in the very long term. What diminishes in the long term is not so much the present generation's need to fulfil its responsibility to future generations as its ability to assure that the desired level of protection will be met with a defined margin of safety or to a defined level of confidence.

It may also be considered that on even longer timescales, over which geological (plate tectonic) processes may dominate, our ability to demonstrate compliance with protection criteria becomes even more questionable. On the other hand, the meaning of safety on timescales this long, i.e. far longer than the duration of existence of single species such as *Homo sapiens*, is also far from self-evident. Perhaps the main point to be taken from this is to recognise that language which suggests that obligations continue unchanged for all time is simply not realistic. On sufficiently long timescales, any statement at all about the impacts of current actions and about obligations of current societies towards the future eventually becomes meaningless.

As a result of the above considerations, we may conclude that responsibility to present and future generations, just like harm, depends on context. Thus, there is a gradually decreasing level of assurance to be expected of calculations of future impacts. In the near term, we must assure that impacts are no greater than would be accepted today. In the longer term, while we continue to aim for this goal, we recognise that we may not be able to state with complete assurance that current levels will be met. For example, while we might not accept a design that was expected to have larger impacts in the future than would be acceptable today, we might accept a design where such impacts could not be ruled out. Even so, we must be able to assure that impacts will not endanger the health and safety of future generations (in the context of the NAPA principles, in order to meet the trusteeship and chain of obligation principles). Rather than attempting to make an absolute promise that we can prevent harm in the future, we may need to adjust our goal to the more realistic one of reducing the potential for future harm to as low a level as we can reasonably achieve, and of demonstrating that in particular the potential for serious or directly observable impacts is very low.

1. Paraphrasing the UK sustainability principle that requires us "to ensure that natural resources needed for life are unimpaired and remain so for future generations", one could formulate the long-term protection goal as one "to ensure that the natural conditions needed for life are unimpaired by the presence of the waste repository for as long as it constitutes an unusual hazard".

Appendix 8

IMPLEMENTATION ISSUES RELATED TO TIMESCALES[1]

A key challenge in the development of safety cases for geological repositories is associated with the long periods of time over which radioactive wastes that are disposed of in repositories remain hazardous. Over such periods, a wide range of events and processes characterised by many different timescales acts on a repository and its environment. These events and processes, their attendant uncertainties, and their possible impacts on repository evolution and performance must be identified, assessed and communicated in a safety case.

The handling of issues related to timescales was discussed at an OECD/NEA workshop held in Paris in 2002 and a short report providing an account of the lessons learnt and issues raised at the workshop, was published in 2004 (NEA, 2004a).[2] There is, however, an evolving understanding regarding the nature of the issues related to timescales and how they should be addressed, which provides the motivation for the present report. The report is based on the analysis of the responses to a questionnaire received from twenty-four organisations, representing both implementers and regulators from thirteen OECD member countries, as well as discussions that took place in several later meetings.

The report is aimed at interested parties that already have some detailed background knowledge of safety assessment methodologies and safety cases, including safety assessment practitioners and regulators, project managers and scientific specialists in relevant disciplines. Its aims are:

- To review the current status and ongoing discussions on the handling of issues related to timescales in the deep geological disposal of long-lived radioactive waste.
- To highlight areas of consensus and points of difference between national programmes.
- To determine if there is room for further improvement in methodologies to handle these issues in safety assessment and in building and presenting safety cases.

The handling of issues related to timescales in safety cases is affected by a number of general considerations, which are described first. Three broad areas in the regulation and practice of repository planning and implementation affected by timescales issues are then discussed:

- Repository siting and design and the levels of protection required in regulation.
- The planning of pre- and post-closure actions.
- Developing and presenting a safety case.

Finally, a synthesis of findings is made, including a review of the statements made in the 2004 "lessons learnt" report in light of the discussions contained in the present report. Many of the issues treated in the course of the project are subject to various interpretations, and remain under discussion

1. This text reproduces the Executive Summary of the Timescales Initiative and Report "Consideration of Timescales in Post closure Safety of Geological Disposal of Radioactive Waste", November 2006, NEA/RWM/IGSC(2006)3.
2. *The Handling of Timescales in Assessing Post-closure Safety, Lessons Learnt* from the April 2002 Workshop in Paris, France, OECD/NEA Nuclear Energy Agency, Paris, France, 2004.

in national programmes, as well as internationally. Therefore, the findings in this report should not be viewed as conclusive, but rather as a contribution in moving ahead the debate and understanding the similarities and differences among approaches in national programmes.

General considerations in the handling of issues of timescales

Ethical principles

Given the long timescales over which radioactive waste presents a hazard, decisions taken by humans now and in the near future regarding the management of the waste can have implications for the risks to which generations in the far future may be exposed. There are thus ethical issues to be considered concerning, for example, our duty of care to future generations and the levels of protection that should be provided. Decisions regarding the phased planning and implementation of repositories, particularly whether to close a repository at the earliest practical time or to plan for an extended open period, also have an ethical dimension. This is because they affect the flexibility allowed to future generations in their own decision making as well as the burden of responsibility passed to these generations. Relevant ethical principles, such as intergenerational and intra-generational equity and sustainability, are open to different interpretations and can sometimes compete. The interpretations made and balance struck between competing principles is a matter of judgement and may vary between different countries and stakeholder groups, and remain matters of discussion internationally, e.g. in the Long-term Safety Criteria (LTSC) Task group of the OECD/NEA Radioactive Waste Management Committee (RWMC).

Evolution of hazard

The hazard associated with radioactive waste results primarily from the external and internal radiation doses that could arise in the absence of adequate isolation (including shielding) and containment of the waste. Although the radioactivity of the waste declines significantly with time, the presence of very long-lived radionuclides means that the waste may continue to present some level of hazard for extremely long times.

Uncertainty in the evolution of the repository system

Geological repositories are sited and designed to provide protection of man and the environment from the hazard associated with long-lived radioactive waste by containing and isolating the waste. Though the sites and engineered barrier designs are generally chosen for their long-term stability and predictability, repository evolution is nonetheless subject to unavoidable uncertainties that generally increase with time. Furthermore, radiological exposure modes, which are closely related to individual human habits, can be predicted with confidence only in the very short term. The decreasing demands on system performance as a result of the decreasing hazard of the waste partly offset the increasing demands that uncertainties place on safety assessment. Nevertheless, while some hazard may remain for extremely long times, increasing uncertainties mean that there are practical limitations as to how long anything meaningful can be said about the protection provided by any system against the hazard. These limitations should be acknowledged in safety cases.

Stability and predictability of the geological environment

Repository sites are chosen for their geologically stability and broad predictability. Although predictions of the evolution of even the most stable sites become uncertain over long enough timescales, many national programmes have identified sites that are believed to be stable and sufficiently predictable over timescales of millions of years or more, based on an understanding of their geological histories over still longer timescales. Others plan to search for such sites. For example, in Germany, any new site selection process is likely to follow the procedure set out by an interdisciplinary expert group (Arbeitskreis Auswahlverfahren Endlagerstandorte – AkEnd), which requires the identification of a site having an "isolating rock zone" that will remain intact for at least a million years, based on the normal evolution of the site.

Repository siting and design and the levels of protection required in regulation

In repository siting and in designing complementary engineered barriers, the robustness of the system is a key consideration. Thus, events and processes that could be detrimental to isolation and containment, as well as sources of uncertainty that would hamper the evaluation of repository evolution and performance over relevant timescales, are, as far as reasonably possible, avoided or reduced in magnitude, likelihood or impact.

The isolation of the waste from humans is regarded as an essential role of the geological environment, and must be considered at all times addressed in a safety case. On the other hand, both the geological environment and the engineered barriers can contribute to ensuring that radionuclides are substantially contained, and the roles of the different system components in this regard can vary as a function of time. Most programmes aim for containment of the major part of the radionuclide inventory at least within a few metres from the emplacement horizon and certainly containment in the geological stratum or immediate rock mass where the repository is located, although, in some disposal concepts, more mobile radionuclides, such as ^{36}Cl and ^{129}I, are expected to migrate relatively rapidly (in terms of geological timescales) if released from the repository. The consequences of these and any other releases need to be evaluated.

Regulations specify what needs to be shown, and in some cases over what time frames, in order that a proposed site and design can be considered to offer acceptable levels of protection from this hazard.

The minimum levels of radiological protection required in the regulation of nuclear facilities are usually expressed in terms of quantitative dose or risk criteria. In the case of geological repositories, quantitative criteria apply over time frames of at least 1 000 or 10 000 years and sometimes without time limit. It is, however, recognised in regulations and safety cases that the actual levels of dose and risk, if any, to which future generations are exposed cannot be forecast with certainty over such time frames. Models are used that include certain stylised assumptions, e.g. regarding the biosphere and human lifestyle or actions. Additionally, the "dose" that is being calculated is what radio-protectionists refer to as "potential dose". Hence, the calculated values are to be regarded not as predictions but rather as indicators that are used to test the capability of the system to provide isolation of the waste and containment of radionuclides.

The concept of "constrained optimisation" put forth by the International Commission for Radiological Protection (ICRP) in ICRP-81 is also often a requirement; it is reflected in various terminology but encompasses the concepts in ICRP-81 that a series of technical and managerial principles, such as sound engineering practice and a comprehensive quality assurance programme are key elements to enhance confidence in long-term safety. For geological repositories, optimisation is generally considered satisfied if all design and implementation decisions have been taken with a view to ensuring robust safety both during operations and after repository closure and if provisions to reduce the possibility and impact from human intrusion have been implemented. In some regulations, alternative or complementary lines of evidence for protection and other more qualitative considerations are required or given more weight beyond 1 000 or 10 000 years, in recognition of the fact that increasing uncertainties may make calculated dose or risk less meaningful.

Generally, although the measures of protection specified in regulations may vary with time, this does not necessarily reflect a view that it is acceptable to expose future generations to levels of dose or risk different to (and higher than) those that are acceptable today. Rather, it reflects practical and technical limitations: in particular, regarding the weight that can be given to results of calculations over such long time frames and the meaning of dose estimates at times when even human evolutionary changes are possible. There is ongoing discussion on the issue of how to define and judge criteria for protection in the furthest future, as a basis for decision making today (see e.g. the ongoing work in RWMC's Long-term Safety Criteria task group).

National policies in the planning of pre- and post-closure actions

Current national programmes vary considerably in the degree to which an extended open period prior to the complete backfilling and closure of a repository is foreseen. The ethical principle that future generations should be allowed flexibility in their decision making favours assigning to future generations the decisions regarding backfilling and closure. Early backfilling and closure may, on the other hand, be seen as more consistent with the ethical principle that undue burdens should not be passed on to future generations, and also guards against the possibility of future societal changes, which could lead to lapses in the necessary maintenance and security. Another concern, particularly for repositories in saturated environments, is that detrimental changes to the system may occur or events take place during the open period, and that the severity of these changes or events will increase with the duration of the open period. In such cases, it may be prudent to work towards closure soon after completion of waste disposal. It is, however, recognised that such technical considerations need to be balanced against other factors, such as policies on monitoring and retrievability, which may require a more prolonged open period, or the views of the local community. In any case, it is widely agreed that flexibility regarding the open period should not extend so long as to jeopardise long-term safety.

Monitoring of a wide range of parameters within and around a repository is likely to be carried out prior to repository closure, and some monitoring may take place in the post-closure period. Other post-closure requirements may include passive measures such as record keeping, and active measures such as restricting access to a site. A key consideration in planning such measures is that they should not jeopardise the isolation of the waste and the containment of radionuclides. The planned duration of active measures, including monitoring, varies between programmes, as does the period during which either active or passive measures can be relied upon in a safety case, in particular to deter human intrusion. A cautious approach is generally applied in which no credit is taken for such measures in averting or reducing the likelihood of human intrusion beyond around a few hundred years. This is because of the potential for societal changes and our inability to predict the priorities of future generations. The target time frame for active measures may be longer than this, however, for example to improve societal acceptance and confidence. Furthermore, measures that are more passive, such as durable markers or record keeping, may in reality inform future generations about the existence and nature of a repository over periods well in excess of a few hundred years.

Developing and presenting safety cases

In the interests of gaining, sharing and showing understanding of a system as it evolves over long timescales, it is useful to both define and develop means to address various time frames in a scientific and logical manner.

How to deal with generally increasing uncertainties in repository evolution and performance is a key problem to be addressed in developing a safety case. Quantitative safety assessment modelling tends to focus on potential radionuclide releases from a repository to the biosphere. The uncertainties affecting these models can generally be quantified or bounded and dealt with in safety assessment using, for example, conservatism or evaluating multiple cases spanning the ranges of uncertainty.

Where the consequence of calculated releases are expressed in terms of dose or risk, the biosphere must also be modelled. The biosphere is affected by human activities and relatively fast or unpredictable surface processes, and there is consensus that it is appropriate to carry out biosphere modelling on the basis of "stylised biospheres". That is, representations of the biosphere can be based on assumptions that are acknowledged to be simplified and not necessarily realistic, but are agreed and accepted internationally as valid for modelling studies.

Where regulations do not explicitly specify the time frames over which protection needs to be considered, the implementer has the challenge of deciding on the level and style of assessment to be carried over different time frames, which will then be subject to review by the regulator. Calculations of releases cannot, however, extend indefinitely into the future. Factors to be considered when deciding the time at which to terminate calculations of radionuclide releases include:

- Uncertainties in system evolution which generally increase with time.
- The declining radiological toxicity of the waste – as noted above, spent fuel and some other long-lived wastes remain hazardous for extremely long times.
- The time of occurrence of peak calculated doses or risk.
- The need for adequate coverage of very slow long-term processes and infrequent events.
- The need to address the concerns of stakeholders.

Truncating calculations too early may run the risk of losing information that could, for example, guide possible improvements to the system. Importantly, if the assumptions underlying the models are questionable in a given time frame, then qualifying statements must be made when presenting the results, so that they may be properly interpreted. The time frames covered by modelling in recent safety assessments range from 10 000 years to one hundred million years, although a million years seems to be emerging as a commonly accepted time frame in recent safety assessments.

In considering safety beyond the time frame covered by calculations of release, some programmes have developed arguments based on comparing the radiological toxicity of waste on ingestion with that of natural phenomena (e.g. uranium ore bodies; although the limitations of such arguments are acknowledged). Other lines of argument refer to the geological stability of a well-chosen site, which can provide evidence, for example, that uplift and erosion will not lead to exposure of the waste at the surface over timescales of millions of years or more. In practice, a number of different arguments may be presented, and different arguments may provide the most confidence in safety over different timescales, and to different audiences.

In the interests of communicating effectively with stakeholders and to build stakeholder confidence, safety cases need to be presented in a manner that communicates clearly how safety is provided in different time frames. This includes early time frames when substantially complete containment of radionuclides is expected, as well as later times, where some limited releases may occur. Non-specialist audiences are often (though not universally) most concerned about safety at early times – a time frame of the order of a few hundred years after emplacement. Especially when presenting safety cases to such audiences, it can be useful to emphasise the strong arguments for safety in this time frame. It may also be useful to devote a specific section of a safety report to explain the handling of different time frames, how uncertainties are treated (and how this varies with time), how multiple safety and performance indicators are used, and how to interpret the results as a function of time.

Refinement of understanding of key issues related to timescales coming from this work

The present document has revisited the various issues discussed in the earlier "lessons learnt" report of 2004, and discussed additional areas such as the planning of pre- and post-closure actions. For some issues, current understanding is unchanged compared to the 2004 document, whereas for others, some differences can be identified.

The timescales over which the safety case needs to be made

The 2004 document argued that ethical considerations imply that the safety implications of a repository need to be assessed for as long as the waste presents a hazard. The present report recognises that there are different and sometimes competing ethical principles that need to be balanced. It seems that the discussion of how to come to a balanced and socially acceptable view is still at an early stage in many nations and internationally. In addition, this discussion should be informed by inputs from a wide range of stakeholders, which is beyond the remit of the working group that produced this report.

The limits to the predictability of the repository and its environment

Both the 2004 document and the present report reflect a view that the limits to the predictability of the repository and its environment need to be acknowledged in safety cases.

Arguments for safety in different time frames

Both the 2004 document and the present report note that the types of argument and indicators of performance and safety used or emphasised may vary between time frames. The present report cites ongoing developments in the approaches to partition future time into discrete time periods and developments in phenomenological and functional analysis in different time frames.

The 2004 document observes that regulations are increasingly providing guidance on the use of lines of argument that are complementary to dose and risk. This observation is confirmed in the present report in the discussions of recent regulations and draft regulations in Sweden and the United States. The present document emphasises that complementary lines of argument are required, not only to compensate for increasing uncertainties affecting calculated releases at distant times, but also to address other aspects of safety, especially continuing isolation, even at times beyond when quantitative safety assessments can be supported. Complementary arguments might be based, for example, on the absence of resources that could attract inadvertent human intrusion and on the geological stability of the site, with low rates of uplift and erosion. The argumentation for safety in the very long term is, however, an issue of ongoing discussion that is likely to require a consideration of ethical principles, since it relates to our ability and responsibility to protect the environment in the very remote future.

Interpretation of dose and risk calculated in long-term safety assessments

Both documents note international consensus that doses and risks evaluated in safety assessments are to be interpreted as illustrations of potential impact to stylised, hypothetical individuals based on agreed sets of assumptions. The assumptions are site-specific. Their basis, derivation, and level of conservatism can vary significantly; for this reason, the calculated results from safety cases should be carefully analysed if they are compared among national programmes.

Complementary safety and performance indicators

The 2004 document states that the use of complementary indicators, their weighting in different time frames, as well as reference values for comparison, are issues that may well deserve further regulatory guidance. Recent regulatory guidance cited in the present report shows that safety indicators and requirements are not only quantitative, but can include more qualitative concepts such as best available technique (BAT) and optimisation. This issue of how to evaluate compliance with requirements expressed in terms of qualitative indicators may, however, require further consideration, as may the interpretation of optimisation of protection when dealing with impacts across different timescales.

Addressing public concerns

Both documents note that the period of a few hundred years following emplacement of the waste may deserve particular attention in documents aimed at the public. The present document makes a number of other specific recommendations regarding the communication of how safety is provided in different time frames.

Conclusion

In conclusion, the range of timescales that needs to be addressed within our safety cases presents considerable challenges. The decreasing demands on system performance as a result of the decreasing hazard associated with the waste with time partly offset the demands that increasing uncertainty (and decreasing predictability) place on safety assessment. Nevertheless, as discussed throughout this report, while some hazard may remain for extremely long times, increasing uncertainties mean that there are practical limitations as to how long anything meaningful can be said about the protection provided by any system against these hazards. Thus, time and level of protection – and assurance of safety – are linked to one another. These practical limitations need to be acknowledged in safety cases.

The various methods and approaches discussed in this report demonstrate that there are a range of approaches available now that can be called upon for developing and presenting safety cases. Furthermore, there is room to develop these approaches, for example, taking account of experience gained from stakeholder interactions to develop presentations suited to the needs of less technical audiences.

A general observation from the timescales questionnaire responses is that, in many programmes, a significant part of the final responsibility for the handling of timescales issues in safety cases is assigned to the implementer. Apart from setting safety criteria (that may or may not vary over time), the regulator's task is generally to review and point out any difficulties in the approaches to the handling of timescales issues adopted by the implementer. Wherever the final responsibility lies, a dialogue between the implementer, regulator and other stakeholders is valuable in resolving the issues in a manner that is widely accepted and such dialogue is ongoing in many programmes.

Appendix 9

SUMMARY OF EXPRESSED VIEWPOINTS AT THE NOVEMBER 2006 WORKSHOP

Background

The objective of the workshop was to explore diverse perspectives on long-term safety regulation, from the starting point that:

(1) This process involves not only technical considerations but necessarily reflects societal values on issues such as the appropriate balance between risks from hazardous activity given the associated benefit.
(2) Differences between criteria in different countries are likely to result largely from such non technical considerations.

To explore these broader aspects of regulation the workshop brought together not only regulators, implementers and technical specialists in the field of radioactive waste management but also philosophers, theologians, researchers, ethicists, sociologists and other experts.

A variety of viewpoints were voiced either in oral presentations or in the ensuing discussions. These viewpoints have been collected and organised in six broad areas. Workshop participants have contributed by reviewing and commenting on the present collection of viewpoints, which is provided here for convenience. More detailed and precise information is provided in the summary of the workshop and the contributed papers.

Necessary diversity of regulatory processes and regulation

- There appear to be wide variations in numerical criteria. However, these should be looked at in the broader frame of:
  - Assessment approaches (e.g. “conservative/bounding” vs. “realistic”, and how to address sources of uncertainty).
  - The basis for criteria (absolute risk; dose based on current radiation protection criteria; or dose based on comparisons to natural levels).
  - Compliance judgements (limit vs. target, “hard” vs. “soft”, …).
  - On whether and how the criteria should change with time scale.
- For the above reasons, simple direct comparison of long-term numerical criteria used in different member countries may provide a misleading picture unless the broader context of how the criteria are implemented is taken into account. Other reasons amplified in the discussion paper include the complexity and non-uniformity of the regulatory decision-making process across nations; different approaches on how to characterise and define protection in the distant future; different approaches to dealing with ethical issues related to the nature of current society obligations to the future; and, reflecting all of this, international guidance that has been evolving in time and still is in the process of evolution (e.g. the recent ICRP guidance development process).
- Regulatory policies and decision making are not solely based on technical matters. They take into account expectations of civil society, international experience, ethical considerations and the

practical needs of implementation. Accordingly, it is important to consider “the regulatory system” or the societal decision making process, rather than simply “the regulator”. The decision-making process involves a range of national institutions encompassing government, parliament and other players besides the lead technical regulatory authority that is responsible for the licensing and approval process.

- Since it must be assumed that, eventually, institutional control of a disposal facility will no longer be maintained, licensing of geological disposal may be seen an act of trust not only in the regulator, but in the broader regulatory system and decision-making process.
- In general, the workshop participants agreed with new ICRP recommendations (draft 2006), which recognise that decision-making processes may depend on a variety of societal concerns and considers that the involvement of all concerned parties is needed to achieve more flexible and sustainable decisions.

Assuring long-term radiological protection

- There was common ground amongst all participants on the importance of providing a high level of protection. On the other hand, the lack of capacity for perpetual active protection should be acknowledged in regulations.
- The public and those affected by implementation of a repository are more likely to accept repository proposals if their cultural, societal and ethical views have been considered alongside the technical considerations in formulating a strategy for testing repository performance. The regulator may want to interact with the public on this specific aspect and receive feedback.
- In Cordoba (1997) there was consensus that numerical criteria for radioactive waste disposal should be considered as references or indicators, addressing the ultimate safety objectives, rather than limits in a legal context. A number of important aspects were emphasised such as the nature of long term performance assessments, which are not predictions but rather illustrations of long-term behaviour and safety. The notion of potential exposure[1] was emphasised.
- The evolution of the international guidelines over time (see ICRP-81) indicates that dose and risk may lose their significance as measures of health detriment beyond a few hundred years, however calculated dose and risk over the long term can be utilised as indicators of protection provided by the disposal system. Virtually any other indicator may be subject to uncertainty over the long term, which has lead to increasing attention being placed on sound engineering practices, and the progressive introduction of additional concepts that reflect the level of confidence that the disposal system can discharge its defined safety functions (e.g. constrained optimization, BAT, and application of sound managerial principles to repository design and implementation).
- There appears to be today an *increasing* use by implementers of the concept of safety functions, whereby one or several system components can contribute to a single safety function or, vice versa, where a single component may contribute to several safety functions.[2] Implementers use the concept of safety functions in order to design, describe and help evaluate the performance of the disposal system.

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1. Dose and risk – as used in the context of long-term management of waste – are potential doses and risks in the sense of ICRP-81. According to the latter: “The term “potential exposures” refers to situations where there is a potential for exposure but no certainty that it will occur, i.e., the type of situations of concern in the long term following closure of a solid radioactive waste disposal facility” [see par. 24]
2. See for instance Sect. 3.1.3 of the “Time Frames” document of the IGSC http://www.nea.fr/html/rwm/docs/2006/rwm-igsc2006-3.pdf

- The Cordoba Workshop (1997) observed that there may be no widely accepted basis for the use of timescale cut-offs, although they may provide a pragmatic basis for regulatory decisions. Accordingly, some nations may choose to focus on a time frame which avoids consideration of a new ice age when all aspects of life may be so impacted that the repository may be minor in comparison; other nations may decide that impacts to the first several generations are more important than those occurring after millions of years. The different approaches respond to different national contexts. It was observed, that where cut-offs are used, their basis and use ought to be explained.[3]
- As shown by the time frames study of the IGSC, the direct radiation hazard from some high-level radioactive wastes remains at significant levels for very long periods, beyond hundreds of thousands of years and beyond conventional periods of regulatory concern.[4] *Isolation* (removal of waste from the accessible environment) thus adds value for much longer times than indicated solely by dose calculations based on ingestion (radiotoxicity) considerations.
- It would be helpful, for decision-making purposes, if the safety case provided comparison with other management options and an indication of the fate of the repository in the very long term.
- In formulating a radiation protection strategy and test for long term performance of the repository, societal, cultural and ethical views along with technical perspectives may be important in the selection of national performance criteria and time frames. International efforts should be directed at promoting exchanges among nations to understand the bases for safety objectives and performance strategies to identify similarities and differences.

Tools to demonstrate repository performance

- The workshop expressed a common view that assuring a high level of radiation protection requires tools to demonstrate acceptable performance of the repository system. To enhance public confidence, many countries are examining a range of complementary indicators to dose and risk, including multiple lines of reasoning. Where complementary indicators are used, it is important to consider the practicality of implementing such indicators in terms of demonstrating compliance with regulatory standards. Also, such indicators should focus on repository system functions most important to repository performance.
- There appears to be an increasing attention to approaches supporting constrained optimisation, use of best available techniques (BAT), use of multiple lines of argument, including and use of supplementary indicators to dose and risk. The concepts of as low as reasonably practicable (ALARP) or best available techniques (BAT) would require, however, additional clarification and international reflection. Some reflections are as follows:
  - Optimisation is constrained by a variety of factors, including societal, economic and technological constraints. Optimisation may thus be applied not only to calculated outcomes of performance analyses, but also to other aspects.
  - Optimisation requires a balance between short- and long-term protection. For instance, keeping a repository open for reasons other than safety needs to be balanced with the risk of increased accidents for mining personnel.

3. (a) There was a plea that regulation not go beyond times that can be reasonably predicted (b) Cut-offs based on ingestion radiotoxicity are undermined by the fact that external exposure due to gamma radiation from SF (and HLW) continues at high-level for several millions of years. (see also next bullet point).
4. The IGSC study, NEA/RWM/IGSC(2006)3, shows that a relatively small piece of HLW glass or SF – if unshielded – is able to give doses in the order of millisieverts per hour over periods of millions of years.

- Some programmes make a distinction between optimisation and BAT. The former is concerned with reducing (radiological) impacts to ALARP based, e.g., on a dose target; the latter is about choosing techniques that minimise, to the greatest reasonable extent, the potential for releases though the barrier systems to occur (system robustness, sound siting and well-proven engineering practices).
- Given that it is not certain that impacts will occur ("potential exposures"), BAT may be regarded as the ultimate guarantee for safety. It is important to recognise that the BAT concept embodies not only technological aspects but also the managed process of implementation, e.g., sound siting and engineering practices; and to recognise as well that it embodies the element of practicability (see the definition of BAT in the IPPC Directive[5] of the EC).
- Accepting the priority of BAT *vis-à-vis* optimisation is a way of saying that safety is an intrinsic property of the system as designed and built. If safety is an intrinsic property of the system as designed and built, it can only be illustrated by means of some indicator (test or measures) related to the system features and functions, i.e., ultimately, indicators related to BAT. This had led to proposals for developing complementary indicators such as radionuclide fluxes through components of the system and radionuclide concentrations in the groundwater.
- The reliance that can be placed on calculated doses and risks decreases with time,[6] leading to an increasing need to consider also other indicators linked to the application of BAT.

- The circumstances in which generic reference values for safety indicators can be drawn from nature are not universally agreed.

- The safety case needs to explain the basis for the assumption that future scenarios are adequately bounded. It must be realised that, at times, hypothetical scenarios are created in order to perform calculations of exposures. For instance, we have come to accept *reference biospheres* and that safety assessments assume that future human beings will not change from those of the present-day. Yet, human beings have existed for only about 200 000 years.[7]

- The workshop participants agreed that a range of technical tools is available for illustrating potential repository performance over the long term. Each of these tools has advantages and disadvantages for implementation and for use in a regulatory system. In selection of these tools for use by different countries, broad perspectives should be considered in determining their value for enhancing public confidence and well as serving as indicators in satisfying regulatory criteria.

Ethical concerns: burdens *versus* responsibility and duties *versus* capacity

- Ethical considerations are important when deriving regulatory requirements.

- Many waste management programmes have concentrated almost exclusively on technical aspects, or have used technical specialists to deal with ethical issues. This can and should be improved.

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5. http://ec.europa.eu/environment/ippc/index.htm
6. It must be recalled that ICRP-81 suggests that dose and risk should not be seen as measures of health detriment beyond a few hundred years (from emplacement of the waste).
7. Indeed, could one not use this argument as one of the basis for cut-off in regulation? [Note that we do similar types of reasoning when we say that (a) no archives may be reasonably kept for more than 500 years, (b) monitoring and active surveillance can operate for a couple of hundred years only, (c) that our obligations are strongest during times that we can comprehend and are the typical times of our democratic institutions (200 years).]

- Most[8] ethicists accept that one generation has responsibilities towards succeeding generations, though views differ on the nature of these obligations and on their duration. There is the view that this responsibility extends so long as the impact persists, i.e. there is no cut-off. This absolutist view is countered by the more pragmatic position that responsibility necessarily must diminish in time reflecting capacity to discharge the responsibility. Even if it is argued, in the context of responsibility towards future generations, that the *duty of protection* does not change over time, it is clearly **accepted** that our *capacity* to fulfil the duty is time dependent.

- Timescales over which we must reflect about burdens and responsibilities to future generations might be sub-divided as follows:
  - The socio-cultural time scale (a few generations).
  - The timescale over which we have reasonable confidence in the safety assessment calculations.
  - The timescales for which materials performance and geological processes are reasonably predictable.
  - The timescales beyond which processes are beyond any reasonable quantitative prediction.[9]

- There is an increasing recognition that the timescale for implementation of any repository, even one that does not explicitly involve retrievability, nevertheless involves several generations, i.e. perhaps equivalent to the socio-cultural timescale mentioned above.

- Transferring burdens to succeeding generations cannot be avoided. Consistent with the sustainability principle, if burdens are transferred, then opportunities/rights should also be given

- It would be useful to have tests for assessing that (a) duties that can reasonably be carried out are, in fact, performed; (b) remaining duties are transferred as responsibly as possible to subsequent generations in order to offer them maximum flexibility to discharge their duties; (c) transferred burdens (cost, risk, effort) are, at least partially, compensated by transfer of information, resources and continuity of education/skills/research.

Making the long-term disposal objectives clear and transparent

- The regulations have to be explained and understood by the public and it is crucial that regulatory criteria and requirements are formulated in such a way that "demonstration of compliance" is facilitated in a credible manner. It is also important to ensure some level of international consistency on fundamental safety and radiological protection objectives and issues. In this context:
  - One of the challenges for the regulator is not to promise, nor require, the impossible.
  - Concepts such as "safety", "reasonable assurance", "potential dose" and "potential risk", complementary safety indicators, etc., used nationally or internationally, ought to be defined clearly. Internationally agreed definitions would be especially beneficial for concepts where here the relevant high-level objectives are common to all programmes. A case in point is the concept of "safety".
  - Regulatory tests need to communicate clearly and honestly what is meant by "safety" (e.g., "no harm" is not the same as "no exposure"), promise no more than can reasonably be delivered by the disposal system, and provide for safety case information that supports and illuminates safety decisions appropriate for different time frames.

8. There are some ethicists who hold that one generation does have responsibilities to later generations, but the rationale for this view is not widely accepted.
9. For such timescales there is no capacity for exercising responsibility.

- Sustainability is a concept that is not well defined in the context of disposal of long-lived radioactive waste. It would be useful to reflect on the opportunities and difficulties that the concept may provide to the regulator and implementer. It is not clear that the sustainability language of the Joint Convention ("needs and aspirations of future generations") is implementable in the normative way that is expected of regulations.

- The precautionary principle applies to all the considered alternative waste management options, including the "do nothing" alternative and any undue delay in taking decisions.
- The public appears to have higher demands with respect to protection from hazards from radiotoxic wastes than from chemotoxic wastes.[10] It may be useful to investigate the reasons for this, in order to ensure that policy and objective-setting aspects of the regulatory process address it effectively.

Foreseeing and explaining the decision-making process

- In the context of the long duration of the project (perhaps more than 100 years) there will be technological progress and incremental development of the repository. Regulators and regulatory guidance will have to adapt to this reality. In this context:
  - There is an increasing attention to the connection between regulation and stepwise decision making. Relevant questions include: should the formulation of regulations be understood as a stepwise process? If so, how can this process and the requirements it creates best be explained? How are judgemental issues going to be addressed? In the same vein, how should short- and long-term protection goals be balanced? What are the attributes of a robust process? How to guarantee a certain degree of stability regulatory positions, e.g., in order to allow a certain degree of legal and investment security for the implementers?
  - Dialogue between regulators and implementers is important in any licensing process. In the case of a stepwise decision-making process it is crucial that this dialogue start in the early phases of the process and continue all along the process. The dialogue ought to be managed so that the independence of the regulator is clearly maintained.
- The ability to intervene (control) is central to normal regulatory practice and to the concept of safety. Relinquishing control requires an act of trust – in the technology and the legal and regulatory systems – taken by the current generation on behalf of future generations. Decision-making process components ought to be designed to improve the perceived legitimacy of the process and therefore lead to improved trust.
- Factual and value-laden components of regulatory guidelines and licensing decisions need to be distinguishable, for the benefit of the public and for political decision makers. One difficulty faced by citizens is that the practical implementation of the regulations is an expert task and may not be transparent to members of the public. For this reason, some member countries recognise that host communities may wish to have access to expert advice on the technical issues under consideration.
- The general public is often concerned that decision making for implementation follows a legitimate process, i.e. one that is established in advance and is subject to democratic ratification. Key elements for success generally appear to include: openness and transparency, a staged process, participation, right to withdraw, partnership, and community benefits. This approach for

10. According to the UK Sustainable Development Committee: "it is impossible to guarantee safety over long-term disposal of (nuclear) waste", which implies that nuclear fission power should be shut down; at the same time, in the same country, CoRWM, the committee on Radioactive Waste Management, recommended geological disposal for existing wastes as a broadly acceptable solution.

decision making may also have implications for regulators, such as openness in decision making, greater consistency of regulation and integration of societal concerns.

- It may be argued that models of participation that have emerged during recent decades require further evolution in terms of providing for appropriate levels of public access to decision making, including the process followed by the regulatory authorities.

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