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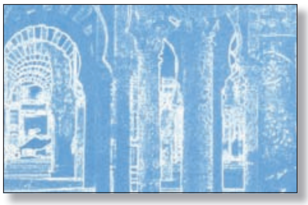
Towards Transparent, Proportionate and Deliverable Regulation for Geological Disposal

Workshop Proceedings
Tokyo, Japan
20-22 January 2009



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FOREWORD

The Regulators' Forum (RF) of the NEA Radioactive Waste Management Committee (RWMC) is a well-established forum of high-level regulators for radioactive waste management and the decommissioning of nuclear facilities. The RF was established in 1998 and current representation brings together regulatory bodies from 17 OECD countries. The forum provides its members with an opportunity to openly discuss and learn about national experience and good practice in regulation with a view to refining the regulatory systems in this field. Through its workshops, the forum also provides an opportunity for effective interaction and dialogue between regulators, implementers, R&D specialists, policy makers and social scientists to the benefit of all.

Since its inception, the RF has been examining the nature of the regulatory system for radioactive waste management and how the regulatory function is fulfilled. In the technical area, the RF has particular interest in safety criteria, the regulatory aspects of waste retrievability provisions, optimisation and long-term monitoring of geological repositories as well as emerging regulatory practices in the field of decommissioning. In terms of regulation and society, the RF recognises the importance of keeping abreast of the ethical issues associated with our responsibilities to current and future generations as well as societal expectations regarding the role of regulators. Further information on the RWMC Regulators' Forum can be obtained from the NEA website (www.nea.fr/html/rwm/regulator-forum.html).

In January 1997, the NEA "Córdoba workshop" on "Regulating the Long-term Safety of Radioactive Waste Disposal" provided an important reference point for regulatory issues in the field of geological disposal of radioactive waste. Twelve years on, these proceedings document the RWMC Regulators' Forum workshop entitled "Towards Transparent, Proportionate and Deliverable Regulation for Geological Disposal", which served to verify the current status and needs in regulation. The workshop was held in Tokyo, Japan on 20-22 January 2009 and was hosted by the Nuclear and Industrial Safety Agency (NISA), in co-operation with the Japan Nuclear Energy Safety Organisation (JNES), on behalf of the Government of Japan. It was attended by approximately 70 participants from 13 countries and 3 international organisations. Participants included regulators, implementers, policy makers, R&D specialists and academics.

Starting from a set of well-targeted questions, the workshop allowed a very wide exchange of views and experience among participants. The final, shared judgment was that the workshop accomplished its main aim, namely to deal with the questions of transparent, proportionate and deliverable regulation for long-term safety in as broad a fashion as possible in order to help assess progress since Córdoba. Themes addressed included duties to future generations, timescales for regulation, stepwise decision making, roles of optimisation and best available techniques (BAT), multiple lines of reasoning, safety and performance indicators and limitations, recognition of uncertainties and the importance of stakeholder interactions.

The main findings of the workshop from the point of view of the regulators were discussed and approved by the members of the RWMC Regulators' Forum at their annual meeting in March 2009. The workshop findings help complete our understanding of the status of long-term safety regulations worldwide and provide the basis for deciding which issues deserve the highest priority and which ones are closer to being solved at the international level. These proceedings include the workshop findings, a summary of all presentations and discussions, and the original contributed papers. The Tokyo workshop proved to be as stimulating as that of Córdoba. One of its outcomes will undoubtedly be to spur further work in the coming years in the field of regulation for geological disposal at both the national and international levels.

Acknowledgements

The NEA wishes to express its sincere thanks to the Government of Japan for hosting the workshop. The NISA and the JNES were especially effective in helping organise the event.

It also wishes to express its gratitude to the Core Group of the Regulators' Forum which acted as the Programme Committee of the event under the Chairmanship of Mr. Georg Arens.

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FACTUAL SUMMARY OF PAPERS, PRESENTATIONS AND DISCUSSIONS

Session 1: Introduction

Session 1 was chaired by Uichiro Yoshimura, Deputy Director for Safety (OECD/NEA). This session provided the opportunity to be informed of the Japanese institutional scene on geologic disposal as well as to acquaint the Japanese dignitaries and workshop participants with the RWMC Regulators' Forum, the challenges we face and the aims of the workshop. A lecture on accomplishments and issues in long-term safety regulation prepared discussions during the workshop.

The session Chairman, **Uichiro Yoshimura (OECD/NEA),** welcomed the participants of the workshop hosted by the Government of Japan through the Nuclear and Industrial Safety Agency (NISA) in co-operation with the Japan Nuclear Energy Safety Organization (JNES). He explained the role of the NEA as policy adviser to its member governments, making authoritative statements and forging common understandings. He then recalled that the objectives of the workshop, which were to debate on the foundations of regulations for geological disposal of long-lived high-level nuclear wastes and take the opportunity to learn about the geological disposal scene in Japan. He acknowledged that dealing with long term safety is a challenge for the regulator. It is important in this domain neither to oversimplify nor to raise unachievable expectations. On behalf of the NEA, he wished all participants a successful workshop.

Eiji Hiraoka, Deputy Director-General for Nuclear Fuel Cycle at NISA welcomed the participants on behalf of the Japanese hosts. He thanked the OECD/NEA Secretariat, the members of the Programme Committee and members of JNES who had made efforts to organise the workshop. E. Hiraoka said that the issue of high-level radioactive waste management is currently a very significant one in Japan's nuclear policy. For the further development of the utilisation of nuclear energy, it is essential to resolve the high-level radioactive waste management and related issues scientifically and rationally as well as to gain the approval of the nation. He stressed the importance for Japan to develop knowledge through safety research. In conclusion, he expressed his wishes for the success of the three-day workshop and for the participants a pleasant visit to Japan.

Georg Arens, Chair of the RWMC-RF, presented the role and work of the Regulators' Forum of the NEA Radioactive Waste Management Committee (RWMC-RF). The RWMC-RF provides regulators with an opportunity for open discussion and exchange of information about national experience and practices for regulation with a view to refinement of regulatory systems in radioactive waste management and decommissioning in the NEA member countries. The RF recognises the importance of effective interaction between regulators, implementers, policy makers and scientists, in order to reach a wider understanding of the issues associated with our responsibilities to present and future generations, and of the societal demands impacting directly on the role of the regulators in the field of management of radioactive materials and waste. He explained the role of the workshops and said that this was the first of a series of workshops in an international context the RF has planned to organise.

G. Arens recalled the regulatory functions explaining that the elements associated with a regulatory system may be conveniently depicted as a cycle that embraces the principle of continuous improvement. These elements include: policy, objectives and independent advice (e.g. in the elaboration of national plans for the long-term management of spent fuel and radioactive waste), regulations/rulemaking and associated guidance, pre-licensing and licensing, supervision and control. The RF comparative study of regulation of radioactive waste management in NEA member countries shows that there is no unique or best way of to deliver the various elements of the regulatory cycle. The formal structures and organisational arrangements depend on the national constitutional structure, legal and institutional framework and, to a large extent, on national regulatory culture, e.g. expectations on how prescriptive regulation should be. In today's context, it has become increasingly important; however, for the regulators to maintain transparent processes that are open to scrutiny and to serve as sources of information and expertise to local communities.

Specific attention has been given so far to the regulatory criteria for the long-term performance of geological disposal. The RF studies have shown differences between national radiological criteria that are difficult to explain in simple terms to the general public. The RF studies observe that our capacity to secure delivery of any defined standard for protection diminishes with time, which raises technical and ethical questions about what we should and can deliver and over what timescales. Sustainability and our obligations to future generations are subjects of central consideration in national policies of long-lived waste disposal and are aspects of great importance to regulatory bodies.

Questions specific to the present workshop have arisen from a series of recent RWMC-RF activities. He also mentioned the survey of countries' regulatory positions that served to prepare the present workshop [NEA/RWMC/RF(2008)5/PROV]. Other workshop materials include (a) a review study on progress in regulation for geological disposal since the Córdoba Workshop of the NEA in 1997, [NEA/RWMC/RF(2008)6], and (b) a review study on guidance in the field of optimisation of geological repositories [NEA/ RWMC/RF(2008)2]. All these materials were shared with the workshop participants ahead of the workshop. The general purpose of the workshop is to deal with the questions of transparent, proportionate and deliverable regulation for long-term safety in as broad a fashion as possible.

Hiromichi Matsuo, Director of the Radioactive Waste Regulation Division (NISA) introduced the main features of radioactive waste management in Japan. The nuclear policy is established by the Atomic Energy Commission (AEC), Cabinet Office. The major actors in the field of nuclear energy are under the responsibility of the Ministry of Economy, Trade and Industry (METI) and the Ministry in charge of Science and Technology (MEXT). The NPPs are operated by utility owners TEPCO and KEPCO, while the Japan Nuclear Fuel Limited (JNFL) has been operating nuclear cycle facilities and activities, and the Nuclear Waste Management Organization (NUMO) established by law in 2000 is planning to operate the facilities and activities of geological disposal in the future. The organisations in charge of the regulation are NISA, an agency of METI, concerning radioactive waste from nuclear fuel cycle facilities, another is a division of MEXT concerning waste from isotope producing facilities. The Nuclear Safety Commission (NSC) of the Cabinet Office develops basic concepts and verifies that radioactive waste is regulated according to these concepts.

H. Matsuo presented the different concepts of radioactive waste disposal. Surface disposals are in operation. Intermediate depth and geological disposals are being developed in the framework of a stepwise approach where R&D, conceptual designs and safety criteria are developed at each stage on the basis of safety reviews. The Federation of Electric Power Companies (FEPC) will present an application for the project of an intermediate depth disposal facility at a depth of 50 to 100 meters that we will reviewed on the basis on a methodology recently recommended by NSC in July 2007.

H. Matsuo insisted on the difficulty to maintain a mutual utilisation of research performed for the operator and the regulator and ensuring the independence of the regulatory research. He stressed the difficulty to be understood by the public on judging safety in the extremely long term and the need to develop an approach in this area. He praised the benefits of international co-operation on research on waste management.

Keigo Kajita, Director, Regulation Review Division (NSC), presented the current activities of the NSC for safety regulations on radioactive waste disposal. The role of the NSC is to establish the basic policy for regulating the safety of low-level and high-level waste management. Recommendations on upper limit concentration of radioactive nuclides for near-surface disposal (with/without engineered barriers) and intermediate-depth subsurface disposal have been established. An interim report on long-term safety assessment of low-level waste was published recently. Its conclusions were that, in reference to ICRP recommendations and based on classification of assumed scenarios into "Likely Scenarios", "Less-likely Scenarios", and "Inadvertent Human Intrusion or Rare Natural Event Scenarios", it would be reasonable to set the "standards" for determination of assessment results according to each scenario to 10 µSv/year, 300 µSv/year, and 10-100 mSv/year, respectively. These standards may be revised according to new ICRP recommendations. High-level waste should be solidified in a stable form and, after being stored for 30 to 50 years for cooling, buried under the ground in a geological disposal facility. The basic policy of safety regulation and site selection for high-level radioactive waste are under discussion. It will consider results from safety workshops organised to collect public opinion.

Tomio Kawata, Executive Director (NUMO) presented the geological disposal programme in Japan. NUMO was created in 2000 by the Radioactive Waste Final Disposal Act which describes the site selection process. The siting process is currently underway including a volunteer approach under NUMO's responsibility. The Final Disposal Act provides for a stepwise process of site investigation with a safety case including a demonstration of compliance with siting factors. The safety case will be refined step by step as the investigations proceed from one stage to the next. One of the key issues is the closure strategy, which is now a part of the overall safety strategy because it is closely linked to post-closure safety and to important issues such as monitoring and retrievability. T. Kawata insisted on the importance to share a common understanding of fundamental issues and a common safety philosophy among the countries involved with a view to successful implementation of the disposal programme in each country. In this regard, he declared that the role of the NEA/RWMC is indispensable.

Kazuyuki Kato, Deputy General Manager (FEPC) presented the current status of disposal of low-level waste at intermediate depth in Japan. He described the waste types, the basic concept, the waste form, the business plan, the safety basis and the safety assessment of the facility.

Claudio Pescatore, Deputy Division Head (NEA) presented a paper entitled "Progress made since the Córdoba Workshop in 1997 on safety regulation of geological disposal of radioactive waste and remaining challenges" by Allan Duncan and Claudio Pescatore. The purpose of the paper was to recall where we stood at the time of the Córdoba Workshop (1997) on the regulation of disposal of long-lived radioactive waste, to review developments since then, to present the key existing issues, and reflect on the remaining challenges and possible responses.

The overview study on progress in regulation for geological disposal since the Córdoba workshop [NEA/RWMC/RF(2008)6], provides a good list of references regarding the first two issues. The presentation of the existing issues takes advantage of the synthesis of the responses to a questionnaire completed by the regulatory organisations in preparation for this workshop. It warns regulators and implementers that international work to date seems to have created an expectation in the mind of the public and in some organisations that nothing less than a guarantee by the regulator is needed of maintaining current levels of protection of both individuals and populations practically forever, regardless of the impracticality of this. This expectation needs to be replaced with a carefully and clearly explained understanding of the choices involved in dealing with long-lived radioactive waste against a background of our responsibilities to both current and future generations and our practical capacity to deliver them.

Concerning the current major challenges faced in regulation, the paper comes back to the issue of the "guarantee" by the regulator and it observes that there is no doubt that there is a willingness to do the best to comply with the principle of protection and that we are broadly convinced that current concepts for geological disposal, supported by multiple lines of reasoning and application of best available techniques (BAT) will meet that principle. However, we do not have the capacity to prove or guarantee this, nor do we believe that it is possible in practice. Although we are advised that it is neither ethically nor morally necessary, we have still to resolve the issue to the satisfaction of the majority of the intelligent lay public and to provide some form of "reasonable assurance". Perhaps the very first step is to review our *technical capability* to provide confident assurance about specific outcomes over specific timescales. This might allow us to build on the work of the NEA Integration Group for the Safety Case (IGSC) by indicating the level of confidence we have in technical, geological and societal systems and in their regulatory assessment over specific periods. There will be a point in time, however, perhaps after about a thousand years from repository closure or relinquishment of institutional control, when we cannot claim total regulatory confidence about outcomes despite our use of current BAT and multiple lines of reasoning. Concerning the period beyond that time, it would be for policy makers and politicians to decide as a matter of policy, on behalf of current society, whether it is ethical or acceptable to leave a residual risk to future generations, e.g., in order to secure the benefits of nuclear power for the current and future generations.

Session 2: Fundamental Concepts and Evolution of International Guidance
[Chair: Marie-Pierre Comets, ASN Commissioner (France); Rapporteur: Carmen Ruiz Lopez, CSN Branch Chief (Spain)

National regulations and guidelines addressing the long-term safety of deep disposal facilities have been developed or revised in various NEA member countries during the last decade or so. The period has also seen these developments reflected in ICRP Recommendations, the Safety Standards of the IAEA and in wide-ranging publications of the NEA. The latter has provided a forum for articulation of the practical experience of waste regulators and has made a major contribution to understanding of national regulatory approaches. The NEA has also stressed the need for stakeholder involvement and for regulatory criteria and processes that are comprehensible and acceptable to the non-specialist public. Currently open issues include clarity on fundamental concepts, and addressing the protection of the needs and aspirations of future generations while also not creating undue burden and in the presence of decreasing capability of control with the passage of time.

One important point is that the use of language in this subject is not conducive to easy understanding by the public, certainly, and perhaps even by others. We need to consider how it might be made more accessible for the purpose of public involvement and regulatory dialogue. This might open the way to creating a readily comprehensible long-term objective for geological disposal that is consistent with the objectives for protecting society from the potential consequences of other activities with long-lived implications. The goal of the following presentations was to give an overall picture on these questions.

Carmen Ruiz López, (CSN) made a presentation on "International Guidance, evolution and trends". The purpose of the paper was to address the evolution of some of the fundamental concepts related to the objective of protecting future generations, with the intention of encouraging the discussion, and to determine whether the recent international guidance implied any change in philosophy and approach regarding the practical interpretation and implementation of such fundamental concepts.

C. Ruiz presented a general overview of the ICRP and IAEA guidance developments as well as the major changes or reorientations introduced by the latest ICRP Recommendations and IAEA Safety Standards that are relevant to long-term issues of geological disposal, namely, ICRP 103 (2009), ICRP 101 (2006), IAEA Safety Fundamentals SF-1(2006) and WS-R-4.

As for the ICRP developments, ICRP 103 confirms the validity of ICRP 81(1998) as the main ICRP reference for long-lived waste disposal. C. Ruiz then noted the extension of the scope of ICPR 81 mentioning some of the principles and recommendations related to the objective of protecting future generations and the view of the Commission for demonstrating compliance.

ICRP 103 and ICRP 101 reinforce the importance of transparency in the decision-making process and in the demonstration of confidence in situations of increasing uncertaintiesabout time, giving more weight to the process itself and strengthening the need for an open dialogue between regulator and implementer. In both recommendations the Commission recognises the influence of societal values in the final decision on the level of radiological protection, as well as the influence of social concerns and political aspects in the decision-making process.

The evolution of internationally agreed safety fundamental objectives and principles can be observed in the changes from the IAEA's Waste Safety Fundamentals of 1995 to the new Safety Fundamentals of 2006. C Ruiz presented a comparison of both documents focussing on the differences in dealing with fundamental concepts related to the safety objective, the protection of future generations and the consideration of "undue burden to future generations". The 2006 document applies to all phases of nuclear activities and facilities and the argumentation of the fundamental safety objective on protection of future generations is more general and less restrictive than in the 1995 document. The requirement of avoiding burden to future generations is now interpreted in the sense of seeking safe and environmentally acceptable solutions while not impeding moving the national programme forward.

Finally, C Ruiz gave an overview of the IAEA's WS-R-4 requirements document focussing on the capability and features of the disposal system to comply with the safety functions for the containment and isolation of the waste as well as on the requirements for confidence in safety. A trend is shown towards the development and use of safety-oriented criteria, and not just radiological-compliance standards.

Thierry Schneider, CEPN (France) presented the ICRP position detailed in a paper entitled *Dose concepts and the achievability of protection for the disposal of long-lived solid waste according to ICRP* by Annie Sugier (ICRP), Thierry Schneider (CEPN) and co-authors.

Th. Schneider introduced the subject explaining that the main strength of the ICRP is to set up a unified protection system applicable to all types of exposure situations. In 2007, the ICRP issued ICRP 103 which formally replaces the previous recommendations that were issued in 1991 as ICRP 60. One of the major features of the new recommendations is the evolution from" the previous process-based protection approach using practices and interventions (…) to a situation-based approach applying the fundamental principles (…) of protection to all controllable exposure situations" in a similar way. In the case of radioactive waste disposal, the long timescale to be dealt with led ICRP to publish the dedicated recommendations ICRP 81 (1999) based on ICRP 60. Th. Schneider presented then a series of issues raised by the radioactive waste management community, relating the recommendations of ICRP 81 to the new orientations provided by ICRP 103.

Radiation detriment is a complex construction based on not directly measurable quantities such as equivalent and effective doses. Effective dose is a risk-related quantity and should not be used in assessing health effects on a specific individual.

Dose and risk as well as the radiation detriment are still appropriate for long term evaluation even though there are uncertainties associated with the assessment of the dose. It would be a mistake to consider that the ICRP dosimetric quantities and the radiation detriment are not appropriate for long term evaluations, but their meaning must be understood. What is at stake is not to evaluate the level of health of a group of population in 10^6 years from now, but to estimate through a comparison (risk indicator associated with several options of protection at the design level of the repository) the level of protection achieved by a radioactive waste strategy.

Current radiological protection criteria are a reasonable basis to assess the disposal strategy. They give a general appreciation of the excess of risk resulting from the exposure of the involved population. In this perspective, ICRP has considered it was neither its responsibility nor a wise position to establish evolutionary scenarios for the health of future generations, which would be among the requirements for converting this general appreciation into an actual prediction of health effects.

For long-term situations the relevant concept is potential exposure although the situation is planned. According to ICRP 103, long lived waste disposal should be dealt with as a planned exposure situation, and the resulting exposures in the long term should be considered as potential exposures**.** This leads to the use of a risk constraint in implementing the optimisation principle, which implies the consideration of the dose and the associated probability of occurrence for each process or event corresponding to the scenario of exposure.

The same level of protection should be achieved for future generations as for present generations. The position of the ICRP on the interpretation of the quote by ICRP 81 that "individuals and populations in the future should be afforded at least at the same level of protection from actions taken today as is the current generation" is that the risk resulting from the evolution of the disposal system should be as low as reasonably achievable below a selected risk constraint. In the demonstration of compliance (performance assessment), which may differ when dealing with natural processes vs. human intrusion, the objective is not to attempt to estimate a radiation detriment for future individuals but rather to test the weaknesses and the robustness of the disposal system. The goal is to compare disposal options. Calculated doses to future individuals should be regarded as indicators of safety. In ICRP 103 it is stated that "in the decision-making process, owing to the increasing uncertainties**,** giving less weight to very low doses and to doses received in the distant future could be considered. The Commission does not intend to give detailed guidance on such weighting, but rather stresses the importance of demonstrating in a transparent manner how any weighting has been carried out". The opinion of the ICRP is that this statement is not contradictory with the key principle to reach the same level of protection, but simply refers to the consideration of individual dose distributions in the ALARA approach.

The protection approach is the same during the active and the passive safety phase. The repository is designed such that if control and knowledge are lost during post-closure, the repository is passively safe (using criteria derived from the principle of protecting future generations). In reality society would try and maintain control over the repository by use of institutional and other controls, essentially forever. The position of the ICRP is that the passive safety phase is a fall-back position. Therefore, for both phases (active or passive), the protection approach is the same: protection criteria have to be set up at the design stage of the installation, taking into consideration the likelihood that it may not always be possible to ensure the monitoring of the installation.

Richard Ferch, consultant to the NEA, made a presentation entitled "Fundamental concepts used in national regulation: is the terminology sufficiently clear?"

R. Ferch gave a series of examples where expressions have different meanings, including "undue burden" and "ultimate safety objectives" which are related to the basis for defining regulatory criteria. Safety and protection are often not defined in regulatory documents. Starting from IAEA definitions, he explained that there are also several dimensions along which we might range various interpretations of the term "safety": absolute protection vs. levels of acceptability; control of the source of the hazard vs. protection of those subjected to the hazard; protection against high-probability low-consequence risks vs. protection against low-probability high-consequence risks; freedom from health hazards vs. freedom from risk of injury or damage; protection against human actions vs. protection against inanimate hazards. He noted that the scope of the IAEA definitions is limited to protection against health hazards arising from exposures to radiation. One important aspect of the use of common-language terms, especially ones that have as much emotional importance as “safety” and “protection”, is the aspect of connotational meanings. For example, the concept of safety often carries connotations of familiarity with the risk and of control over the risk. Allowing time to build familiarity is often cited as one of the reasons for adopting a phased, staged or stepwise approach to repository development and contributes in some countries to requirements for reversibility and retrievability. The discussion of the meaning of terms is further complicated when translations between languages are involved. Some languages may not have separate words for concepts of “protection”, “safety”, “security” and “safeguards”. The challenge for regulators is to develop regulatory criteria that protect present and future generations from the hazards contained within a repository but also that are likely to be understood by and acceptable to the generations immediately following us who must bear the burden of duty to complete the implementation of projects we start today. Clarity and transparency of terminology can play an important role in meeting this challenge.

Daniel Metlay (NWTRB) made a presentation on “Ethical issues and societal expectations”**.**

D. Metlay declared that institutions had always recognised an ethical obligation to manage high-level radioactive waste in unprecedented ways. This obligation has not only endured, but has become more explicit and multidimensional and it now subsumed under a more general rubric of “societal expectations.” D. Metlay directed attention toward the proceedings of previous RWMC-RF workshop[1], which contains five essays, authored by Kjell Andersson, Andrew Blowers, Carl-Reinhold Bråkenhielm, François Dermange, and Patricia Fleming, that are relevant to the question of ethical issues and societal expectations. D. Metlay observed that “societal expectations” are hard to define and thus very hard to measure. They may vary considerably with time and from country to country. As an illustration he referred to an inquiry performed by a task group 30 years ago in a document entitled “*Proposed Goals for Radioactive Waste Management”* (NUREG-0300) on behalf of the U.S. Nuclear Regulatory Commission. Conclusions from D. Metlay are that, for the most part, societal expectations in the United States appear to be quite stable over a period of more than 30 years. In two areas, however, there are clear differences in emphasis between expectations articulated in the last few years and those recorded in 1978. (1) While then there was emphasis on the operational reliability of organisations and institutions. In particular, much care was taken to discuss the inherent limitations on *bureaucratic error-correction* in the future. The focus is nowadays more on *bureaucratic behaviours* associated with carrying out decision-making processes in the present. (2) While there is current emphasis on the importance of trust, transparency, and accountability, the NRC document may cast some doubt on the reliability of a stepwise decision-making process. In the domain of radioactive waste management, error signals are notoriously unclear, and strong disagreements over objectives and value trade-offs often arise. Also, the key prerequisite for reliable error detection – independence – is often at odds with the key prerequisite for reliable error rectification—interdependence. He concluded that it is unclear just how far we have come in the last 30 years in meeting societal expectations for post-closure and post-monitoring repository performance.

Main findings from the table discussions

The major issue underlying Session 2 is to understand better what are the ultimate safety objectives that we are trying to achieve through regulation. The preparatory work for the workshop within the RF had not provided an unequivocal and clear answer to this question. There were also varied views on what would constitute “undue burden”. Finally, there was ambiguity on the meaning of “dose” in the long term, in particular whether estimated dose constitutes, as it may for the short term, a measure of health detriment. These topics are the fundamental basis for most of what follows

1. NEA/OECD (2008), *Regulating the Long-term Safety of Geological Disposal of Radioactive Waste: Practical Issues and Challenges* – Workshop Proceedings Paris France 28-10 November 2006, OECD, Paris.

in regulation. Transparency requires that the ultimate goals and the terms used be agreed upon and understandable now and in the future by the general public, regulator and implementer. The table discussions allowed exploration of those points, by focusing on specific questions identified during the workshop preparation.

Question 1: How should "undue burden" be interpreted? In practice, what are our responsibilities towards future generations and the environment that can be fulfilled?

In responses to a questionnaire before the workshop, the term "undue burden" was interpreted by some to mean financial burden, and by others to mean the burden of potential radiological exposure. The concept of "undue burden" involves actually many aspects: to provide technology, financing, human and environmental protection and it also implies no limitations of resources, preservation of option. During the discussions at the workshop, the burden on immediately succeeding generations of the duty to complete disposal projects begun in the present was also mentioned.

A general observation is that burdens to future generations cannot be avoided. Responsibility is passed to the next and succeeding generations, but is tempered by our capability to establish a legal and regulatory framework, a financial support system, general societal support, and flexibility to adapt to changing circumstances (e.g. retrievability). The real question is: How do we know what future generations will expect?

In a more general way, the term "undue burden" was seen as an ambiguous term which may have different interpretations since it is not defined at either the international level or the national level. The term also has a negative connotation. A new term was suggested: "responsible management…" but a definition would be necessary.

Starting from these conclusions, it would be desirable to move forward and provide solutions. It should be recognised that, in the recent IAEA requirements document WS-R-4, geologic disposal is considered by definition to be the management option that places the least burdens on future generations.

Question 2: Are "safety" and "protection" the same concept?

Results from the table discussions indicated that there is a difficulty in making a distinction between safety and protection. Safety is the control of a source but protection deals with an individual. Radiological protection is an element of safety. Safety is a broader concept than protection, including both radiological hazards and non radiological hazards. There is also a distinction between the views from the public and the views from the practitioner. Safety is associated with the facility, the systems, and the components. It is an attribute of a technical system and a way that protection is realised, and the concept needs to be precise to be really workable in terms of acceptance criteria.

There is a lack of clarity on terminology and on fundamental concepts. This could, in the worst case, lead to loss of trust and confidence between regulators, implementers and the public resulting from misinterpretations or conflicting understandings of the meaning of these terms. International agreement on basic terminology and fundamental objectives could go a long way towards improving clarity in regulation and facilitating communication.

Question 3: What do you consider to be the most important, workable long-term objectives in regulation?

Outcomes from the table discussions indicated that there is an agreement on a general objective expressed as protection of human health and the environment. A series of workable sub-objectives or criteria were listed such as: demonstrability by process of measurement, dose/risk criteria, the ALARA principle, etc. The trend is to use safety oriented criteria linked to system requirements. Other quantitative criteria have been proposed: e.g. general measures of water contamination, as well as qualitative criteria such as maintaining documentation and human knowledge, and institutional control.

The long term objectives concern the safety of persons and environment, which implies both radiological and non-radiological issues. The long term objectives should be incorporated in law or regulations. A well defined process and allocation of responsibilities is essential, making the project clear and transparent. We need to have a reliable and competent technical regulator. How do we know we have done enough?

General conclusions were that even though there is a general agreement on a fundamental objective expressed as protection of humans and the environment now and in the future, the main difficulty is achieving agreement on practicable criteria to be applied to consequence analyses for times in the distant future. While there is consensus that the goal should be to provide the same level of safety to future generations as to persons in the present, there is little consensus on how best to demonstrate this in regulatory judgement, or even on what "same level of safety" actually means (same level of stylised effective dose calculation for members of a stylised critical group assuming current living habits and habitats, same level of mortality risk averaged over presumed populations, or similar levels of inconsequentiality relative to other naturally-occurring hazards). Continuing dialogue on this topic will be needed to move towards consensus.

Question 4: How should regulator(s) and implementer achieve and communicate confidence in their long-term safety decisions in the absence of controls, in the presence of uncertainty, and for situations where international guidance (ICRP) suggests that dose/risk estimates should not be regarded as measures of health detriment?

Outcomes of the table discussions indicated that even though demonstration of compliance is related to dosimetric calculations, confidence in the safety case is, however, strengthened by the use of multiple lines of reasoning and evidence leading to complementary safety arguments that can compensate for shortcomings in any single argument. These arguments include considerations of the safety functions provided by subsystems and barriers, system measurements, performance confirmation, use of natural and archaeological analogues. Other arguments for confidence such as large-scale demonstration tests, sound engineering and scientific basis, and quality assurance should also be used.

Confidence is not only brought by technical elements but also by the whole process. There needs to be confidence in the actors (including politicians, implementer, regulator…), a clear definition and distinction of the implementer's and regulator's roles, and transparency in the decision making process. The implementer should get the public involved early in the project and should be competent and accountable. It is important also to include politicians early in the process to get the public involved in the project (e.g in France, public consultation process is laid down by law). The regulator needs to be credible and has to emphasise the independency of its work and of its advisory bodies or reviewers. Regulators have to define as early as possible the "rules of play". High-level requirements are honesty and integrity, and use of understandable language. There are important transnational differences in how confidence is achieved and communicated. The focus should be on international similarities, experiences and regulations. Communication with stakeholders is important. In this context transparency, openness, fairness of the process are major contributors to confidence building.

Question 5: Should we communicate the difference between safety in the sense of meeting criteria and in the sense of freedom from risk, or can a common ground be found?

This question was formulated alternatively: If the public was asked to suggest the criteria, would the latter criteria be different? The public may want:

- Not necessarily different end-points.
- More barriers (increased disposal depth, for instance).
- More control of the future (monitoring).
- Better understanding: individual protection may be hard to understand in the presence of uncertainties; some concentration-release-flux oriented criteria would be perhaps easier to understand.
- Some understanding of the meaning of the detriment even if environmental pollution criteria have been defined.

Session 3: Establishing Regulatory Criteria that Account for the Inherent Difficulties Associated with the Long-time Frames for Protection
[Chair: Walter Blommaert, Head Waste Management Division (FANC); Rapporteur: Esko Ruokola, Head Waste Management Division (STUK)]

Even though there have been significant developments in recent years and experience feedback from a number of ongoing geological disposal projects, international guidance remains rather difficult to understand and apply. The recent work from the RWMC-RF on long-term safety criteria for geological for geological disposal also shows that there are important differences between national criteria as well as differences in regulatory approach. It has emerged that we have no common basis for setting criteria as between different NEA countries and that the process of setting criteria is not readily explicable to the general public. Furthermore we are required, for the purposes of the international Joint Convention on the Safe Management of Spent Fuel and Radioactive Waste, to protect, amongst other things, the ability of future generations to meet their needs and aspirations. There is no guidance or general agreement as to who these future generations are or what their needs and aspirations are likely to be, and international work to date seems to have created an expectation in the mind of the public and some organisations that it implies a need for nothing less than a guarantee, on the part of the regulator especially, of current levels of protection of both individuals and populations forever, in effect, regardless of the impracticality of "guaranteeing" today any particular outcome over a period in the order of many hundreds of thousands of years. This session covered many of the issues relative to protection in long time frames.

Atika Khan, NWMO (CANADA) presented the point of view of the implementer on the dialogue with citizens in a presentation entitled "Planning for the Long Term: Perspectives of the Canadian Citizens"**.**

In order to determine the best societal approach for long-term used fuel waste management in Canada, NWMO conducted a dialogue with Canadian citizens over a three-year period (2002-2005) under the mandate given to it by the Nuclear Fuel Waste Act. This dialogue was conducted by different means including telephone surveys and discussions sessions and involved thousands of Canadian citizens. The result of this dialogue is that Canadians want phased implementation of a final solution on an extended timeframe allowing to adapt to and incorporate new learning and developments in science and technology and also allowing future generations flexibility to make their own decisions. The Canadian public want the ability to take part in the monitoring of the disposal themselves and for future generations to assess their stewardship over the nuclear waste as a precondition to future retrieval. Therefore they want the waste to be retrievable in case monitoring indicates that safety is compromised.

Used fuel was also viewed as a potential resource for future generations therefore decisions and actions taken now should not foreclose future opportunities – i.e. show respect for the future generations by ensuring that the used fuel is properly cared for but remains available.

Bruno Cahen, Director Safety Division (Andra) presented the point of view of the NEA Integration Group for the Safety Case (IGSC) on "What do implementers need in terms of regulatory safety criteria for the post-closure phase?"

B. Cahen acknowledged that the national experience in siting and developing conceptual designs of geological disposal is growing rapidly. It implies increasing opportunities for interactions between implementers and regulators. There has been large development of international guidance in the recent years. Many regulators have already developed a regulatory framework. The implementers need practical, transparent and deliverable regulations. These regulations should draw on experiences gained from development of geological disposal projects. The IGSC has identified five key questions that the RF may focus on:

1. Over what time frame are the waste deemed to present a hazard?
2. Over what time frames are regulatory criteria applied and do they change over time?
3. Over what time frame(s) are safety assessments required to be conducted?
4. How do implementers have to address uncertainties in the long time frames?
5. What happens after cut-offs: are additional analyses needed? What types of arguments are to be used?

Stable, understandable and practical criteria mean, namely, that they need to be developed on a strong scientific and societal basis, that there is consistency of safety options and requirements for different types of waste, that, in the longer time frames, the emphasis is given to robust systems, passive safety and multiple safety functions and that the criteria should fit the various phases of the project (siting, designing, operating, closure and post-closure).

Experience feedback from safety cases shows that safety priorities depend very much on time frames. The derived safety criteria for the individual components should lead to measurable, verifiable specifications. The assessment of geological repository post-closure safety relies on a number of qualitative and quantitative arguments. One issue is to derive safety criteria in relation with these arguments. The assessment of the induced impact of the repository on man and the environment is one element in demonstrating safety. The corresponding criterion is usually dose or risk. Specific aspects are important in the safety assessment in order to increase the confidence in the safety case. The safety assessment should be based on the detailed understanding, description and modelling of the processes governing the migration of individual radionuclides. Different components and functions of the repository system will be brought forward depending on the type of radionuclide.

Scientific knowledge leads to reliable quantitative information on the repository evolution resulting in a transparent safety case. The detailed understanding of the system allows identification of intermediate safety indicators bringing confidence on the overall evolution of the system, the dose being the ultimate safety indicator. In the framework of a stepwise approach an optimisation process comes into play and all the elements of the safety case should be adequately weighted. It is based on the assessment of the performance of a series of indicators linked with the properties of individual components of the repository system and would certainly contribute to confidence and help uncertainty management. It appears more and more important to carefully balance long-term safety and operational safety.

The IGSC feels that international developments, following experience feedback from implementation of ICRP-81 and ICRP-103 in national regulations, should deserve a particular attention. The IGSC has an interest in the technical implications of operational safety considerations on long-term repository performance, and in terms of design constraints needed to balance operational safety and long-term safety requirements. A stepwise approach to explore this issue was initiated, beginning with an IGSC Topical Session in 2008 (IGSC-10) to define the issue and gather national experience and challenges. Workshops on this subject are planned on period 2010-2012.

Esko Ruokola (STUK) presented an example of regulatory approach in a paper entitled: “Consideration of Timescales in the Finnish Safety Regulations for Spent Fuel Disposal”.

E. Ruokola explained that the Finnish spent fuel disposal program is progressing towards the construction license stage. The Government Decree on the Safety of Nuclear Waste Disposal which entered into force on 1st December 2008 will be detailed by a STUK Guide that is currently being updated. These regulations distinguish three post-closure time periods for which different safety criteria are defined:

The Environmentally Predictable Future

During this first period, extending up to several thousands of years, predictable environmental changes will occur. People may be exposed to the disposed radioactive substances only due to limited early failures of engineered barriers, due to e.g. fabrication defects. Disposal shall be so designed that as a consequence of expected evolutions:

1. The annual dose to the most exposed members of the public shall remain below 0.1 mSv.
2. The average annual doses to other members of the public shall remain insignificantly low.

STUK provides guidance for the different elements of the safety assessment including potential exposure pathways, potential changes in the environment to be considered, assumption on climate change and human habits, as well as the reference conditions for the most exposed individual and people living in the surroundings.

Era of Extreme Climate Changes

Beyond about 10 000 years, great climatic changes, such as permafrost and glaciation, will occur and a conservative approach is followed. For this time period, the radiation protection criteria are based on release rates of radionuclides from the geosphere to biosphere (geo-bio flux constraints). The STUK guide specifies the nuclide specific constraints for the activity release to the environment for individual radionuclides. The selected approach by STUK implies that the implementer need not to consider the biosphere scenarios when preparing his safety case for the time period discussed as the regulator has taken upon itself the identification of the impacts on the biosphere from the releases of disposed radionuclides.

The Farthest Future

At about 250 000 years, the total radioactivity in spent nuclear fuel becomes very close to that in the natural uranium from which the fuel was fabricated. In this timeframe, the hazard posed by a spent fuel repository will be comparable to that of a medium sized natural uranium deposit and the repository might be regarded as being part of the nature. Accordingly, for the time period beyond one million years, the regulations do not require any rigorous quantitative safety assessments but the judgement of safety can be based on more qualitative considerations, such as bounding analyses with simplified methods, comparisons with natural analogues and observations of the geological history of the site.

Main Findings from the Table Discussions

The issue of time frames catalyzes many of the questions that arise when formulating criteria for long-term protection of man and the environment. A common finding is that the period of geological stability is being cited as the defining time for cut-offs (soft or hard). Important ancillary issues are, however: (a) equal protection for all and at all times? (b) Should regulatory criteria change within time? If so, how? Should several kinds of "yardsticks" be used? The table discussions allowed exploration of these points and others, by focusing on specific questions identified in advance of the workshop.

Question 1: Should safety and protection be defined in the same way in the short term as in the long term?

There was some uncertainty what is meant by short-term vs long-term; it was however deemed that short-term in context of geological disposal extends up to 1000-10 000 years and long-term goes beyond that. There was agreement that the fundamental protection and safety objectives should be the same for the short term and the long term. However, the safety indicators need not be the same for different time periods. Safety criteria are given differently for short and long time periods in some national regulations, notably in those of the USA, France, Sweden and Finland.

Question 2: Is it reasonable to fix a cut-off in time, if so, based on what considerations?

Discussion on time frames and time cut-offs still elicits a wide variety of points of view without any clear consensus. Many countries have adopted in their regulations soft or hard time cut-offs for compliance assessments. There appears in some countries, including USA, Sweden, Finland and Switzerland, to be some agreement with an upper limit on compliance demonstration on the order of one million years. The following justifications for the time cut-off were proposed: the peak impact has been passed, reliance on geological stability is not adequate, or assessment results are not meaningful due to uncertainties. As these factors depend on waste inventory, disposal concepts and host medium, it may not be prudent to set a universal time cut-off for geological disposal. It was deemed also that the use of time cut-off depends on the aim of assessment: whether it is intended for compliance demonstration or comparison between options. In the latter case, a time cut-off is more justified.

It was proposed that beyond the time cut-off, comparisons with natural analogues might be used instead of performance assessments, albeit it was also argued that a uranium deposit is not a fully valid analogy for a spent fuel repository.

The conclusion was that more discussion is needed on time cut-offs for compliance.

Question 3: Should numerical criteria, such as dose or risk constraints, change over different time-scales? Should the same weight be given to potential exposures in far future as to actual exposures in the present or near future?

It was agreed that in principle, no greater impacts than currently acceptable should be imposed on future generations. However, it was also deemed that, in practice, hard constraints may be adopted for the short term and soft ones for the long term.

ICRP has no definite position on the issue; the Commission, however, has stated that less weight could be given to long-term doses. On the other hand, it was argued that larger weight should be given to distant future exposures, because the future generations have no direct benefit from the activity producing the waste, they cannot sue the current generation, and the number of potentially affected individuals in the far future is very large.

The conclusion is that there is still much to be done before reaching consensus on the relative importance of different time frames.

Question 4: If estimated dose and risk are not measures of health detriment in the long term, may they still be useful for regulatory acceptance purposes (indicators of containment/isolation, attributes for optimisation)?

It was discussed what is meant by the statement that an estimated long-term dose is not a measure of health detriment. A conclusion was drawn that the uncertainty is related as much or more to the estimation of dose, e.g. to processes in biosphere and to future human habits, as to the dose-detriment relationship. Also, it was recalled that collective doses integrated over long timescales are not meaningful and should not be used as a measure of health detriment.

There was a general agreement that albeit the uncertainties, long-term risk or dose estimates can be used as an indicator for compliance assessment or as an attribute for optimisation or other comparisons among alternatives. If assessment of future environmental conditions is not feasible, stylised modelling based on present biosphere and human habits can be used for these purposes.

Question 5: What other indicators than dose could be used for regulatory acceptance purposes?

It was pointed out that the advantage of dose and risk as indicators is that they integrate the impacts of a number of radionuclides and exposure pathways. The use of other criteria, e.g. those related to the containment and isolation capability of the disposal system, may involve fewer uncertainties but the determination of quantitative acceptability levels is more difficult. Also, one should avoid setting subsystem performance criteria at an early phase of the disposal facility development.

Other indicators are mostly used as complementary ones. A number of other potential indicators were listed, such as:

1. Radionuclide fluxes or concentrations.
2. Engineered containment capability.
3. Geological containment and stability indicators.
4. Groundwater flow rate, travel time and age.
5. Indicators related to safety functions.
6. Qualitative criteria like simplicity, robustness and redundancy.

Session 4: Optimisation, BAT and Related Topics
[Chair: Juhani Vira (Posiva); Rapporteur: Ian Barraclough (EA)].

As disposal programmes approach their industrial implementation, the concept of "optimisation" and related requirements are receiving increased attention. The guidance is, however, generic at this stage. Exchanges within NEA groups have shown that both regulators and implementers would benefit from a review of the relevant concepts and available guidance and experience, both at the national and international level and there is already strong interest shown in this area by the NEA RWMC Regulators' Forum (RWMC-RF) and the Integration Group for the Safety Case (IGSC). This is described in a separate NEA report[2] prepared for the workshop [NEA, 2008c] designed to stimulate discussion of this topic and promote shared understanding on how optimisation concepts and related requirements may be interpreted and how regulatory requirements may be formulated so as to be

2. NEA/OECD (2006), "The Concept of Optimisation for Geological Disposal of Radioactive Waste: A Concise Review of National and International Guidance and Relevant Observations" [NEA/RWM/RF(2006)5/PROV], OECD, Paris.

transparent, understandable and deliverable during the many-decades-long, stepwise decision-making process that accompanies the development of any deep disposal project.

Philippe Raimbault, consultant to the NEA, presented a paper entitled "Optimisation: an overview of concepts" by Philippe Raimbault and Claudio Pescatore.

Ph. Raimbault summarised and reviewed the concepts relevant to the "optimisation" of geological disposal systems as they are outlined in national and international guidance as well as in the work of NEA groups. The main objective of optimisation is to find the "optimal" or "best" combination of characteristics in terms of balancing imperatives of current and future safety while respecting the interests of present and future generations. There are, however, several ways to tackle the issue as "optimisation" may mean different concepts to different groups of people, as expounded in the written paper and in the NEA report supporting this workshop.

Most of the international guidance on optimisation of geological disposal is provided by ICRP (ICRP-81 and ICRP-103), IAEA (WS-R-4) and the European Union IPPC (Integration Prevention Pollution and Control) Directive. Although international guidance on optimisation exists, it is varied and not always clear. In particular, there is no specific recommendation on methods to balance operational and post-closure safety.

Countries have been preparing regulatory guidance on demonstrating long-term safety. The interpretation of international guidance and the level of detail of the implementation of the optimisation concept vary depending on the country but it remains on a very general level. Most countries observe that a stepwise approach should be followed, which means that design options may evolve with time. In this sense, one may view that protection becomes optimised as the result of the process of repository development.

The principle of optimisation of the safety of the repository is closely linked to the decision making process. The latest ICRP recommendations state that the optimisation of protection is a forward-looking iterative process involving all parties and aimed at preventing and reducing future exposures. It would seem, however, ineffectual to base optimisation on just one criterion – that related to radiological exposure – when in fact system optimisation is, by its nature, a multi-criteria endeavour. There is currently a trend to consider optimisation more as a process than an outcome and to strive towards system optimisation. At the same time, people tend to expect hard criteria on which regulators can base their decisions, and it is difficult for regulation not to be normative.

Wolfgang Weiss (BfS), vice-chair of ICRP Committee 4, presented the "ICRP view on optimisation as applicable to geological disposal". He recalled that the role of optimisation is to select the best protection options under the prevailing circumstances based on scientific considerations, societal concerns and ethical aspects as well as considerations of transparency. An important role of the concept of optimisation of protection is to foster a "safety culture" and thereby to engender a state of thinking in everyone responsible for control of radiation exposures, such that they are continuously asking themselves the question, "Have I done all that I reasonably can to avoid or reduce these doses?" Clearly, the answer to this question is a matter of judgement and necessitates co-operation between all parties involved and, as a minimum, the operating management and the regulatory agencies, but the dialogue would be more complete if other stakeholders were also involved.

What kinds of checks and balances or factors would be needed to be considered for an "optimal" system? Can indicators be identified? Quantitative methods may provide input to this dialogue but they should never be the sole input. The ICRP considers that the parameters to take into account include also social considerations and values, environmental considerations, as well as technical and economic considerations. Wolfgang Weiss approached the question of the distinction to be made between system optimisation (in the sense of taking account of social and economic as well as of all types of hazards) and optimisation of radiological protection. The position of the ICRP is that the system of protection that it proposes is based on both science (quantification of the health risk) and value judgement (what is an acceptable risk?) and optimisation is the recommended process to integrate both aspects. Indeed, there has been evolution since the old system of intervention levels to the new system, whereby, even if the level of the dose or risk (which is called constraint in ICRP-81) is met, there still is an obligation to show that protection is optimised. He stated further that the ICRP recommends applying BATNEEC (best available technology not entailing excessive cost) concept rather than BAT. The principles of optimisation and BATNEEC complement each other. Namely, the control of residual doses (human health) is driven by optimisation, whilst BATNEEC is applied as a means to control effluents in cases where humans are not directly affected.

In the optimisation process responsibilities are shared among stakeholders. The requirement of the optimisation of protection is the responsibility of the operating management, subject to the requirements of the competent national authorities. Operating management, propose and implement optimisation, and then use experience to further improve it. Appropriate competent authorities require and promote optimisation and may verify that it has been effectively implemented. Regulatory requirements should include the need for an active safety culture in both the authority itself and all regulated operating management.

Finally, regarding responsibilities to future generations, Wolfgang Weiss pointed out the position stated in ICRP-101, which shows that at this stage a variety of approaches could be taken as long as they are properly justified by the regulator.

Brittain E. Hill (US NRC) gave a presentation on the "NRC position on Optimisation for a Potential Geologic Repository". Regulations governing the potential repository at Yucca Mountain are contained in 10 CFR Part 63, which covers both the pre-closure, operational period and the period of time following closure of the repository. B. Hill explained that following a public comment period on the proposed revisions, NRC is currently updating its regulations to be consistent with the revised EPA standards for the 10 000 yr to 1 000 000 yr post-closure period. One of the requirements in Part 63 for the pre-closure, operational period is to reduce radiation exposures to As Low As Reasonably Achievable during the operational phase of the potential repository. Detailed radiation protection criteria are provided as well.

For the period following permanent closure of the repository, NRC has numerous regulatory requirements to protect public health and safety, the environment, and the defence and security needs of the collective people of the United States. These requirements, which are presented in the accompanying paper, represent an optimised approach that ensures that regulations are appropriately protective and provide a transparent basis to judge the safety of the proposed repository far into the future. They include demonstration of the understanding of the capability of barrier performance, a total-system performance assessment which must be used to demonstrate compliance with safety standards. Confidence that the geologic repository is optimised to protect public health and safety and the environment also is achieved through a performance confirmation programme and repository oversight must continue following permanent closure.

NRC considers that compliance with these requirements is sufficient, and appropriately optimised, to ensure public health and safety. The ALARA principle, while appropriate for pre-closure and decommissioning operations, does not apply to post-closure. If the repository system is shown to be safe, further design modifications incur additional costs with values that are difficult to judge against speculative changes in future societies and economies. As an additional consideration, deep geologic disposal, by its very nature, already is viewed as ALARA. There are few technological alternatives in repository design (10 CFR Part 63). Thus, NRC concludes that its post-closure regulatory requirements represent a sufficiently optimised approach to protecting the public. In summary, safety of the potential geologic repository at Yucca Mountain will be evaluated by considerably more than compliance with a numerical dose standard.

Björn Dverstorp, Swedish Radiation Safety authority (SSM) presented "The current regulatory requirements on optimisation and BAT in Sweden in the context of geological disposal".

In Sweden, a nuclear waste repository will be evaluated according to both to general environmental legislation (the Environmental Code, SFS, 1998:808) and according to more specific requirements in the Act on Nuclear Activities (SFS, 1984:3) and the Radiation Protection Act (SFS, 1988:220). The evaluations according to these laws will be carried out according to two separate, but coordinated, legal-review and decision-making processes. This will be a basis for the siting process.

Although the requirements on BAT and siting in the Environmental Code apply to radiological protection, they aim at a broader system optimisation. The more specific requirements on optimisation and BAT of radiological protection of geological disposal systems are given in the regulations associated with the Radiation Protection Act. The Swedish radiation protection regulations (SSM, 2009) comprise three corner stones: a risk target, environmental protection goals and the use of optimisation and BAT. In SSM's guidance optimisation is defined as a means to reduce risk, guided by the results of risk calculations. In case of a conflict between BAT and optimisation, measures satisfying BAT should have priority. Application of optimisation and BAT on different timescales are described as well as for human intrusion scenarios.

B. Dverstorp explained that because of uncertainties in the long term there is a need for additional arguments in the safety case in support of decision making. It is in this context that the requirements on optimisation and BAT should be seen as supplementary to the risk target, in providing evidence that the developer has taken into consideration, as far as reasonably possible, measures and options for reducing future doses and risks. Both principles focus on the proponent's work on developing the repository system and should be applied to the whole process of developing a disposal system, i.e. all steps from siting, design, construction, operation to closure of the repository.

There are limits on what can be expected in terms optimisation and BAT. The principle of voluntary participation in the Swedish Nuclear Fuel and Waste Management Co (SKB) site investigations on part of the municipalities is one example of a government-accepted societal limitation on site selection. Cost considerations also set boundaries to SKB optimisation process. However, society may provide feedback to SKB on optimisation and BAT considerations during the development process, through the recurrent regulatory reviews and subsequent government decisions on SKB programme for research, development and demonstration (RD&D programme). Finally, technical constraints could be availability of technology and the effectiveness of various measures for enhancing the repositories protective capability.

Regulatory review of optimisation and BAT will be based on demonstrating compliance with Swedish radiation safety regulations. It is the responsibility of SKB to motivate the balancing between radiological protection and societal and economical factors. Because we cannot foresee exactly what issues that will appear in SKB's safety case, it is more or less impossible to, a priori, define a comprehensive set of acceptance criteria for BAT and optimisation. In this respect, SKB will not get the final answer to what is an appropriate level of optimisation and BAT until the licensing review. However, a stepwise process of developing a repository makes it possible to provide guidance along the way. Different ways are used to provide regulatory feedback to SKB, prior to the license application.

Nevertheless it is important that the safety case/license application contains a road map of the most important BAT considerations, i.e. the ones really affecting safety, throughout the development of the repository system so they can be reviewed and presented to the decision makers.

Examples of issues that may need further clarification at the international level include:

- How to best present optimisation and BAT considerations in a safety case/license application?
- How to value BAT and optimisation in relation to risk calculations for different time periods? This is particularly relevant for situations where the calculated risks and doses are close to the regulatory targets.
- Optimisation to or below the risk target? Recent ICRP recommendations (ICRP, 2007) are not very prescriptive in this respect.

Main Findings from the Table Discussions

Session 4 provided a lively and wide-ranging exploration of the issues but relatively few definitive conclusions. The background report circulated by the NEA Secretariat identified many issues and raised many questions. The two "conceptual" presentations (by Philippe Raimbault and Wolfgang Weiss) suggested answers to some of these questions, but raised some more. The two "practical" presentations (by Brittain Hill and Björn Dverstorp) illustrated two very different approaches to national application of the optimisation principle – the US approach in which the implementer is not subject to any explicit requirement for optimisation of long term performance, and the Swedish approach in which the implementer is required explicitly to apply both optimisation of long-term radiation protection and best available techniques (BAT) to minimise long term releases of radionuclides. These scene-setting presentations helped to provoke very diverse discussions at the different tables and a vigorous discussion in plenary. The questions posed by programme committee as the basis for table discussions were thus only some of a wide range of issues discussed, but they nevertheless provided a reasonable structure for reporting the main points of the discussion.

Question 1: What are the kinds of check and balances or factors that would be needed to be considered for an "optimal" system? Can indicators be identified?

There seemed to be a general view that many factors could be relevant to optimisation, and that the range of potential factors was relatively well understood. The difficulty tended to be more in deciding which of these many factors were most appropriate for inclusion in a specific optimisation decision, a question for which there was no general answer – rather, the factors to be considered in a particular case need to be agreed by the relevant stakeholders.

At the same time, a number of difficulties in actually handling these different factors were identified. These included the inherent uncertainties involved in meaningfully quantifying factors such as long term impacts, finding ways of treating those factors that cannot be directly quantified systematically in the analysis, and then weighting the trade-offs between the various quantitative and qualitative factors. A further more general difficulty that recurred throughout the discussion was that of when the process should be considered to be complete and the solution identified to be the "optimum".

Question 2: Should a distinction be made between system optimisation (in the sense of taking account of social and economic as well as all types of hazards) and optimisation of radiological protection? What could be criteria?

In extreme terms, this could be expressed as asking whether optimisation aims to meet dose/risk constraints at the least overall cost, or to apply all reasonable means for reducing doses/risks further.

On this question in particular there was extensive discussion but no consensus. ICRP's current view (as expressed in Publications 101 and 103) is evidently that there should be no significant distinction – both should be processes of systematically evaluating options for reducing impacts. However, there was some concern that this was a change from the ICRP 81 position that optimisation of the long term impacts of geological disposal could be assumed to have been achieved if constraints are met and good science and engineering practice have been applied, a position that had been adopted in the IAEA Safety Requirements WS-R-4.

The table discussions were lively, but led to different conclusions at different tables. With more time, it might have become clearer whether the differences of view were as profound as they seemed or were based more on misunderstandings and semantic variations. As it was, the question remained essentially unresolved.

Question 3: How can "optimisation" or best practice aspects be made visible in the regulatory process?

There seemed to be general agreement with the view that the optimisation process should involve a dialogue between implementer, regulator and other stakeholders as appropriate. Provided that this process was conducted in a transparent manner, it should be visible in the regulatory process. Transparency would demand that the "rules" of the dialogue process are published, and the main outputs of the dialogue recorded and made publicly available. Key aims of the process would be to document openly and comprehensively the decisions taken and the role that optimisation had played in them, including which options were considered, which factors were taken into account and how (including reference to any factors that were considered too uncertain to include in the decision), why the preferred option was chosen and why the other options were not chosen.

Question 4: Does the process of stepwise decision making constitute a part of system optimisation? To what extent? Is this best practice?

There was general agreement that stepwise decision making can complement optimisation, helping to break down complex optimisation problems into a series of more manageable and transparent questions. However, this would only be the case if the process is managed properly, the process and principles properly defined and respected, and the contribution that optimisation made to decisions at each step adequately documented.

The discussion also identified a need for some caution in applying optimisation in a stepwise decision making process. In particular, there was concern that the "rules" for revisiting decisions taken at earlier steps in the process need to be clear. Optimisation can at best identify the optimum solution based on the conditions and information available at the time it is done, and so in principle earlier optimisation-based decisions could be subject to a series of reviews as the stepwise decision making process continues over years or decades. Whilst it was recognised that a stepwise process must, almost by definition, allow the possibility to go back and re-evaluate an earlier step if there is a real problem, the implementer also needs some level of certainty that soundly-based decisions on optimisation at one step are not repeatedly or frivolously questioned at later steps.

Question 5: How should factors like stakeholder acceptability (e.g. in selecting a site) taken into account in the concept of optimisation?

It was generally accepted that stakeholders' roles and rights need to be made clear. This includes defining who are to be considered "stakeholders" in respect of any specific decision or optimisation. There was a clear view that which stakeholders are important depends on what decision needs to be taken – in some cases this might be largely just the implementer and regulator, while wider stakeholder involvement might be appropriate only for some types of decision.

In cases where stakeholder acceptance is given high priority, it was noted that this may constrain the optimisation, by requiring particular options to be excluded (e.g. a specific location considered unacceptable to stakeholders) or included (e.g. providing for retrievability), when they might not have been otherwise. This could lead to decisions that are technically "non-optimal", in order to accommodate stakeholder concerns. The one generally accepted qualification to this, however, was that such accommodation of stakeholder concerns should not be allowed to jeopardise technical safety.

Question 6: Should the same weight be given to the distant future and to the near future with regards to optimisation and regulatory decision making? If not, how should this be reflected in regulation?

Opinions varied, but the conclusion was that there was no generally applicable answer to the question. There might be arguments of principle or practicality for weighting far future risks higher than, lower than or the same as near future risks, depending on the circumstances (including the views of stakeholders), but these needed to be considered case by case. This being so, it was noted that it will be important to document the reasons for the judgements that are made in specific cases. This is essentially the position adopted by ICRP in Publications 101 and 103. This was recognised not to be very helpful, but it was acknowledged that there might not be any more useful general advice that could have been given. As something of an aside, it was noted in one of the table presentations that the "concentrate and contain" concept, which is central to geological disposal, might be considered implicitly to weigh short-term protection higher than that in the far future by encouraging measures that delay releases. However, this was not discussed further.

As seen earlier, in order to better handle the subject it might be helpful to distinguish between three classes of generations: the present and immediately following generations (a few hundred years), who benefit from nuclear energy and handle the responsibility of the construction, operation and closure of the repository facility; the future generations in the medium term (hundreds to thousands of years), who may possibly bear the burden of additional control and monitoring the repository and could also take actions directly related to the repository; and the far-future generations (e.g. after a few thousand years), who may have forgotten the existence of the repository and to whom our ability to directly assure protection is necessarily decreasing.

Session 5: Regulatory Research and Development Activities
[Chair: Yutaka Kawakami (NSRA); Rapporteur: Hans Wanner (ENSI)]

The role of research and development carried out by and on behalf of the regulator is to contribute to transparent and effective regulation by equipping the regulator with the knowledge to test the arguments presented by an applicant. The session at this workshop was intended to prepare the ground for a wider-ranging discussion on the role of regulatory research within the RF.

Hans Wanner, Swiss Federal Nuclear Safety Inspectorate (ENSI) made a presentation on the "Needs of Research for Regulatory Purposes".

H. Wanner presented a general overview of regulatory research at the international level based on a preliminary input from international colleagues and observed that the question of active involvement of nuclear regulatory and supervisory bodies in R&D projects has become a topic of increasing interest in recent years even if the way in which research is included in regulatory activities varies from country to country. The range spans from countries with no regulatory R&D activities to countries with extensive activities that are often carried out by independent research organisations acting on behalf of the regulatory body. In a few countries, the regulator and implementer have their research carried out by the same research institutes. As an example H. Wanner explained the organisation of R&D work in Switzerland.

He presented the potential merits of R&D work carried out by the regulator and introduced a number of questions that would gain from being addressed at an international level. He stressed that the R&D work performed by the implementer must be comprehensive and there should be, in principle, no need for complementary work by the regulatory body. Nevertheless, R&D work of the regulator has still several merits. It improves the regulator's necessary competence to review the safety case allowing it to rely on the scientific community. It provides the regulator's independence, allowing a different view on the safety case from the implementer's view. By bringing to the fore the scientific and technical ability of the regulator, R&D work by the regulator provides additional confidence to the stakeholders in the credibility of the regulator.

There may exist further motivations for the regulator to carry out its own R&D projects, among which is the verification of key safety issues or the investigation of topics not addressed by the implementer, i.e., to fill scientific gaps. The question whether or not it is the duty of the regulator to carry out such complementary work is the subject of controversial discussions. A further issue is the source of the budget from which research for regulatory purposes should be funded since frequent sources of funding are the waste producers and the national budgets.

The question of how much regulatory research is needed is difficult to answer on a general basis. It appears obvious that the regulator must achieve the objectives of competence and independence. The research needed for this purpose is the least the regulator must undertake. The verification of key safety issues and the investigation of issues not addressed by the implementer may be considered as optional.

Christophe Serres from IRSN (France) presented a paper on "Safety research carried out for reviewing safety cases" in France.

He described the independent role of the IRSN regarding research related to nuclear safety in the context of the French Planning Act of 28 June 2006 foreseeing a licence application to be submitted in 2015 for the creation of a deep geological repository. IRSN research programme is organised along research activities devoted to addressing independently-identified "key safety issues". These "key issues" should also be of prime concern for the implementer since they relate to the demonstration of the overall safety of the repository, and the level of funding that the implementer should afford to research activities of concern for safety.

He explained that the quality and independency of the research programme carried out by IRSN allow building and improving a set of scientific knowledge and technical skills that serves the public mission of delivering technical appraisal and advice, e.g., on behalf of the national safety authority. In particular they contribute to improving the decisional process by making possible scientific dialogue with stakeholders independently from regulator or implementer.

The current IRSN R&D programme is developed along the following lines:

- Test the adequacy of experimental methods for which feedback is not sufficient.
- Develop basic scientific knowledge in the fields where there is a need for better understanding of complex phenomena and interactions.
- Develop and use numerical modelling tools to support studies on complex phenomena and interactions.
- Perform specific experimental tests aiming at assessing the key parameters that may warrant the performances of the different components of the repository.

These studies are carried out by means of experiments performed either at IRSN surface laboratories, or in the Tournemire Experimental Station (TES), an underground facility operated by IRSN in the south-east of France.

Targeted actions on research related to operational safety and reversibility issues are being defined. Ch. Serres explained as well organisational aspects related to research stressing the need of synergy between research engineers, universities and experts in safety assessment. He described the international cooperative research programmes in which IRSN is involved.

Shinichi Nakayama (JAEA, NSRC) presented the "Regulatory Research and Development Activities in Japan". A stepwise approach is being applied in Japan to site selection for geologic disposal. According to the Implementation Act of 2000, areas for candidate sites are to be narrowed down to finally identify the repository site. In 2002, the NSC has provided guidelines for the first step to select the preliminary investigation areas. Guidelines for the subsequent steps will be given in accordance with the progress of the disposal programme. The implementer, NWMO will submit the license application for regulatory approval after the repository site is identified, and NISA will judge the compliance with the regulatory law. The role of NISA is twofold; 1) to make a technical review on site selection, and to devise safety requirements and 2) to make technical judgements on safety assessment. Regulatory research is needed in both areas. The Agency needs to keep technical competence based on best available science and technology, and accumulates research resources to keep the competence. The purpose of the research to support technical review on site selection is to identify geologic conditions that may cause adverse effects on operational and post-closure safety and therefore to select important scenarios that are associated with large uncertainty and, hence, are critical from a safety point of view. The following study subjects are envisioned:

- Long-term leaching characteristics of vitrified waste.
- Long-term alteration of engineered barriers.
- Re-saturation of groundwater in buffer materials and gas transport.
- Effects of geological evolution on hydrogeology.

These studies will provide scientific and technical basis to judge the robustness of implementer's safety assessment methodology. JAEA has been developing a probabilistic safety assessment tool to check independently the implementer's assessment. The study topics will be evolving to more design- and site-specific ones with the progress of site selection. Emphasis is at the moment given to handling and quality check of shared data and knowledge with the implementer, and to international co-operation with other regulatory support organisations.

Main findings from the table discussions

These scene setting presentations helped to provoke very diverse discussions at the different tables and a vigorous discussion in plenary. These were helped by a set of questions indentified ahead of the workshop.

Question 1: What are the main current research needs related to establishing long-term safety criteria?

It was mentioned that regulators should put more emphasis on addressing non-technical issues such as communication, credibility, social and ethical aspects, risk perception and timescales. It was felt that in general, regulators should increase their research activities and responsibilities. Also mentioned were pre-monitoring at different potential repository sites and the development of stylised approaches regarding inadvertent human intrusion.

Question 2: What are regulatory competences and research capabilities needed to review the implementer's R&D plans and results, and how to maintain those competences?

It was felt that it is often difficult for the regulator to keep up with the variety of research in performance assessment, and that closer international co-operation may help. It was said that the regulator needs to acquire the competence to assess the completeness of the list of possible scenarios

(FEPs: feature, events and processes) and to review the safety case. Some felt that in verifying elements of the safety case the regulator should not duplicate the implementer's research. It was said that international courses for training regulators might be a widespread need, and that the regulator needs in-house expertise.

Question 3: One of the purposes of R&D is to reduce uncertainties in areas where knowledge is lacking. What is the role of the regulator in requiring, sponsoring and/or carrying out such R&D?

In order for the regulator to better focus his R&D activities, the R&D programmes of the implementer should be available as early as possible. The regulator should then focus on key safety issues and strive to fill critical gaps. The regulator should be in dialogue with the implementer and define to what extent uncertainties should be reduced. It was said that the regulator cannot fully rely on his experts and consultants in this respect because they will always find reasons for more research, and that it is up to the regulator to say when enough research has been done.

Question 4: Should a regulator undertake R&D on safety assessment methodology necessary in order to develop an independent means of judging long-term safety?

There is consensus that research is essential for the regulator to build and maintain his competence. Limited resources oblige the regulator to focus on key questions and key safety issues. The independence aspect was discussed extensively. The regulator should establish links to independent research institutes such as universities. It was also mentioned that research is never strictly "independent" because it is always financed by someone. More important than "independence" is "quality" of the research.

Question 5: What research is needed by regulators to develop an understanding of which aspects of a long-term safety case require greatest levels of scrutiny?

As a general rule, the kind of research required should be derived from the results of the safety case. The long-term aspects of geosciences and the long-term behaviour of the safety barriers were mentioned among the key areas that may require a high level of scrutiny. Further research areas are areas of large uncertainty as well as building up the necessary skills for the regulator and, in general, developing and maintaining the regulator's competence.

Question 6: On what basis can it be determined that uncertainties have been reduced sufficiently?

Whether or not uncertainties have been reduced sufficiently may be determined on the basis of expert judgement, on the basis of an iterative, stepwise approach, or on the basis of meeting the safety margins. It was felt that it is the regulator's duty to identify areas where the uncertainty should be reduced, but that the reduction of uncertainties is the responsibility of the implementer.

Question 7: Is regulatory research needed to support the stylisation of human actions, biosphere, and climate change scenarios?

There was no agreement on this question. While two groups were convinced that stylisation is not a result of research but rather a policy decision, one group felt that the regulator needs research to support the setting of standards, including those for stylised models. They also felt that the regulator needs research to be able to assess the use of stylised models.

Session 6: Human Actions
[Chair: Daniel Schultheisz (EPA); Rapporteur: Klaus Fischer-Appelt (GRS)].

A variety of approaches to deal with human actions is presented in the responses to the questionnaire, both as regards the analysis of this scenario and as regards ways to reduce human activities.

There was a broad consensus that regulation for site selection, repository designing, construction and closure should require measures aiming at reduction of the likelihood and the consequences of intrusion. In detail, documentation on the repository position and its radiological potential, the application of markers, disposal in deep geological formations as well as keeping distance from resources which could be of potential interest for future generations were regarded as appropriate measures.

Hiroyuki Umeki, Chairman of the IGSC presented the "IGSC perspective on human intrusion".

H. Umeki indicated that when updating its programme of work, in 2007, the IGSC raised a number of issues that the group recommended RWMC-RF to consider for further discussion. The conclusions from different IGSC studies were that there is agreement at a conceptual level on the treatment of human intrusion, but a range of approaches are adopted for addressing it in safety assessment, and the degree to which these are specified in regulations also varies considerably among national programmes. The requirements and constraints for considering human intrusion are stylised and, therefore, are largely specified in regulations; in many national programmes, relatively few (or no) aspects are left to the discretion of the implementer. Human intrusion is considered as a sensitive issue for many programmes since it can be an issue of high interest to stakeholders and decisions on approaches are normally undertaken after extensive consultation; those who have already taken decisions are generally satisfied with the outcome and would not welcome work that might undermine or re-open the issue. Thus, a detailed re-examination of safety assessment of human intrusion and of the conclusions that have been reached previously is not a priority. This issue remains of interest to IGSC, however, as it must be addressed in some fashion within all safety cases. The key questions are:

- Should regulations require measures to reduce the likelihood or consequences of human intrusion? What "credit" can be taken for such measures? Is there new thinking or methods in terms of memory and markers?
- What types of stylised human intrusion should be considered in a safety case? What are the roles of the regulator and implementer in doing so?
- What consequences should be considered? What are the protection criteria against which to assess human intrusion scenarios?
- Are the answers to any of these questions site-, culture-, concept- or waste-specific?

A concluding question may be: Is there still consensus on the areas of agreement, or has thinking evolved?

Klaus Fischer-Appelt (GRS) presented a paper on the "German Viewpoints on the Integration of Human Intrusion Scenarios in Safety Cases."

K. Fischer-Appelt indicated that there is a broad consensus that site selection, repository design, construction and closure should require measures aiming at a reduction of both the likelihood and consequences of human intrusion. In Germany, two documents apply primarily concerning the treatment of human intrusion scenarios in a safety case: the BMU Draft Guideline for the disposal of radioactive wastes in geological formations: "Safety Requirements Governing the Final Disposal of Heat-Generating Radioactive Waste" /BMU 08/ and the conclusions of a Working Group on Scenario Development relative to Human intrusion: "Position of the Working Group on "Scenario Development: Handling of human intrusion into a repository for radioactive waste in deep geological formations" /SCD 08/.

Conclusions from both documents coincide regarding the following recommendations:

- Only inadvertent human intrusion has to be treated in the safety case.
- The reduction of the likelihood of human intrusion can be ensured by information maintenance, and intrinsically, by a strategy of deep disposal.

- There is no possibility for stipulating protection criteria since human behaviour in the distant future is absolutely speculative.
- A limited number of selected (stylised) scenarios based on current human activities and technical abilities have to be treated in the safety case. A Guideline with specifications of reference scenarios for human intrusion is regarded as helpful but is not yet available today.

Saïda Engström-Laârouchi (SKB) presented a paper entitled "Means to Reduce Human Activities at the site: Markers, Records… Where do We Stand?"

S. Engström-Laârouchi presented the main SKB activities related to preservation of information about a geological disposal. A draft action plan on the subject will be presented in connection with the applications for the site selection process in 2010. The aim with information preservation is to avoid damage by accident and allow for our and future generations to make decisions based on knowledge as much as possible.

In the draft action plan, suggestions on implementation of preservation of information are given. They cover the type of information of interest to be preserved, time horizons to consider as well as the potential incidents or events to envisage, their possible consequences and the measures to mitigate these consequences. Target groups are identified as well as strategies for preservation (from generation to generation, directly into a distant future). Different media for archives are envisaged. An international perspective on the focus for information preservation was also presented. Saïda Engström concluded by declaring that SKB is receptive to international co-operation on the subject, for example under the umbrella of the IAEA or the NEA.

Main findings from the round table discussions

The round tables discussions addressed a few questions identified in advance of the workshop.

Question 1: Should regulations require measures to reduce the likelihood and/or consequences of intrusion (e.g. physical markers, institutional controls or design features)?

There was a broad consensus that regulation for site selection, repository design, construction and closure should require measures aiming at reduction of the likelihood and the consequences of intrusion. Documentation of the repository position and its radiologic potential, the application of markers, disposal in deep geological formations as well as keeping distance from resources that could be of potential interest for future generations were regarded as appropriate measures. The effectiveness and feasibility of measures to reduce the likelihood and the consequences of intrusions should be evaluated by expert judgement.

Regarding documentation, technologies and practices should be used that assure information maintenance over a long time period, as a basis for future institutions to preclude human activities in the vicinity of the repository. However, information maintenance and future institutional control itself are not regarded as a matter of regulation since such requirements cannot be addressed to future authorities, which may not even exist currently. Documentation should be provided after the closure phase of a repository and, if applicable, during further steps of periodic information update. It was pointed out that the local community of the repository site as the keeper of the legacy could be one of the most important addressees. Additionally, broad information dissemination at an international level would effectively reduce the possibility of complete knowledge loss in the future. For most of the participants, the concept of geological disposal intrinsically reduces the likelihood of human intrusion via the depth of the repository. In general, markers indicating the location of a repository and its hazardous potential are seen as appropriate measures for reducing the likelihood of inadvertent human intrusion, but there are still a couple of open practical questions concerning the feasible lifetime and the avoidance of misunderstanding in such a way that markers could attract future generations to inspect the site without knowing about its hazardous potential.

- *What are appropriate criteria for judging acceptability of intrusion scenarios?*

The participants agreed that radiological criteria are regarded as inappropriate for the reduction of radiological consequences of intrusive actions and therefore should not be considered as compliance criteria. However, as far as foreseeable, disastrous developments initiated by human intrusion, leading to high radiological exposures for a large number of people in the vicinity of the repository, should be avoided as far as possible by appropriate site selection and repository design. Furthermore it was agreed that the results of human intrusion scenarios could also be used in a safety case to demonstrate the robustness of the repository system and the safety concept.

- *Should the consequences to the intruder be considered?*

The table groups unanimously agreed that consequences to the intruder who comes into direct contact with the waste should not be required to meet regulatory protection goals. As a consequence of the principle of waste concentration, radiological consequences for intruders inevitably could lead to lethal doses for the intruder in some scenarios, e.g. when drilling directly into the waste. These consequences may need to be calculated but they should neither be evaluated against quantitative target values nor be used as a crucial criterion for the repository optimisation process.

Question 2: What is the role of the regulator in specifying human intrusion scenarios?

As a preliminary note to the question on the regulator´s role in specifying human intrusion scenarios, it was pointed out that the public is aware of the issue of human intrusion and the resulting consequences. Accordingly, an appropriate and proportionate consideration of human intrusion in a safety case will be an important element in terms of confidence building. Hence, the role of the regulator is considered as crucial in providing guidance specifying the boundary conditions (e.g. completeness and depth of detail) of stylised human intrusion scenarios to be considered by the applicant and in defining requirements on site selection and repository design, on documenting the repository location and its radiological potential, as well as in defining further measures aiming at a reduction of the likelihood of human intrusion.

- *Which stylised human intrusion scenarios should be considered in a safety case?*

Concerning the kind of human intrusion scenarios to be considered in a safety case, there was general agreement that only inadvertent intrusion scenarios should be taken into account, although situations of partial information loss might also be considered. These scenarios should be site specific and based on current practices, taking into account the proximity to resources of potential interest for future generations. There was a broad consensus that the results of stylised analyses of human intrusion scenarios can contribute to the demonstration of the repository system's robustness in a safety case. There were diverging opinions on the question of whether drilling into the plume release of the repository should be regarded as human intrusion or if human intrusion scenarios should be restricted to direct intrusion into the repository/radioactive waste. This divergence indicates that there is not one single answer to the provided question.

Question 3: Have regulatory requirements evolved in the last decade?

The participants in Session 6 felt that there has been no outstanding evolution in regulatory requirements in the last decade. Some regulatory evolution in some countries, e.g. Germany, Japan and the U.S., has taken place, but these regulations still leave a lot of latitude on how human intrusion scenarios should be defined and considered in detail in a safety case.

Session 7: What Was Heard so Far: the View from Outside
[Chair: Phil Metcalf, Unit Head (IAEA)]

Following the NEA FSC model for workshops, two specialists other than regulator: an independent scientist and a university professor provided their personal perspective on what they heard at the workshop. This gave other participants an "outsider's" perspective on expectation from regulation and a chance for clarification and discussion.

Michael Sailer [Oeko-Institute and Chairman of Germany's ESK (Waste Management Commission)] presented his observations at the closure of the workshop from the perspective of an independent scientist.

General Remarks

This RWMC-RF workshop was a very good and fruitful workshop with very open discussion, broad exchange of opinions, a lot of exchange of experience regarding rulemaking, application of rules, and interaction with stakeholders. The questions for the table discussions were well prepared and contributed to a discussion in a focused and very productive manner.

International Guidance

International guidelines have an important role to play for the national debate. They give strong support for implementing specific items or ideas in national regulations and national processes. There is, however, a lack of consistency in international guidelines.

Terminology

Basic definitions should be clear and agreed. Further discussion of the interpretation of "safety case" and its roles; "multiple lines of reasoning", "optimisation" as well as others would be helpful. Another problem is the transfer to other languages:

Transfer of International Guidance to National Regulations

The transfer of international guidelines to national regulations has to respect the compatibility with national law (e.g. licensing procedures, rights of stakeholders, separation between nuclear law and other fields of law). The compatibility of international guidelines with the national culture of decision making is also important. Examples are: different roles of numerical values in the decision making and in court cases; hard vs. soft criteria in the decision-making processes. It might lead to different "translations" into national regulations regarding different countries.

Qualitative Factors

Regarding the qualitative factors in the guidelines a need exists for more detailed discussion of some ideas. Guidelines ask for different lines of argumentations ("multiple lines of reasoning"). He was very much in favour of that because he has limited trust in model calculations. But the guidelines do not give clear ideas, how that issue shall be handled in a safety case (additive to the long-term safety calculations? with the same weight as quantitative results? with which types of argumentation?). A clear need exists for a more detailed description of specific qualitative argumentation (e.g. what is sound engineering/sound geological judgement? what are possible indicators for isolation?). Without that, we just rely on numerical results and do not take into account the principal limitations of the modelling of scenarios.

Carl Rheinhold Bråkenhielm, Professor of Theology at Uppsala University and member of the Swedish National Council for Nuclear Waste presented his observations from the perspective of an expert in ethics.

Prof. Bråkenhielm elaborated on two important questions raised during the workshop:

- Should the same weight be given in regulatory decision-making to potential exposures to persons in the distant future as is given to actual exposures to persons in the present or near future?
- What are our responsibilities to future generations?

From utilitarian ethics the answer is that an action is right if it – in comparison to all alternative possible actions – realises the least amount of evil or harm for all those affected by the action. In this evaluation, all human persons and all human generations should be treated alike. If they live far away geographically or in time, it is not relevant. Even if the results of our actions are not predictable in the future, plausibility arguments can and should be made. Such plausibility arguments should be required by the regulators from the implementers. Regulators are thus on the right track when they base their regulations upon an undiscounted utilitarian argument of equal moral standing of all generations.

On the other hand, one argument – known as the principle of humanism – speaks in favour of a modified utilitarianism approach. Namely: regard for the other does not exclude regard for ourselves and we should not be obliged to sacrifice almost everything we have for the sake of the well-being of future generations. Nor should our children, our grandchildren and so on, be similarly morally obligated. Thus it must be acknowledged that there is a limit to how much we should provision for the well being of future generations. Based on such thinking, the economist Kenneth Arrow arrived at an ethical position, which he calls discounted utilitarianism: each generation will maximise a weighted sum of utility to itself and to the ensemble of all future generations taken together, with less weight placed on the latter ensemble. In this approach, all distant generations are treated all alike.

Session 8: Stocktaking and Closure of the Meeting

In this session, the various each session rapporteur provided a short presentation of the main observations from his/her session, followed by a final presentation by the Chairman of the RWMC Regulators' Forum.

Main Messages from Session 2 on Fundamental Concepts and Evolution of International Guidance

Carmen Ruiz Lopez gave the main messages from Session 2. The main lesson to be learnt from the session is that there have been significant developments in recent years, and feedback on experience from a number of ongoing geological disposal projects is available, but *international guidance remains rather difficult to understand and apply*. A quick reading is clearly not sufficient in order to get the message from IAEA and ICRP documents. Underlying argumentation is often necessary for understanding but not always available or at least not clearly communicated. The link between the various versions of documents issued by different international organisations is not very clear, especially to "non-insiders". Consensus international documents must be compatible with a variety of approaches, often leading to apparent incoherencies. Additional complications arise from the need to translate guidance originally written in English into other languages and to transfer international guidance into national laws compatible with different national cultures. There were lively discussions during the session on the meaning of ICRP guidance and on changes in wording between older and more recent guidance, which some attendees took to represent a shift in meaning, while others considered that there had been no fundamental change. There was a clear lack of consensus on how to interpret guidance relating to optimisation (is it aimed at meeting criteria in the most effective way, or at reducing consequences to be as low as practicable?) and to the meaning of effective dose and calculated potential doses. Continuing discussion of terms and their interpretation will be helpful. To this effect, communication of the exact meaning of the radiological yardsticks is a special issue of concern.

Main Messages from Session 3 on Establishing Regulatory Criteria

Esko Ruokola gave the main messages from Session 3 dealing with establishing regulatory criteria that account for the inherent difficulties associated with the long time frames for protection. The main conclusion of the session is that *there is still much to be done before reaching consensus on the relative importance of different time frames and the approach to be followed to define criteria in these different time frames.*

Whatever the criteria and the arguments behind the criteria, it is important that stakeholders understand the bases for decision making. One important issue is that it is very difficult for all publics to understand the bases on which the regulatory authority will judge safety over the different timescales, including the long term. Clarity on this depends strongly on clarity on the meaning of concepts such as safety, protection, disposal (is lack of control an essential part of the design, or an inevitable but undesired contingency to be planned for but not insisted upon?), system optimisation and duties to future generations as a function of time.

In order to better handle the subject of protection in the different time frames it might be helpful to distinguish between three classes of generations: the present and immediately-following generations (a few hundred years), who benefit from nuclear energy and handle the responsibility of the construction, operation and closure of the repository facility; the future generations in the medium term (hundreds to thousands of years), who may possibly bear the burden of additional control and monitoring the repository and could also take actions directly related to the repository; and far-future generations (e.g. after a few thousand years), who may have forgotten the existence of the repository and to whom our ability to directly assure protection is necessarily decreasing. Some countries do adjust their regulatory criteria and/or the relative weighting given to compliance on different timescales, but in the interests of clarity it would be beneficial for all countries if the underlying argumentation were discussed and compared internationally.

Main Messages from Session 4 on Optimisation, BAT and Related Topics

Ian Barraclough gave the main conclusions on Session 4. Overall, it was clear from the discussions that there are significant differences and questions concerning optimisation in the context of geological disposal:

- National implementation of the concept seems to vary widely. The differences, however, were perhaps not explored in sufficient detail to determine whether the sum total of what is considered and done in different countries is really substantively different rather than similar things being done but by different people at different points and using different terminology.
- There was a recurring theme that some basic concepts and terms (e.g. what to optimise, who decides, etc.) are not well defined or commonly understood. There was, however, little investigation of whether real practical difficulties arose from these questions.
- Weighting actual doses here and now against potential doses in the far future remains a contentious issue, attracting diverging views both in principle and in practice.
- Whether optimisation for the long term should simply focus on meeting dose/risk constraints, as in ICRP-81, or on reducing doses/risks further as in ICRP-103.
- Whether optimisation and BAT are the same thing, complementary concepts or even potentially conflicting.

However, it was also clear that there are substantial areas of agreement:

- Optimisation is increasingly recognised to be more about the process than producing a "scientific" result. Optimisation is not a mathematical process that will necessarily produce a single "correct" answer, but rather a way of considering and judging the best way forward under the prevailing circumstances.
- International guidance is very definite about the importance of optimisation but is not always very clear about exactly what it is and how to do it. Wolfgang Weiss stigmatised this in his presentation when he said "*Optimisation is very simple but very complex*".
- An undercurrent in much of the discussion over a range of issues was that there is to date relatively very little real experience of applying optimisation to real decisions in real geological repository programmes. Ultimately, the resolution of questions and differences over what the principles mean may come from practical application and experience. Since this must come from a limited number of projects worldwide, forums such as this can provide a valuable opportunity to disseminate and exchange examples of such experience.

Main Messages from Session 5 on Regulatory Research and Development Activities

Hans Wanner gave the main conclusions on Session 5. From the discussions it can be concluded that there is consensus that competence and independence are the key requirements for any regulator, and that regulatory research will help in many ways to fulfil these requirements. The discussions in this session will be followed up in a topical session at the RWMC meeting in March 2009.

Main Messages from Session 6 on Dealing with Human Actions

Klaus Fisher-Appelt gave the main conclusions of Session 6. An appropriate and proportionate consideration of human intrusion in a safety case would be important in terms of confidence building. Hence, the regulator has a crucial role in providing guidance specifying the boundary conditions (e.g. completeness and depth of detail) of stylised human intrusion scenarios to be considered by the applicant and in defining requirements on site selection and repository design, as well as on documentation of the repository location and its radiological potential and further measures aiming at a reduction of the likelihood of human intrusion. Although deep disposal is a planned activity, it may lead to unplanned, potential exposures. As a planned activity, a geological repository should remain under control as long as it is a potential source of exposures. The issue of the duration of control, the types of events that may lead to loss of control, and the types of controls that may be relied upon over different timescales need to be better understood and addressed. The issue of maintenance of control is a challenge to regulators, as well as to implementers and policy makers.

General Conclusions from the Workshop

George Arens, Chairman of the RWMC Regulators' Forum gave the main conclusions from the workshop focusing on interesting results and suggesting directions for further RF work. In his concluding remarks G. Arens focused on the following points:

A new, more participatory method of work was applied for the discussion of topics of interest in relation with the mandate of the Regulators' Forum. This method of work has proven to be successful and will be improved in the future.

There is a great interest to benefit from international guidance in national debates and for the development of national regulations. But even though great progress has been made in international guidance (IAEA standards, ICRP recommendations), national regulations and disposal concepts there is still a need for clarification or consensus on terminology. What is the meaning of "safety"? Does it mean that an adequate level of protection is achieved, or that there is sufficient reliability of meeting the protection criteria or does it describe the perception (emotional) of society or the stakeholders involved? The same is true for "optimisation" and "undue burden to future generations".

Misinterpretation of guidance has to be avoided. The messages delivered from IAEA and ICRP documents are often not clear and sometimes confusing. An underlying argumentation would be often necessary but is not always available or at least not clearly communicated. In the worst case this could lead to distrust between regulators, implementers and the public.

It is confirmed that a transparent, stepwise and iterative process of decision is essential for optimisation. The practical constraints and expectation to the optimisation process have to be clear from the beginning on. There is a tendency in regulations to extend the optimisation process to long term safety aspects, but it is not common practice.

The debate about how to protect people and the environment in the far future on the same level as at present is still ongoing. There seems to be a growing consensus about considering several time frames for regulatory compliance and the use of dose and risk as only indicators of protection in the long term. Considering limitations on accuracy and reliability of assessments in the long term, the use of these indicators and how they should be interpreted should be clearly communicated.

It was confirmed that the regulator has to be supported by research independent from the implementer. For building up and maintaining its competence the regulator may need to initiate and direct its own research. The Regulators Forum will proceed by working on this topic during this year.

The regulation regarding human actions close to the disposal site or human intrusion into the repository still raises questions as the deep underground is becoming more and more part of the human sphere. The public is aware of this issue. Consensus exists that individual dose criteria are inappropriate to regulate it. Maintaining documentation is a very important measure. The aspect of preservation of memory deserves more attention in regulations.

The workshop provided a number of interesting ideas the Regulators Forum will capture in the workshop documentation and that will serve as a basis for future work.

George Arens, on behalf of the Regulator's Forum, expressed thanks to NISA and JNES and the government of Japan for hosting and organising the workshop.

MAIN FINDINGS: LESSONS TO BE LEARNT

Workshop Methodology

This method of work has proven to be successful.

Starting already in the first plenary session, and continuing through the table discussions and the closing plenary session, there was a high level of participation from all present. The participants had the opportunity to meet persons from other countries and other backgrounds and to carry on stimulating discussions on topics of interest. The method of having reference questions prepared in advance and dividing those questions up among the tables ensured that a variety of issues were addressed and that the collective knowledge of all participants was leveraged. There were few definitive conclusions reached at the workshop, but many comments were made and issues were raised that complete our understanding of the status of regulations on long-term safety in NEA countries and that provide the basis for judging which issues deserve the highest priority and which ones are closer to solution at the international level. This is consistent with the expectations for this series of workshops.

Participants appreciated the high level of interaction with the other colleagues, especially in view of the variety of expertise that was represented at the workshop.

Participants appreciated the high level of interaction and involvement of persons from a variety of backgrounds. There were lively discussions after each invited presentation and during the following table discussions. The discussions were very open, lively and interesting, and many noteworthy viewpoints were expressed. Everyone participated fully and had many chances to state their own views and listen to differing viewpoints. The table discussions also allowed a fruitful exchange of practical experiences among participants.

The method also affords the participants the opportunity to learn about the status of waste management in the host country, and to come into contact with the main actors. Conversely, the method also affords the host country programme added visibility at the international level.

During the first session, representatives of the main Japanese organisations in the field of radioactive waste management made presentations on their country's high-level waste management programme, the roles of the organisations involved and some of the key policy and regulatory questions being considered at this time. Participants from other countries appreciated this opportunity to learn about the Japanese programme. During the table discussion sessions, there were representatives of the host country at every table, and this afforded other participants further opportunities to learn about the status of waste management in Japan and to come into contact with its main actors. At the same time the Japanese hosts appreciated the opportunity to make their work and issues more visible and to allow a larger number of their specialists to be exposed to the international debate than would otherwise have been possible. The work of the RWMC and its Regulators' Forum was highly praised.

National Regulations and International Guidance and Bases for Criteria and Regulatory Judgement

There is reasonable consensus amongst national regulations on fundamental regulatory objectives, but much less agreement on the most appropriate criteria.

There was general agreement on a fundamental objective expressed as protection of humans and the environment now and in the future. One difficulty is achieving harmonisation on criteria to be applied to consequence analyses for times in the distant future. While there is consensus that the goal should be to provide the same level of safety to future generations as to persons in the present, there is little consensus on how best to demonstrate this in regulatory judgement, or even on what "same level of safety" actually means (same level of stylised effective dose calculation for members of a stylised critical group assuming current living habits and habitats, same level of mortality risk averaged over presumed populations, or similar levels of insignificance relative to other naturally-occurring hazards). Continuing dialogue on this topic will be needed to move towards consensus.

From the pre-workshop survey:

The responses to the question [on ultimate safety objectives] were varied. Some specific responses of interest: (Finland) small fraction of background; (Sweden, Spain) protection of human health and the environment; (Germany) likewise, adding "without imposing undue burden…"; (Switzerland) ditto but with the additional word "permanently"; (United Kingdom) to safeguard the interests of people and the environment now and in the future, to command public confidence and be cost-effective; (US) ultimate objectives include multiple barriers as well as dose/release limits.

The United Kingdom's ultimate safety objective is stated very generally ("safeguard the interests"). This recognises the ICRP/IAEA caution about using stylised calculations as predictions of actual health detriments in the distant future, and would allow for variability in quantitative criteria with time and/or the use of criteria other than dose and risk. Ultimate objectives which are defined in terms of dose/risk/release limits implicitly assume that dose calculations for all times represent health detriment equally well, and may to a greater or lesser extent preclude the use of other performance indicators or of variable criteria. This appears to be a significant difference in philosophy.

Consensus is nationally and internationally hampered by the lack of common definition of concepts and terms.

In the responses to the questionnaire distributed before the workshop, there were varied responses to questions requiring interpretation of fundamental terms such as "safety", "undue burden" and "optimisation". For example, the term "undue burden" was interpreted by some responders to mean financial burden, and by others to mean the burden of potential radiological exposure. During the discussions at the workshop, the burden on immediately succeeding generations of the duty to complete disposal projects begun in the present was also mentioned. Similar differences were seen in the responses on safety and on optimisation.

It was felt that continuing discussion of terms and their interpretation would be helpful.

From the pre-workshop survey:

Although all countries agreed with the principle of avoiding undue burden, most responses were at the level of principles. Specific guidance or requirements related directly to this principle were found in three areas: the requirement in several countries that risks or doses predicted to be experienced by future populations must not exceed levels that would be acceptable today; requirements for measures related to institutional controls and record keeping; and financial requirements to ensure that there would be no economic burden. "Undue burden" was not defined, except implicitly (e.g. financial burden, and dose or risk constraints identical to current values).

Some related concepts of interest that appeared in individual responses: (Sweden) the law requires the energy producer to take the necessary actions (research and development) to safely dispose of the nuclear waste; (Switzerland) requirements for measures to permit rapid closure of the repository after emplacement of wastes should it become necessary to do so; (Japan) creating of a protective zone surrounding the facility in which land use and mineral rights are controlled; (Spain) allocation of responsibilities for developing repositories and for conducting associated research was included among the measures taken to avoid undue burden.

Few of the responses had much to say about [the definitions of safety and protection], and those that did respond tended to do so by defining safety in terms of compliance with criteria rather than in terms of the underlying principles to which compliance with the criteria contributes. Some (Sweden, Spain) made a distinction between safety of sources and protection of people and the environment. Safety for a sealed repository may be strongly related to fulfilling safety functions such as prevention or delay of release of radionuclides, but in the Swedish legislation the explicit definition is mainly relevant for the operational phase (e.g. preventing radiological accidents).

International guidance is interpreted in different ways in each country.

International guidance on fundamental concepts has been evolving in recent years and national regulations do not always reflect these recent changes. For instance, only few national regulations take full account of the concepts of potential (effective) dose and of constrained optimisation and give heed to the ICRP warning that dose or risk in the long term should not been interpreted as direct measures of health detriment.

There were lively discussions on the meaning of ICRP and IAEA guidance and on changes in wording between older and more recent guidance, which some attendees took to represent a shift in meaning, while others considered that there had been no fundamental change. There was a clear lack of consensus for instance on how to interpret guidance relating to optimisation (is it aimed at meeting criteria in the most effective way, or at reducing consequences to be as low as practicable?) and to the meaning of effective dose and calculated potential doses.

To this effect, communication of the exact meaning of the radiological yardsticks is a special cause for concern.

International guidance is rather difficult to interpret, understand and apply.

The information and guidance in IAEA and ICRP documents is not self-contained and a simple reading is clearly not sufficient in order to get the messages. Underlying argumentation is often necessary for understanding but it is not always available or clearly communicated. Inconsistencies are also apparent, likely due to the fact that consensus international documents must be compatible with a variety of approaches. Additional complications arise from the need to translate guidance originally written in English into other languages and to transfer international guidance into national laws compatible with different national cultures. Finally, the link between the various versions of documents issued by the different international organisations is not very clear, especially to “non-insiders”.

It is important that stakeholders understand the bases for regulatory judgements.

One important issue is that it is very difficult for all stakeholders to understand the bases on which the regulatory authority will judge safety over the different timescales, including the long term. Clarity on this depends strongly on clarity on the meaning of concepts such as safety, protection, disposal (is lack of control an essential part of the design, or an inevitable but undesired contingency to be planned for but not insisted upon?), system optimisation and duties to future generations as a function of time. International agreement on basic terminology and fundamental concepts could go a long way towards improving clarity in regulation and facilitating communication. At the very least there should be consistent use of terminology and reference concepts within countries.

Important factors that contribute to confidence building and acceptance by the general public and that may not receive sufficient attention include:

- Documented and controlled decision making processes.
- Demonstration of technology.
- Continued dialogue with regulators.
- Support from international consensus.
- Explanation of the fate of the facility once waste is emplaced: how will control be exercised?
- Continued monitoring and memory preservation.

These points should be addressed in policy and/or in regulation, and deserve further discussion. Overall, as much as safety is related to control, regulation should perhaps place increased emphasis on control-related provisions and criteria, and reflect clearly whether lack of controls is considered to be an unwanted (albeit inevitable) situation or whether it is the reference, expected situation. The answer to this question is important also for the definition of appropriate radiological and other performance criteria.

From the pre-workshop survey:

The expression "other than technical indicators of safety" [in a question asking whether national regulations explicitly take into account factors other than technical indicators of safety] was interpreted diversely. The actual examples given were mainly technical (use of natural analogues, use of environmental safety indicators, requirements on technical barriers). The Swedish response stated explicitly that purely ethical issues are not considered to be within the regulatory framework. However, sustainable development was seen as a point of departure for the derivation of the regulatory risk constraint. The Spanish response stated that purely non-technical aspects are considered and the main instruments to accomplish this are the EIA and SEA legislation incorporating the corresponding European Directives and the Aarhus Convention.

As conclusion [from this and other questions] it seems to be that the regulatory requirements themselves are thus confined to technical issues, i.e. the social aspects such as acceptance within the community are dealt with outside the formal licensing process, whether during siting, during environmental impact hearings, or in a national or regional debate on waste management strategy. The role of the regulator during such debates was not mentioned, perhaps because it is usually not spelled out in regulations.

Optimisation

The fundamental goals of optimisation need to be clarified.

On the question of the distinction between system optimisation (in the sense of taking account social and economic as well as all types of hazards) and optimisation of radiological protection, there was extensive discussion but no consensus. In extreme terms, this could be expressed as asking whether optimisation aims to meet dose/risk constraints at the least overall cost, or to apply all reasonable means for reducing doses/risks further. ICRP's current view (as expressed in Publications 101 and 103) is evidently that there should be no significant distinction – both should be processes of systematically evaluating options for reducing impacts. However, there was some concern that this was a change from the ICRP-81 position that optimisation of the long term impacts of geological disposal could be assumed to have been achieved if constraints are met and good science and engineering practice have been applied, a position that had been adopted in the IAEA Safety Requirements WS-R-4.

From the pre-workshop survey:

All countries recognise the basic principle of optimisation of exposures, and all countries apply the constraint of limitation of individual doses during time frames where uncertainties are not so large as to prevent meaningful interpretation of dose calculations. Differences are evident in the way optimisation is applied when dose estimates are below the constraint, and/or for very long time frames where uncertainties dominate. In Sweden, in situations where uncertainties are large, the application of BAT is prioritised over optimisation. In Japan, in the case of intermediate depth disposal a number of different constraints or guide values are applied depending on the relative likelihood of the scenarios.

In the majority of cases there is some form of optimisation requirement, i.e. simple compliance with a numerical dose or risk criterion is not considered sufficient. However, such optimisation requirements are not always quantitative or rigorous. The German response indicated that other factors such as long-term geological stability and consequences of human intrusion are taken into account during the course of optimisation. In the US, ALARA beyond licensing criteria is not required, for reasons described in the response: Optimisation of future doses is considered problematic and introduces intergenerational equity issues. The question is dealt with by the use of constraints well below current dose limits to ensure that future doses are reduced well below currently accepted values.

Optimisation of design (including BAT as a qualitative form of optimisation) is recognised in only a few countries as a regulatory requirement. Even where design optimisation is a requirement, specific techniques and criteria may not be prescribed (e.g. Germany, Spain and Sweden). In the United Kingdom, current BPM and BPEO requirements are being replaced by BAT, and guidance will be developed further.

Optimisation of long-term vs. short-term safety remains problematic.

Optimisation as applied to long-term safety is an issue. While all countries accept optimisation for the period of regulatory control, long-term optimisation is not mentioned in some countries, not only because of the need to balance short-term imperatives with long-term ones, but also because optimisation of future doses is considered problematic and introduces intergenerational equity issues.

Opinions did vary on the relative weight to be given to the distant future and to the near future with regards to optimisation and regulatory decision-making, and the conclusion was that there is, at present, no generally applicable answer to the question. There might be arguments of principle for weighting far-future risks higher than, lower than or the same as near-future risks, depending on the circumstances. Different stakeholders may well have different views on such arguments. It was pointed out that the strategy of concentrating and containing waste for disposal intrinsically gives priority to protection of current and closely-succeeding generations against actual risks over protection of future generations against potential risks, although there is clearly also an intent not to expose future generations to harm. Practical issues related to the choice of workable protection criteria for the far future, and the balance between risk criteria and design criteria such as the use of best available techniques (BAT), may also contribute to the discussion.

From the pre-workshop survey:

In response to the question about balancing the needs of current and future generations, most of the responses were not very specific. In Sweden the implementer should report potential conflicts between operational and post-closure safety but the guidance does not provide specific criteria. The response to this question is also related to the next question about criteria vs. timescale. The Swiss and US responses indicated that both present and future generations must be protected to the same safety standards. In the Swiss guidance, conflicting situations are consistently resolved in favour of future generations. In the United Kingdom, on the other hand, the risk levels used as constraints for the near future are treated as risk targets at long timescales, i.e. are not applied equally strictly, in recognition of the increasing difficulty in interpreting results of calculations with increasing timescale.

No country uses formal methods of weighting of exposures or other indicators. Most countries indicated that the same weight is given to protection of present and future generations. The Swedish response recognised that exposure scenarios in the near and distant future might be evaluated differently with a shift from radiological risk at early times to more robust measures of repository performance for the distant future, and some other responses indicated a general shift from prediction of numerical indicators (dose/risk) towards qualitative indicators (e.g. multiple lines of argument) with increasing timescale, although not an actual change in weighting as such.

The process of performing optimisation is more important than the numerical or scientific result.

Optimisation is increasingly recognised to be more about the process than producing a "scientific" result. Optimisation is not a mathematical process that will necessarily produce a single "correct" answer, but rather a way of considering and judging the best way forward under the prevailing circumstances. There is to date relatively very little real experience in applying optimisation to real decisions in real geological repository programmes. Ultimately, the resolution of questions and differences over what the principles mean may come from practical application and experience. Since this must come from a limited number of projects worldwide, forums such as the RWMC-RF can provide a valuable opportunity to disseminate and exchange examples of such experience.

A transparent, stepwise and iterative process of decision making is essential for optimisation.

There seemed to be general agreement with the view that the optimisation process should involve a dialogue between implementer, regulator and other stakeholders as appropriate. Provided that this process was conducted in a transparent manner, it should be visible in the regulatory process. Transparency would demand that the rules of the dialogue process are published, and the main outputs of the dialogue recorded and made publicly available. Key aims of the process would be to document openly and comprehensively the decisions taken and the role that optimisation had played in them, including which options were considered, which factors were taken into account and how (including reference to any factors that were considered too uncertain to include in the decision), why the preferred option was chosen and why the other options were not chosen.

There was general agreement that stepwise decision making can complement optimisation, helping to break down complex optimisation problems into a series of more manageable and transparent questions. However, this would only be the case if the process is managed properly, the process and principles properly defined and respected, and the contribution that optimisation made to decisions at each step adequately documented. In this area, expertise from the social sciences could be brought to bear in developing guidance on processes.

From the pre-workshop survey:

Several responses interpreted stepwise decision-making to mean the normal sequence of licensing approvals for siting, construction, operation and closure. In this sense, all countries follow a stepwise approach. However, a few countries allow this concept to be taken further, by allowing for hold points and decision-making during the implementation and operational phases. Some (Germany, Sweden and the United Kingdom) allow for a stepwise approach but do not make it a regulatory requirement, although in Sweden the legislative and regulatory system was said to assume that a stepwise approach would be followed whether it was required or not.

The basic, broad rules for decision making and involvement of stakeholders need to be defined in advance.

It is important, in order to build confidence and therefore gain acceptance of the project, to define the basic, broad rules of the process in advance. In addition to defining the rules to be applied by the regulator to the implementer's submissions, these rules should also define the type of involvement of concerned members of the public and the levels of decisions for which they will be consulted. The situation in individual countries may be very different depending on the cultural context. In cases where public acceptance is given high priority, it was noted that this may constrain the optimisation, by requiring particular options to be excluded (e.g. a specific location considered unacceptable to stakeholders) or included (e.g. providing for retrievability), when they might not have been otherwise. This could lead to decisions that are technically "non-optimal", in order to accommodate stakeholder concerns. The one generally accepted qualification to this, however, was that such accommodation of stakeholder concerns should not be allowed to jeopardise safety.

Technical Indicators for Safe Performance

The relative importance of different safety indicators varies with timescale.

There was agreement that the fundamental protection objectives should be the same for the short and long terms. However, the safety indicators need not be the same for different time periods. This is because the roles and predictability of safety barriers and functions change with time. In the short to medium term, the radioactivity of waste is high and protection is ensured mainly by engineered containment and, to some extent, by institutional control. In the long term, loss of engineered containment cannot be ruled out and the safety is ensured primarily by the isolation (limitation of releases) provided by both the engineered barriers and the host formation. There is a general tendency for hard protection criteria used in the short term to give way to softer criteria in the long term. Also, the use of multiple lines of reasoning and evidence of the robustness of the disposal system are significant for the long time periods.

There is still much to be done before reaching consensus on the relative importance of different time frames.

In order to better handle the subject it might be helpful to distinguish between three classes of generations: the present and immediately-following generations (a few hundred years), who benefit from nuclear energy and handle the responsibility of the construction, operation and closure of the repository facility, the future generations in the medium term (hundreds to thousands of years), who may possibly bear the burden of additional control and monitoring the repository and could also take actions directly related to the repository, and the far-future generations (e.g. after a few thousand years), who may have forgotten the existence of the repository and to whom our ability to directly assure protection is necessarily decreasing. Some countries do adjust their regulatory criteria and/or the relative weighting given to compliance on different timescales, but in the interests of clarity it would be beneficial for all countries if the underlying argumentation were discussed and compared internationally.

From the pre-workshop survey:

There seem to be a number of different approaches to timescales. In the most common approach, criteria are constant with timescale, and applied until a time cut-off chosen to include the time of maximum expected consequences (a number of countries seem to have settled on one million years). In another approach (France, United Kingdom) a single numerical criterion is used but is interpreted differently for different timescales (hard constraint for relatively near timescales, but a target at longer timescales). Some other countries recognise a number of time periods (Finland, Sweden), typically with a change in emphasis on calculation outcomes and use of varying performance measures with different timescales.

Responses [to the question on numerical criteria for different timescales] varied. Some countries claimed not to change criteria (although in some of those cases the use to which the criteria are put changes, e.g. targets vs. constraints as in France and Sweden). In the United Kingdom, there is a change between pre-closure (or period of authorisation) and post-closure constraints, but post-closure (or more accurately, after the period of authorisation), the criteria do not change, although the way in which they are used varies with time. Finland recognises a change in criteria with timescale; the new regulations in the US may do likewise.

More discussion is needed on time cut-offs for regulatory compliance.

Discussion on time frames and time cutoffs still elicits a wide variety of points of view without any clear consensus. There appears in some countries to be some agreement with an upper limit on compliance demonstration on the order of 1 million years, based on a number of arguments (e.g. geological stability, inability to deal with uncertainties, decreasing ability to control impacts at very long timescales, decreasing consequences at longer times due to radioactive decay), but this is certainly not universal. More discussion of the reasons behind these cut-offs would be helpful.

From the pre-workshop survey:

The understanding of "cut-off in time for the application of regulation" is different depending on the country. In fact, the end of the period of proven geological stability (at least 10 000 years) in the French guideline is used in almost the same way as a cut-off as in the Swiss and German cases (1 million years). In some countries that quoted the one million year figure, it was not clear what, if anything, would be used for longer timescales. Sweden does not require reporting of radiological consequences beyond 1 million years but the guidance asks for a description of the evolution of long-term radiological toxicity (irreducible long-term hazards have to be dealt with when selecting a strategy for waste management).

More discussion on the meaning and applicability of protection criteria is required.

The use of the word "dose" by itself may be misleading, as it may be taken to mean absorbed dose by an individual, which is a *very* different concept to effective dose as used in regulatory applications. The concept of effective dose, even when used for present situations, is a stylised indicator quantity rather than a true measure of health detriment to, or the risk run by, a particular individual. Added to this are the uncertainties and difficulties relating to long-term future calculations. Indeed, ICRP-101 states that: "The Commission feels that our current state of knowledge and our ability to predict populations and exposure pathways can appropriately contribute to decision-making for exposures to occur over a time period covering a few generations. Beyond such time frames, the Commission recommends that predicted doses should not play a major part in decision-making." Nevertheless, it was also stated at the workshop that "It is a mistake to consider that the ICRP dosimetric quantities and the radiation detriment are not appropriate for long term evaluation." Thus, while potential effective doses may be calculated as relative performance indicators and contribute importantly to decision making, they should not be interpreted as predictions of actual impacts on future persons and used as absolute limits. The distinction is subtle, and the use of calculated effective doses as a primary criterion for acceptance, even at very long time frames, should be reconciled carefully with these recommendations.

From the pre-workshop survey:

Interestingly, except for Germany, Spain, Sweden and the United Kingdom, the responses appeared not to explicitly acknowledge the point made in both ICRP-81 and WS-R-4 about the interpretation of calculations of doses in the distant future; that is, that such calculations should not be considered to be direct measures of health detriment, but only as comparative indicators. Indeed, in at least one case (Switzerland), while the point was recognised in earlier guidance, current guidance no longer mentions it. The Japanese response cited the lack of an alternative indicator as a reason for not explicitly mentioning this principle.

The question of the duration of control is taking on increasing importance.

Although deep disposal is a planned activity, it may lead to unplanned, potential exposures. As a planned activity, a geological repository should remain under control as long as it is a potential source of exposures. The issue of the duration of control, the types of events that may lead to loss of control, and the types of controls that may be relied upon over different timescales need to be better understood and addressed. The issue of maintenance of control is a challenge to regulators, as well as to implementers and policy makers. This issue is closely connected to the issues of transfer of responsibilities, information and memory preservation as well as to the meaning of safety, which is often presented as being related to maintaining control.

From the pre-workshop survey:

The responsibility of the regulator terminates either with licensing of closure or with the end of a post-closure monitoring or institutional compliance period of up to a few hundred years.

The Finnish, German, Japanese, Spanish and Swedish responses [to the question on transfer of responsibilities in the long term] recognise that the ultimate responsibility rests with the national government (in Sweden, the fact of ratifying the Joint Convention was seen as acknowledging this fact). Other responses did not deal with this question.

The responses as a whole did not really deal with the question [on how regulations take into account decreasing capability of control over time] beyond a short period immediately after closure. For the most part, they appeared to assume that issuance of approval for closure, based on the applicant's submission, would be sufficient to overcome any questions that might arise.

Most responses [to the question on how regulators achieve and communicate confidence in long-term safety decisions in the absence of controls] went into some detail about the means by which quantitative analyses were assessed and accepted for licensing purposes. Most regulators rely on compliance with quantitative dose and/or risk criteria, although some mention the concept of reasonable assurance (US) or multiple arguments (Finland). The Swedish response discussed the role of optimisation in achieving confidence, and the German response indicated that there was an emphasis on the demonstration of geological stability and isolation of radionuclides from the biosphere, not only on dose calculations. Difficulties in achieving a broader level of confidence outside the regulator were not mentioned except in the Spanish response, where the integrity of the regulator was cited as one of the factors influencing confidence.

Regulatory Research and Development Activities

Regulators have R&D needs different from those of the implementer.

Some of the current research needs identified included non-technical issues such as communication, credibility, social and ethical aspects, risk perception and timescales in connection to regulatory expectations. Also mentioned were pre-monitoring at different potential repository sites and the development of stylised approaches regarding inadvertent human intrusion. The issue of guidance on the conduct of regulatory activities, i.e. how to be a regulator, was also raised as an area both for R&D and for international guidance.

Regulators need to sponsor and participate in R&D activities in order to maintain competence and credibility.

It was widely agreed that in order to maintain technical competence, regulatory staff need to be familiar with current research and development themes and issues of safety significance. It was also agreed that regulatory staff need to sponsor, and be closely involved in, research projects to achieve this;

reading about and attending presentations on research carried out by others may not be sufficient. There is a need for independence of the regulator from the implementer, but the quality of the work is pre-eminent, and joint participation with implementers and support organisations should not be ruled out.

Limited resources oblige the regulator to focus on key questions and key safety issues rather than trying to cover all aspects.

It is impossible for the regulator to keep up with the variety of research sponsored or carried out by implementers. Close international co-operation among regulators and supporting expert organisations may help in this regard. It was noted that, especially for performance assessment, the regulator needs to acquire the competence to assess the completeness of the list of possible scenarios (features, events and processes) and to review the safety case. Competence and independence are key requirements for any regulator, including for attracting new staff into regulatory positions. Regulatory research can thus help in many ways.

From the pre-workshop survey:

Almost universally, the responsibility for managing uncertainties was considered to be the operator's, with the regulator's role being limited to those of identification of uncertainties not already addressed by the operator and of assessment of the operator's treatment of uncertainties in order to be able to reach a conclusion about the acceptability of the licence application.

Human Actions

Reduction of the likelihood and the consequences of intrusion are important goals.

There was a broad consensus that regulation for site selection, repository designing, construction and closure should require measures aiming at reduction of the likelihood and the consequences of intrusion. In detail, documentation on the repository position and its radiological potential, the application of markers, disposal in deep geological formations as well as keeping distance from resources which could be of potential interest for future generations were regarded as appropriate measures. The effectiveness and feasibility of measures to reduce the likelihood and the consequences of intrusions should be evaluated by expert judgement.

From the pre-workshop survey:

There was a range of responses on [the question on human intrusion], from no explicit requirements for assessment of intrusion events (Spain and Switzerland) to detailed guidance (the United Kingdom). In many cases (France, Germany, Japan, Sweden, United Kingdom, United States), human intrusion scenarios are reported separately; in Finland human intrusion events are addressed together with other disruptive events.

Almost all responses [to the question on requirements for measures to reduce the likelihood of intrusion] indicated that some such requirements, usually including formal retention of records and land use controls, existed. Requirements for avoidance of sites associated with mineral resources and for establishment of physical markers exist in a number of cases. These requirements may be administered by agencies other than the regulatory body responsible for licensing. There did not appear to be any attempt to reconcile the timescale for survival of physical markers with the timescale for assessment of consequences.

Measures are required to assure information maintenance over a long time period.

For documentation, technologies and practices should be used which assure information maintenance over a long-time period, as a basis for future institutions to preclude human activities in the vicinity of the repository. Regulators should assess the regulatory significance of information maintenance and memory preservation over different timescales, taking into consideration the likelihood of changes in the institutions and organisations that will be responsible for acting on the information. Documentation should be provided after the closure phase of a repository and, if applicable, during further steps of periodic information update.

It was pointed out that the local community of the repository site, as the keeper of the legacy, could be one of the most important keepers of this kind of information. Additionally, broad information dissemination at an international level would effectively reduce the possibility of complete knowledge loss in the future.

The results of human intrusion scenarios should be used in safety cases to demonstrate robustness, but more work is needed on criteria and indicators.

The participants agreed that radiological constraints should be considered inappropriate as compliance criteria for the consequences of intrusive actions. However, as far as foreseeable, disastrous developments initiated by human intrusion, leading to high radiological exposures for a large number of people in the vicinity of the repository, should be avoided as far as possible by appropriate site selection and repository design. Furthermore it was agreed that the results of human intrusion scenarios could also be used in a safety case to demonstrate the robustness of the repository system and the safety concept. There was unanimous agreement that consequences to the intruder who comes into direct contact with the waste should not be required to meet regulatory protection goals. These consequences may need to be calculated but they should neither be evaluated against quantitative limit values nor be used as a crucial criterion for the repository optimisation process.

More regulatory guidance is needed in the field of human intrusion aspects.

An appropriate and proportionate consideration of human intrusion in a safety case will be an important element in terms of confidence building. Hence, the role of the regulator is considered as crucial in providing guidance specifying the boundary conditions (e.g. completeness and depth of detail) of stylised human intrusion scenarios to be considered by the applicant and in defining requirements on site selection and repository design, as well as on documentation of the repository location and its radiological potential and further measures aiming at a reduction of the likelihood of human intrusion.

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Session 1

Introduction

Chair: Uichiro Yoshimura (OECD Nuclear Energy Agency)

Opening Remarks from Session Chair

Uichiro Yoshimura
OECD Nuclear Energy Agency, France

Ladies and Gentlemen,

As the session Chair and representative of the Nuclear Energy Agency of the OECD, I would like to welcome you to this important event hosted by the Government of Japan through its Nuclear and Industrial Safety Agency (NISA) in co-operation with Japan Nuclear Energy Safety Organization (JNES).

Over a period of two and a half days, we will learn about the geological disposal scene in Japan and we will debate on the foundations of regulations for geologic disposal of high-level and long-lived nuclear wastes.

This workshop comes at a time when some leading countries are putting in place national strategies and plans for management of all types of radioactive waste that include detailed roadmaps for establishing the necessary decision frameworks for implementing disposal facilities. The availability of transparent, proportionate and deliverable regulation constitutes an important component of the frameworks needed for progressing with the national plans.

Decision makers and opinion leaders, like you, are being called to play an important role in moving this issue forward. Hence the value of a forum such as this where, through the exchange of information with other colleagues faced with similar tasks worldwide, decision makers and opinion leaders can debate possibilities in formulating safety regulation for geological disposal.

Perhaps, I should say a few words to explain why it is the NEA that organises the workshop. And what is the NEA?

The NEA is a specialised agency of the OECD, an organisation whose member countries represent pluralistic democracies and the most developed market economies in the world. The OECD acts a monitoring organisation by providing its member governments with one of the world's largest and most reliable sources of comparative statistical, economic and social data. The OECD also acts a think-tank on behalf of its member governments by providing policy advice.

Over 80% of the world nuclear installed capacity is in OECD countries, and this predominance in the nuclear field is projected to hold for decades to come. As part of the NEA mission to our 28 member countries, we utilise international co-operation to maintain and further develop the scientific, technological and legal bases that are required for a safe and economical use of nuclear energy for peaceful purposes. At the NEA we also provide authoritative assessments on the status of the art and we help forge common understandings on key issues. The aim is to inform both our member governments' deliberations on nuclear energy policy and the broader OECD policy analyses in such areas as energy and sustainable development.

Safety in all parts of the nuclear-electricity production chain is the foremost priority in the NEA technical programme of work. We have thus activities in the fields of reactor safety, repository safety and decommissioning safety. These activities are typically supported by specialised projects involving data acquisition and data- and codes-maintenance.

We are important actors on the international scene and we participate as peers in major international efforts, such as the updating of the IAEA Basic Safety Standards. We have collaborated strictly with the ICRP in its decade-long efforts to formulate their December 2007 recommendations; we co-author policy- and safety-related documents with other international organisations, namely, with the IAEA.

For over 30 years now, the NEA has been a leader in the area of geologic repository safety. Our first major study dates from September 1977, when we issued the so-called "Polvani report" on "Objectives, concepts and strategies for the management of radioactive waste arising from nuclear power programmes". We have now a specialised group, the Integration Group for the Safety Case (IGSC) that deals with the technical aspects of the repository safety case. This is the international group that has developed the modern concept of the disposal safety case.

We also have other groups that help our member countries move forward on the way to safe disposal. These groups include the Forum on Stakeholder Confidence (FSC), which examines stakeholders' issues as they relate to long-term radioactive waste management and the Radioactive Waste Management Committee (RWMC), which oversees the whole work of the NEA in this area. Last autumn the RWMC released a collective statement on the need to move forward with geological disposal of radioactive waste. The collective statement has been distributed with this workshop papers.

Most our groups include R&D specialists, implementing organisations and regulators. Indeed we believe strongly in dialogue and we make sure that boundaries, when they exist, are not there to hinder but, in fact, are there to make more understandable to others the sensitivities and variety of viewpoints that may exist.

The Regulators Forum (RF) is the regulation-specific independent forum constituted by the regulator members of the RWMC. They are at the origin of this workshop. I will not tell you more about the RF, as Mr. Arens, the Chairman of the RF and also Chair of this meeting, will present the work of the Forum.

As a session chair of the introductory session to the workshop, let me reflect on what could be expectations from the workshop and the rest of the session.

When dealing with the long term we need to understand and communicate clearly what is practicable and deliverable, and over which timescales. Attention should be made neither to oversimplify nor to raise unachievable expectations. This poses challenges to the regulators.

If what may be practically deliverable, by the regulator and other, changes with time, how is then time to be factored in regulation? Time is basically never an issue in other regulations in society. Elsewhere, in other regulatory fields, it is always assumed that a regulator will exist both to implement the regulation and to adapt it in the face of experience. Regulation in the field of radioactive waste disposal seems to have moved apart from the regulatory approach concerning other equally long-lived hazards.

It can be observed further that verification, controls and monitoring will take place long after a repository is filled. The existence and role of the regulator over important timescales, reaching possibly into several hundreds of years, should constitute important aspects of both technical and stakeholder confidence, especially if adequate importance is also given to stepwise decision making. How can that be taken into account?

Indeed, while at one time disposal of high-level waste and spent fuel was viewed as an activity to be completed in the time span of perhaps a single generation, the implementation of a disposal project has come to be viewed as an incremental process, perhaps taking several decades to complete and with many decisions to be rendered along the way. This changing vision involves not only the concept of protection of future generations, but incorporates as well the assumption that they will be involved in the process and that we need to preserve their ability to exercise choice. How much do we then need to address now in regulation and how much can we pass on to future colleagues and generations?

Overall we should ask ourselves if we have the tools and relevant concepts for regulating over different timescales, and we should discuss the communication that needs to be made to policy and decision makers about residual risks that it would be for them to decide upon.

Regarding this first session I observe that

- Mr. Hiraoka, NISA Deputy Director General, will provide opening remarks on behalf of the Japanese hosts, whom I thank for the excellent venue and arrangements they are providing.
- Mr. Arens, the Chairperson of the RWMC Regulators Forum and Head of the Radioactive waste Division in the BMU in Germany, will introduce his international group and what has led to the organisation of this workshop.
- We will have then an overview of the Japanese radioactive waste disposal scene. The speakers are high-level Japanese colleagues: Mr. Matsuo, Director of the Radioactive Waste Regulation Division at NISA; Mr. Kajita, Director of the Subsequent Regulation Review Division at NSC; Mr. Kawata, Executive Director at NUMO; and Mr. Kato, Deputy General Manager at FFPC**.**
- Finally, a presentation on the current status of long-term safety regulation will be provided by Dr. Pescatore, Deputy Division Head for Radioactive Waste and Decommisioning at the NEA, who will also speak on behalf of Mr. Allan Duncan, who could not be here. Mr. Duncan was previously Director and Chief Inspector of Her Majesty's Inspectorate of Pollution and Head of Radioactive Substances Regulation in the Environment Agency in the United Kingdom. He is an historical figure in the world of environmental and waste disposal regulation.

Final remarks

Dear Colleagues, your participation in this workshop witnesses the commitment of your countries to the dialogue, at all levels, on the management and disposal of long-lived radioactive waste. On behalf of the NEA I can say that we look forward to keeping the dialogue ongoing and to helping all parties fulfil their different roles towards regulating and implementing geological disposal of radioactive waste. I wish all of us a successful workshop.

First RWMC-RF Workshop Opening Remarks

Eiji Hiraoka
Nuclear and Industrial Safety Agency (NISA),
Ministry of Economy, Trade and Industry (METI), Japan

Good morning, ladies and gentlemen,

Let me introduce myself, I am Eiji Hiraoka, the Deputy Director-General for Nuclear Fuel Cycle of the Nuclear and Industrial Safety Agency (NISA). On holding the first Workshop for the OECD/NEA Radioactive Waste Management Committee Regulators' Forum (RWMC-RF), it is my great pleasure to welcome all here in attendance on behalf of the Japanese hosts.

It is a great honor for us to host this Workshop where numerous representatives of regulatory organisations and operators for disposal, and experts from all over the world have come to discuss international issues on safety regulation for geological disposal of radioactive waste.

We wish to extend our heartiest thanks to the OECD/NEA Secretariat, who have planned and prepared for this Workshop, and to the members of the Programme Committee. We would also like to express our great appreciation for the co-operation from the Japanese experts, and specifically Japan's Nuclear Energy Safety Organization (JNES).

I would like to mention as well that we are very grateful for the OECD/NEA activities to enhance international nuclear safety, and NISA is happy to participate in the work of the OECD/NEA committees including the Committee on the Safety of Nuclear Installations (CSNI), the Committee on Nuclear Regulatory Activities (CNRA), the Committee on Radiation Protection and Public Health (CRPPH) and the Radioactive Waste Management Committee (RWMC). We will continue to contribute to such NEA activities.

As for the current status of nuclear safety regulation in Japan, the most significant topic is the matter of seismic safety. Two years ago a serious earthquake occurred near the Kashiwazaki-Kariwa NPPs. As soon as the earthquake took place, all four operating units at Kashiwazaki-Kariwa automatically shut down and fulfilled their basic safety functions. However, other facilities of lesser safety significance were damaged by the earthquake. This unfortunate event has had the side effect of increasing our knowledge of seismicity.

NISA has had NPP operators improve their seismic safety, and the knowledge of seismic safety gained from this earthquake helps them. We hope that the knowledge and experience concerning seismic safety that Japan has acquired so far will be used for improving the seismic safety of power plants around the world. We are now considering the establishment of the internationally valuable technological basis for seismic safety, in co-operation with the International Atomic Energy Agency (IAEA).

The main topic of this Workshop is geological disposal of high-level radioactive waste. This is one of the most significant issues in Japan's nuclear policy. It is essential to resolve these issues scientifically and rationally as well as to gain the approval of the nation, for further development of the utilisation of nuclear energy.

With regard to the current status of radioactive waste management in Japan, we have arranged for subsequent speakers to present it here in session 1, after my presentation. NUMO, the implementing organisation, is expected to make progress in siting and in establishing technical feasibility; NISA, the safety regulatory authority, is expected to make progress in establishing the safety regulation rationally. It is also important for NISA to increase our knowledge basis through safety research done by means of research organisations and experts. I think that this can apply also to other issues.

The OECD/NEA RWMC has consistently helped us with outcomes such as safety cases for long-term safety of waste disposal and the retrievability of wastes. We are grateful for these efforts of the NEA committees. We, the Japanese delegation, would like to contribute to NEA activities, in expectation of further outcomes.

I sincerely hope that attendants in this Workshop will achieve constructive proposals about the topics considered in order to establish long-term safety criteria for geological disposal and will collect profitable leads for further work that the Regulators' Forum will be able to take up as significant themes in the future.

In conclusion, I would like to express my best wishes for the success of this three-day Workshop and hope your visit to Japan will be a pleasant one.

Thank you for your attention.

The Role and Work of the Regulators' Forum of the NEA Radioactive Waste Management Committee

Georg Arens
Federal Ministry for the Environment,
Nature Conservation and Nuclear Safety, Germany

Introduction

The Regulators' Forum (RF) of the NEA Radioactive Waste Management Committee (RWMC) is a well-established forum of senior regulators having a comprehensive vision of the regulatory framework of radioactive waste management and decommissioning in the NEA member countries. It provides regulators with an opportunity for open discussion and exchange of information about national experience and practices for regulation with a view to refinement of regulatory systems in this field. The RF recognises the importance of effective interaction between regulators, implementers, policy-makers and scientists, in order to reach a wider understanding of the issues associated with our responsibilities to present and future generations, and of the societal demands impacting directly on the role of the regulators in the field of management of radioactive materials and waste. This is the first of a series of workshops in an international context the RF has planned to organise.

RF Mandate and Profile

The RF was established in 1998 and current representation brings together regulatory bodies from 17 OECD countries: Australia, Belgium, Canada, Finland, France, Germany, Hungary, Italy, Japan, Korea, Norway, Slovak Republic, Spain, Sweden, Switzerland, United Kingdom and United States. Both nuclear and environmental safety authorities are represented. All members of the forum are also members of the RWMC.

The forum provides its members with an opportunity for open discussion and learning about national experience and good practice in regulation with a view to refinement of the regulatory systems in this field. The forum promotes exchange of experience with other NEA committees and international organisations, and maintains a strong interaction with the specialised working parties of the RWMC. Effective interaction is promoted at RF meetings and workshops between regulators, implementers, R&D specialists, policy makers and social scientists.

RF Activities and Publications

Communication and learning within the forum is by way of studies and surveys on regulatory issues, often with the support of specialised parties of the RWMC, through annual meetings and workshops on themes of particular interest to regulators, and through exchange of information with other NEA committees, such as the Committee on Nuclear Regulatory Activities.

At regular meetings information is exchanged on national developments, study findings are discussed, and topical sessions allow members and outside speakers to address a central issue from many perspectives. Mandates may be given to subgroups to carry out specific work.

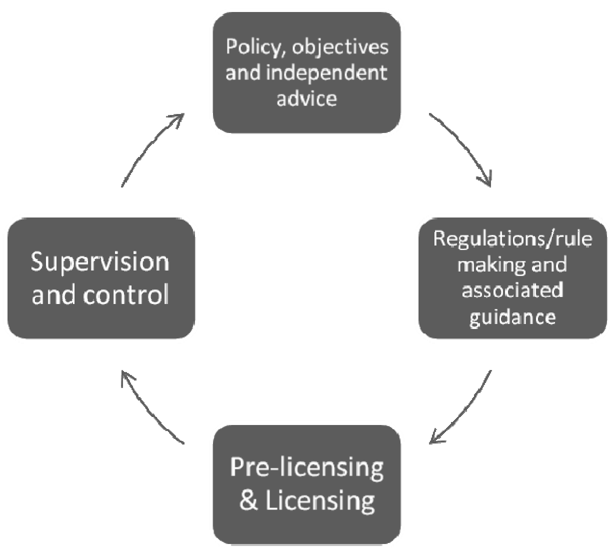
At workshops, specific topics are dealt with in depth, taking advantage of a wide range of expertise beyond traditional regulatory or technical specialists. Participants also have the opportunity to learn about the host country's waste management programme and its national context.

The RF has a policy of producing documents for wide distribution. Typically these address the development and refinement of the regulatory system with a view to improve regulation and regulatory practice, to illustrate the nature of the underlying issues, and to further establish the forum as an importance source for regulatory guidance.

Publications and reports of the RF are available for downloading from the RF website at *www.nea.fr/html/rwm/regulator-forum.html*

The Regulatory System

Regulatory functions are carried out not only by technical regulatory authorities, but involve, especially at the policy level, other bodies such as Parliament, Government, and regional authorities. Also, there may be more than one technical authority issuing guidance, taking part in licensing, and carrying out control and supervision. The RF has found that the elements associated with a regulatory system may be conveniently depicted as a cycle that embraces the principle of continuous improvement as illustrated in the diagram.



Current Topical Areas

Within the four main areas of the regulatory cycle, and taking the major responsibilities of the technical authorities into account, the RF focuses its programmes as follows:

Policy, objectives and independent advice Emphasis is placed on aspects of policy where input from regulatory authorities is expected to have significant weight, e.g. in the elaboration of national plans for the long-term management of spent fuel and radioactive waste.

Regulations/rulemaking and associated guidance Emphasis is placed on the regulatory aspects of the operational phase of a repository, practical aspects of repository regulation for the long term, and regulating legacy and non-fuel cycle waste.

Pre-licensing and Licensing Emphasis is placed on the regulator-implementer dialogue, definition and implementation of the concepts of Best Available Techniques and optimisation for geological repositories.

Supervision and control Emphasis is placed on the supervision of decommissioning projects and on the waste acceptance process. A special area is the oversight of the arrangements on costing and funding of radioactive waste management and decommissioning and the role of the regulator.

The Regulatory Function

The RF comparative study of regulation of radioactive waste management in NEA member countries shows that there is no unique or best way of to deliver the various elements of the regulatory cycle. The formal structures and organisational arrangements depend on the national constitutional structure, legal and institutional framework and, to a large extent, on national regulatory culture, e.g. expectations on how prescriptive regulation should be. In most cases, major regulatory decisions emerge only after co-ordination of a wide range of relevant and authoritative inputs, e.g., from central Government departments and other governmental technical authorities, from local communities, and from independent advisory bodies or commissions. [see *The Regulatory Function and Radioactive Waste Management: International Overview*, (NEA-6041, 2005)]

Regulating Long-term Waste Management

Specific attention has been given so far to the regulatory criteria for the long-term performance of geological disposal. The RF studies have shown differences between national radiological criteria that are difficult to explain in simple terms to the general public. The study of long-term regulatory criteria has introduced elements of ethical consideration and of social acceptance. Ethical issues arise because of the long timescales involved and the impossibility of guaranteeing contemporaneous regulatory control over such periods of time. The RF studies observe that our capacity to secure delivery of any defined standard for protection diminishes with time, which raises technical and ethical questions about what we should and can deliver and over what timescales. Sustainability and our obligations to future generations are subjects of central consideration in national policies of long-lived waste disposal and are aspects of great importance to regulatory bodies. [see *Regulating the Long-term Safety of Geological Disposal: Towards a Common Understanding of the Main Objectives and the Bases of Safety Criteria*, (NEA-6182, 2007)]

Regulating Decommissioning

Decommissioning of disused nuclear facilities involves both conventional and radiological hazards. For the RF, important issues include authorisations during the dismantling process, the disassembly of large components, and the management of all materials. Specific attention has been given so far to adapting regulatory practice to the dynamic work environment and the changing risk profile of a facility undergoing dismantling. One emerging practice involves greater use of internal authorisation systems for plant modifications of minor safety significance, with a first level of oversight by an independent committee established by the plant operator. In this situation regulatory resources are focussed on issues that are most important for safety. [see *Regulating the Decommissioning of Nuclear Facilities: Relevant Issues and Emerging Practices*, (NEA-6401, 2008)]

The Regulator's Evolving Role

In the areas of rulemaking, control and supervision of nuclear installations, the roles and responsibilities of regulators traditionally include the following core tasks: identification of regulatory options, evaluation of their consequences under different conditions and making choices among these options. The regulator then communicates these choices, and the bases for its decisions, to the affected parties. In today's context it has become increasingly important, however, for the regulators to maintain transparent processes that are open to scrutiny and to serve as sources of information and expertise to local communities. Regulators provide stakeholders with understandable explanations of the mechanisms of regulatory oversight and decision making, including the opportunities for stakeholder participation. [see *The Regulator's Evolving Role and Image in Radioactive Waste Management,* (NEA-4428, 2003)]

Expectations for this Workshop

Questions specific to the present workshop have arisen from RWMC activities, including the RF recent report on "*Regulating Long-Term Safety of Disposal*" (NEA-6182), the 2006 RF Workshop NEA-6423, and the IGSC work on timescales, (EA/RWM/IGSC(2006)3. Additionally the RF carried out a survey of countries' regulatory positions that served to prepare the present workshop. NEA/RWMC/RF(2008)5/PROV. The survey results were provided with the workshop materials. Other workshop materials include (a) a review study on progress in regulation for geological disposal since the Córdoba workshop of the NEA in 1997, NEA/RWMC/RF(2008)6, and (b) a review study on guidance in the field of optimisation of geological repositories, NEA/ RWMC/RF(2008)2.

The general purpose of the workshop is to deal with the questions of transparent, proportionate and deliverable regulation for long-term safety in as broad a fashion as possible.

Subsidiary aims towards this goal are to help the RF and its partners:

- Evaluate and update the current regulatory position in the past decade, namely since the output of the NEA Córdoba workshop of 1997, and add more recent developments/international guidance.
- Complete the current understanding of the process for establishing long term safety criteria and the major motivation for differences.
- Establish areas of agreement/disagreement (e.g., duties to future generations, timescales for regulation, stepwise decision making, roles of optimisation and BAT, multiple lines of reasoning, safety and performance indicators and limitations, recognition of uncertainties, importance of stakeholder interactions, etc.).
- Identify the elements of a successful process of regulation for the long term.
- Carry out the first phase of a RF project to study the regulator's needs for research and development on regulatory-related issues.

Regulation for Geological Disposal in Japan

Hiromichi Matsuo
Nuclear and Industrial Safety Agency (NISA),
Ministry of Economy, Trade and Industry (METI), Japan

This talk describes how radioactive waste management is organised and carried out in Japan and introduces the current activities in view of the implementation of geological disposal, including consideration of intermediate depth disposal for some waste. I will also cover safety research on geological disposal.

Governmental and major organisations relevant for research, development and utilisation of nuclear energy

In Japan promotion of the utilisation of nuclear energy for peaceful purposes is governed by the "Atomic Energy Act". The Atomic Energy Commission (AEC), Cabinet Office, established nuclear implementation policy in "The Framework for Nuclear Energy Policy". The current policy has been in place since October 2005.

In accordance with Japan's policy, the Ministry of Economy, Trade and Industry (METI) is responsible for commercial facilities such as the nuclear power plant (NPP), and the Ministry of Education, Culture, Sports, Science and Technology (MEXT) is responsible for research reactor facilities.

As for the operators of nuclear facilities in Japan, Electric Power Companies such as the Tokyo Electric Power Company and the Kansai Electric Power Company have been operating NPPs, while the Japan Nuclear Fuel Limited (JNFL) has been operating nuclear cycle facilities and activities. The Nuclear Waste Management Organization (NUMO) is planning to operate the facilities and activities of geological disposal in the future.

Current Status of Major Nuclear Facilities in Japan

Commercial NPPs

The Electric Power Companies currently operate 53 plants.

Facilities other than Commercial NPPs

A large number of facilities exist covering all phases of the nuclear fuel cycle. Of special interest are: Monju, a fast-breeder research reactor under construction at Tsuruga city, Fukui prefecture. In Rokkashomura, Aomori prefecture, JNFL is operating several nuclear fuel cycle facilities and getting ready for a reprocessing plant for spent nuclear fuel.

Overview of Radioactive Waste

Classification of Radioactive Waste

We divide the radioactive wastes into high-level waste and low-level waste, and classify the low-level waste, as waste generated from NPPs and TRU waste from nuclear cycle facilities. (See Table 1)

Table 1. **Classification of Radioactive Waste in Japan**

<table>
<tr><td rowspan="8">Classification</td><td colspan="3">HLW</td></tr>
<tr><td rowspan="6">LLW</td><td rowspan="3">Waste from nuclear power plants</td><td>Relatively higher radioactivity</td></tr>
<tr><td>Relatively lower radioactivity</td></tr>
<tr><td>Very low-level radioactivity</td></tr>
<tr><td colspan="2">TRU waste (Waste containing transuranic nuclides)</td></tr>
<tr><td colspan="2">Uranium waste</td></tr>
<tr><td colspan="2">RI and waste from research facilities, etc.</td></tr>
<tr><td colspan="3">Material that does not need to be treated as radioactive waste (waste below the clearance level)</td></tr>
</table>

Concept of Radioactive Waste Disposal

In Japan, we have three concepts for radioactive waste disposal. They are: surface disposal, intermediate-depth disposal and geological disposal according to the classification of various kinds of radioactive waste (Table 1).

Surface disposal facilities are in operation in Aomori and Ibaraki prefecture. Intermediate-depth disposal and geological disposal are under consideration of research and development for feasibility.

Regulatory System for Radioactive Waste Management

Two ministries are in charge of the regulation of radioactive waste: METI is in charge of the regulation of wastes generated from NPPs and nuclear cycle facilities under the Reactor Regulation Law; MEXT has been regulating wastes from radioisotope utilisation under the Radiation Hazards Prevention Law. Within METI, the specialised Agency that takes care of radioactive waste is NISA, within which I am the director of the division that regulates waste.

The Nuclear Safety Commission (NSC) is the administrative organisation of the Cabinet Office and is in charge of nuclear safety guides, such as defining the basic concepts for safety to be complied by both ministries.

Geological Disposal (HLW and TRU Waste of Higher Radioactive Concentration)

In Japan, a law was enacted in June 2000 in which the responsible organisation, NUMO, and a stepwise siting process of geological disposal were established. NUMO is now addressing the stepwise siting process of geological disposal site.

Stepwise Siting Process for Geological Disposal Facility

The stepwise siting process encompasses three steps. The first step is a literature survey, the second step consists of a preliminary site investigation and the third step is detailed site investigation. In selecting any site, NUMO shall submit a report about the relevant site for approval by the Minister of METI; the NSC will implement the safety review. NSC released in September 2002 its basic reference criteria for reviewing the results of the first investigation step. NSC will establish the criteria for every subsequent step.

Status of Safety Regulation

After a geological disposal site is selected through the stepwise siting process, safety regulation on geological disposal shall be applied. First, before construction, NISA shall review design principles of the repository in the application submitted from NUMO. NSC shall re-check safety aspects of the review results by NISA, and after NSC judges the safety, NISA shall grant NUMO the license to operate geological disposal. In the future, NSC is to establish the review guidelines. Once the project is started, subsequent regulations such as inspection and approval of closure of a tunnel are to be enforced by NISA. The detailed concept and design of the repository will be shown in the upcoming presentation by NUMO.

Intermediate Depth Disposal

At present, the waste with relatively higher radioactivity generated from NPPs, such as spent control rods, and the TRU waste with a certain range of radioactivity concentration, is due to be disposed of at a depth of approximately 50 to 100 meters. In July, 2007, the NSC formulated its recommendations on the evaluation methodology based on the risk informed concept and approach in order to assess the long term safety in the presence of uncertainty for this concept. The intermediate-depth disposal concept provides useful information for discussing the evaluation methodology of the geological disposal. In upcoming presentations, the NSC will show its evaluation methodology for intermediate depth disposal, and the Federation of Electric Power Companies (FEPC) will present the project of intermediate-depth disposal.

Safety Research and Development for Geological Disposal

Safety research has two basic aims: one is the establishment of the technological basis for geological disposal, namely the construction of the facility design and the operational safety measures as operator of the facility; another is making standards for regulation and reviewing the safety as regulator of the facility. However, as researchers intend to yield results that are science-based, most of these results can serve both the implementation and the regulatory objectives.

Regulatory Research and Development Activities

Current Status

At present, NSC and NISA are considering the next phase of the safety research plan, targeting from 2010 to 2014. As mentioned previously, we think that we need to make the structure for mutual utilisation of the outcomes between the operator's research for establishment of the technological basis for geological disposal and the regulatory research, in a specific field, such as geological disposal, in which many data are needed to be stored accurately and steadily over a long period. Of course, ensuring the independence of the regulatory research should also be a premise. Furthermore, we would like to cooperate with other countries' organisations in the research field that are facing similar issues as us. One important issue is that it is very difficult for the public to understand the basis on which the regulatory authority will judge the safety in the long term. Therefore, we would like to consider a common approach to deal with this problem at present. I hope that these topics will be discussed in Session 5 in detail.

Thank you for your attention.

Current Activities in Nuclear Safety Commission (NSC) for Safety Regulations on Radioactive Waste Disposal in Japan

Keigo Kajita
Secretariat of Nuclear Safety Commission, Japan

Role and Responsibility of NSC

The Nuclear Safety Commission (NSC) of the Prime Minister's Cabinet Office is an independent administration office established in 1978 based on the Atomic Energy Basic Law and the Law for Establishment of the Atomic Energy Commission (AEC) and the Nuclear Safety Commission. The NSC's role is to administer the function of safety regulation by the nuclear regulatory organisations and thereby to ensure and enhance safety in utilisation of nuclear energy and use of nuclear fuel and materials.

NSC is given the authority to make recommendations under the name of the Prime Minister to the regulatory organisations of the relevant administration, if needed.

Main activities of NSC are shown as follows:

- Ensure safety: safety review, development of regulatory guides, review and audit of the subsequent regulation, radiation protection, etc.
- Establish Knowledge Base: nuclear safety research, etc.
- Prepare for nuclear emergency: emergency technical advice, etc.
- Continued communication with the public: white paper on nuclear safety, etc.

NSC consists of five commissioners, the administration office and advisory groups. The Prime Minister with approval of the Diet appoints the commissioners. The role of advisory groups to NSC is to provide technical advice to the NSC's activities in the regulatory safety examination of nuclear facilities, the development and revision of regulatory guides and the preparedness for nuclear emergency.

Activity in Radioactive Waste Management

Our Goal: Safe Disposal of Radioactive Waste

Safe disposal of radioactive waste is the essential and indispensable issue for nuclear utilisation. For safe reposition and disposal of radioactive solid waste, the NSC deliberates, at its Special Committees and the Subcommittees, the relevant issues including the following:

- Policy planning of safety evaluation and ensuring.
- Definition of standard values (criteria) of radiation concentrations for waste disposal.
- Regulatory guides for reviewing the safety of disposal facilities and the clearance level, etc.

In accordance with the results, the regulatory bodies develop the necessary legal framework for solid waste burial businesses, etc.

Recent Activities of Low-level Radioactive Waste Disposal

Basic policies of safety regulations for ground disposal of low-level radioactive solid waste

The NSC authorised in October 1985 the "Basic Concept of Safety Regulation for Land Disposal of Low-Level Solid Radioactive Waste" [1]. Based on the basic policies defined, the NSC has been deliberating relevant regulatory issues concerning the ground disposal of low-level radioactive solid waste.

The NSC deliberation

The NSC deliberates the basic concept of safety regulations for formulating relevant regulatory guides and guidelines with due consideration to the properties of low-level radioactive waste, its types, radiation concentrations, etc.

Recent Activities

- Upper Bounds of Radioactive Concentrations for Burial of Low-Level Radioactive Solid Waste (May, 2007) [2]: this report recommends upper limit concentration of radioactive nuclides for Near-surface disposal (with/without engineered barriers) and intermediate-depth subsurface disposal.

- Basic Policy for Safety Regulations Concerning Land Disposal of Low-Level Radioactive Waste (Interim Report) (July, 2007) [3]: this report describes the concept for the safety assessment on all types of low-level radioactive waste (LLW) disposal including intermediate-depth subsurface disposal.

Recent Activities of High-Level Radioactive Waste Disposal

The Leading Principle to Stand On

The Atomic Energy Commission of Japan authorised in June 1994 the "Long-Term Plan of Nuclear Research, Development and Utilisation of Nuclear Energy". The plan defines, concerning the treatment and disposal of high-level radioactive waste, the principle of "To be solidified in a stable form and, after being stored for 30 to 50 years for cooling, buried under the ground by the geological disposal method."

The NSC Approach of Safety Regulation

The NSC has been deliberating at its Advisory Board on high-level waste repository safety and on the basic policies of safety regulation for formulating relevant regulatory guides for high-level radioactive waste, with due consideration to the national and international R&D outcomes and to the trends of international safety standards.

Also being deliberated are the environmental requirements for selecting the candidate site for disposal.

In order to collect public opinions on the matter for its deliberation, the HLW safety workshops are convened with the participation of a broad spectrum of the public.

Recent Activities

NSC has issued an interim report for the licensing procedure for the safety regulation of specified radioactive waste disposal and the roles and responsibilities of the Nuclear Safety Commission in the regulatory process (May, 2007) [4]: recommendation on NSC involvement with a stepwise approach for geological disposal programme, being aimed at helping deliberation at the Diet on legislation of geological disposal regulations.

LLW Report which was Discussed on Long-term Safety Assessment

Significance of NSC Interim Report

The theme of this workshop is "Towards Transparent, Proportionate and Deliverable Regulation for Geologic Disposal". This report deals with the contents of the NSC interim report for LLW disposal including the intermediate depth disposal for the waste including long-lived radioactive nuclides. These findings can be expected to contribute to the regulation of the geological disposal to be discussed from now on. The abstract of the NSC interim report is shown in next paragraph.

Abstract of Basic Policy for Safety Regulations Concerning Land Disposal of Low-Level Radioactive Waste (Interim Report), July 2007

Uncertainty in the safety assessment for a very long period of time associated with long-term assessment is inevitable. For each of the scenarios for long-term safety assessment, it is difficult to quantify the risk, which is usually obtained as the sum of the products of the probabilities and the impacts of individual scenarios.

It is reasonable to adopt the dose as a "standard" derived from the risk of human health effects based on the disaggregated dose/probability approach. The approach assesses the risk individually by comparing the likelihood with the degree of its impact in each scenario, in deciding on the long-term safety of radioactive waste disposal.

From the examination, it was concluded that, based on the classification of assumed scenarios into "Likely Scenarios", "Less-likely Scenarios", and "Inadvertent Human Intrusion or Rare Natural Event Scenarios" types, it would be reasonable to set the "standards" for determination of assessment results according to each scenario to 10 μSv/year, 300 μSv/year, and 10-100 mSv/year, respectively, in reference to ICRP recommendations, etc. However, the values provided by ICRP and referenced in this study are under discussion in the process of formulating new recommendations. Therefore, it would be appropriate to consider the latest findings when setting dose standards as specific control rules in the future.

Current Work

NSC is currently revising the regulatory guide for low-level radioactive waste disposal based on the above discussions.

References

[1] NSC (1985), *Basic Concept of Safety Regulation for Land Disposal of Low-Level Solid Radioactive Waste* (in Japanese), NSC, Tokyo, www.nsc.go.jp/anzen/shidai/genan1985/genan035/siryo1.htm.

[2] NSC (2007), *Upper Bounds of Radioactive Concentrations for Burial of Low-Level Radioactive Solid Waste* (in Japanese), NSC, Tokyo, www.nsc.go.jp/haiki/page3/070521.pdf.

[3] NSC (2007), *Basic Policy for Safety Regulations Concerning Land Disposal of Low-level Radioactive Waste* (Interim Report), NSC, Tokyo, www.nsc.go.jp/NSCenglish/topics/radioactive_waste/20070712_e.pdf.

[4] NSC (2007), *Licensing Procedure Relating to the Safety Regulations of Specified Radioactive Waste Disposal and Involvement of Nuclear Safety Commission in These Activities* (Interim report in Japanese), NSC, Tokyo, *www.nsc.go.jp/haiki/page4/070507.pdf*.

Geological Disposal Programme in Japan

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In June 2000, the Specified Radioactive Waste Final Disposal Act was legislated in order to institutionalise the geological disposal of high-level radioactive waste (HLW), including a managed funding system. Based on this Act, the Nuclear Waste Management Organization of Japan (NUMO) was established in October 2000 as the implementing entity responsible for final disposal of HLW. The Act states that the disposal site shall be selected in three investigation stages: a literature survey followed by preliminary surface-based investigations and, finally, detailed investigations. Before investigations can proceed from one stage to the next, the government has to listen to and respect the opinions of the mayor of the affected municipality and the governor of the prefecture in question, who in turn reflect the opinions of the local residents.

In December 2002, NUMO announced the commencement of the first stage of this site selection process based on a volunteer approach. According to press reports, by 2006 around 10 municipalities had expressed an interest in applying for a literature survey. Toyo town in Kochi prefecture became the first municipality to submit an application for a literature survey in January 2007. However, escalation of opposition activities resulted in the resignation of the mayor and his loosing the following election. The newly elected mayor withdrew the application and the literature survey for the town was called off in May 2007. No other municipalities have applied since then.

Reflecting the lessons learned from this experience, in November 2007 an advisory body of the Ministry of Economy, Trade and Industry (METI) proposed additional measures aimed at enhancing public relations activities both nationally and locally and establishing a system whereby the government can nominate municipalities with the offer of a literature survey; this is in addition to NUMO's volunteer approach. Since then, METI and NUMO have been cooperating in holding symposia with relatively large audiences as well as small workshops with local non-profit organisations (NPOs) in various cities throughout the country.

The ultimate goal of geological disposal is to ensure the protection of human health and environment in the present and the future without imposing undue burdens on either current or future generations. To meet this goal, it is necessary to (1) select a suitable disposal site; (2) ensure appropriate design, construction and operation of the repository; (3) carry out comprehensive safety assessments.

In each investigation stage during the site selection process, NUMO is required by the Final Disposal Act to compile and submit a report on selection of designated areas to METI. This report has to include geological and environmental information obtained from the investigations and a demonstration of compliance with the siting factors set for each investigation stage. The report will be supplemented by a second document which describes the repository concept, alternative designs for each area and the associated safety assessment. The report and the supplementary document constitute the core of the safety case for each investigation stage. The safety case will be refined step by step as the investigations proceed from one stage to the next.

The safety case for the post-closure period differs, in some key aspects, from the demonstration of safety for other types of nuclear facilities. Because of these differences, the implementer is required to prepare a well constructed safety strategy, taking the unique nature of geological disposal into account. Similarly, the regulators need to establish an adequate regulatory framework that can deal with these differences. From this perspective, iterative development and presentation of the safety case by the implementer from an early stage of the programme will help the regulators to establish their safety evaluation guidelines, safety requirements and so forth in a timely manner.

One of the key issues is the strategy for repository closure. The amended Law on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors states that the closure plan has to be approved by METI before actual closure activities start. Although actual closure will only take place many decades in the future, it is important to consider the closure strategy now as a part of the overall safety strategy, because it is closely linked to post-closure safety and to important issues such as monitoring and retrievability.

The HLW disposal programme is a unique and challenging project from both an implementation and regulatory perspective. Continuous dialogue is needed between the implementing and regulatory bodies to achieve harmonisation between safe disposal and a rationalised regulatory framework. Although each country has different cultural, legal and geological settings, it is important to share a common understanding of fundamental issues and a common safety philosophy among the countries involved with a view to successful implementation of the disposal programme in each country. In this regard, the role of the NEA RWMC is indispensable.

Current Status of L1 Disposal (Yoyushindo Disposal) in Japan

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Introduction

Since 1992, low-level wastes (LLW) from nuclear power plants in Japan have been disposed of at Rokkasho LLW Disposal Centre. The Rokkasho LLW Disposal Centre, located in Aomori-prefecture, which is the northernmost prefecture of the Mainland of Japan, is the only operating repository for radioactive waste in Japan. Its acceptance is limited to LLW from operating nuclear power plants, and now, two Disposal Areas are available: No.1 Disposal Area is designed for disposal of homogeneously solidified waste, such as 200 litre drums filled solidified liquid waste with cement; and, No.2 Disposal Area, which has been operated since 2000, is designed for disposal of solidified dry active waste, including metallic piping, plastic material, etc.

Since 2001, the investigation of geology and ground water in Japan Nuclear Fuel Limited (JNFL) Rokkasho-mura site was performed in order to acquire basic data for design and safety assessment for the currently-planned L1 disposal facility with engineered barriers.

Current Status of L1 Disposal in Japan

Reference Waste

The L1 (Yoyushindo) disposal facility under planning would accept wastes whose concentration levels can be a few orders higher than those disposed of in the current Rokkasho LLW disposal centre. The reference waste consists of reactor core surrounding parts, ion exchange resin, reactor core-internals from refurbishing or decommissioning and some of the waste from nuclear fuel cycle such as from the operation of reprocessing plant and decommissioning.

Basic Concept of L1 Disposal in Japan

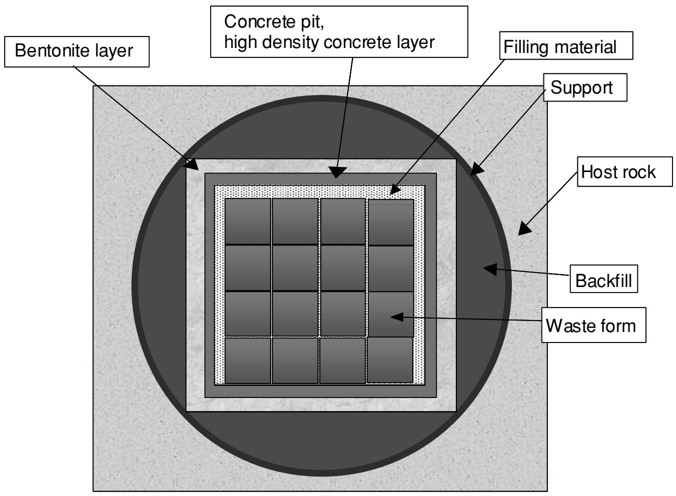
In 1998, the Atomic Energy Commission of Japan (AEC) reported [1] that the L1 disposal facility requires (1) enough depth not to restrict general use of underground i.e. 50-100 m depth, (2) no existence of natural resources, (3) sufficiently long groundwater pathway and (4) preservation and openness of records on the repository.

In 2007, the Nuclear Safety Commission of Japan (NSC) reported [2] on the upper bounds of radioactive concentration on LLW in line with most findings such as ICRP. Based on this result, the threshold to divide the radioactive waste disposal into Category 1 and 2 is defined. Category 1 is applied to geological disposal; on the other hand, Category 2 is applied to trench, pit and L1 (Yoyushindo) disposal. The upper limit of each disposal concept is stipulated by rules.

Concept of the Facility

The conceptual design of the facility is being carried out taking into account the detailed investigations of the site. The diameter of the tunnel could be about 20 m based on the results of detailed investigation. A concrete pit will be constructed in the tunnel and the multiple engineered barrier system can consist of metallic containers, cement, the bentonite and the backfill as shown in Figure 1. The host rock works not only to support the engineered barrier but also as a natural barrier.

Figure 1. **Example of the Cross-section of L1 Disposal Facility**



Waste Forms

Radioactive waste properly preconditioned will be packed into the waste package, loaded into a transportation cask at waste origin and transported to the disposal facility.

The waste package is under consideration, and is supposed to be a cubic container made of carbon steel with a function of radiation shielding of external dimensions 1.6 m×1.6 m×1.6m, as an example. The surface dose rate of the waste package is up to 500 mSv/h. The maximum weight of waste package is about 28 tons.

Business Plan (from licensing to closure)

It is expected that it will take several decades to complete the backfill and closure of the access tunnel. After the completion of closure of the access tunnel, institutional control will last for several hundreds of years. A safety review system is imposed under the regulatory framework every twenty years from the approval of licensing to the end of business.

Safety of the Facility

For assuring long-term safety of L1 disposal, it is necessary to predict precisely the function of engineered barriers and the natural barrier. A key issue is how to conduct safety assessment with due consideration to long-term uncertainty. The Special Committee in the NSC has already published an interim report on LLW disposal. Table 1 summarises its findings. These figures are defined in line with ICRP recommendations.

Table 1. **Approach to safety assessment scenarios [3]**

	Safety Assessment Scenario	Recommended Standard
Post Institutional Control Period	Basic Scenario (Normal scenario with high likelihood)	10 μSv/year
	Variable Scenario (Scenario with low likelihood)	300 μSv/year
	Human/ Rare Event (Scenario of human activity or natural event with extremely low likelihood)	10~100 mSv/year

Conclusion

An overview and current status of the project for L1 disposal facility have been briefly provided.

JNFL and The Federation of Electric Power Companies of Japan are jointly working out a conceptual design and safety assessment taking into account the site investigation along with the concept of the NSC.

References

AEC (1998), *The Basic Concept for the LLW Beyond the Current Regulatory Upper Limit,* AEC, Tokyo.

NSC (2007), *Upper Bounds of Radioactive Concentration for Burial of Low-Level Radioactive Solid Waste*, (in Japanese), NSC, Tokyo, *www.nsc.go.jp/haiki/page3/070521.pdf*

NSC (2007), *Basic Concept of Safety Regulation on Low-Level Radioactive Waste Burial* (Interim Report), NSC, Tokyo.

**Safety Regulation of Geological Disposal of Radioactive Waste:
Progress since Córdoba and Remaining Challenges**

Allan Duncan and Claudio Pescatore[1]
[1]OECD/NEA

Introduction and Overview of the Main Points

The purpose of this paper is to recall where we stood at the time of the 1997 Córdoba Workshop on the regulation of disposal of long-lived radioactive waste, to review developments since then, to present the key existing issues, and reflect on the remaining challenges and possible responses.

Sections 2 and 3 address the first two items. The overview study on progress in regulation for geological disposal since the Córdoba workshop of the NEA in 1997 provides a good list of references [NEA 2008a].

The presentation of the existing issues in Section 4 takes advantage of the synthesis of the responses to a questionnaire completed by the regulatory organisations in preparation for this workshop. It warns regulators and implementers that international work to date seems to have created an expectation in the mind of the public and in some organisations that nothing less than a guarantee by the regulator is needed for maintaining current levels of protection of both individuals and populations practically forever, regardless of the impracticality of this. This expectation needs to be replaced with a carefully and clearly explained understanding of the choices involved in dealing with long-lived radioactive waste against a background of our responsibilities to both current and future generations and our practical capacity to deliver them.

Section 5 summarises what are felt to be the current major challenges. The section comes back to the issue of the "guarantee" by the regulator and it observes that there is no doubt that there is a willingness to do the best to comply with the principle of protection and that we are broadly convinced that current concepts for geological disposal, supported by multiple lines of reasoning and application of Best Available Techniques (BAT) will meet that principle. However, we do not have the capacity to prove or guarantee this, nor do we believe that it is possible practice. Although we are advised that it is neither ethically nor morally necessary, we have still to resolve the issue of the satisfaction of the majority of the intelligent lay public and to provide some form of "reasonable assurance". Perhaps the very first step is to review our *technical capability* to provide confident assurance about specific outcomes over specific timescales. This might allow us to build on the work of the NEA Integration Group for the Safety Case (IGSC) by indicating the level of confidence we have in technical, geological and societal systems and in their regulatory assessment over specific periods. There will be a point in time, however, perhaps after about a thousand years from repository closure or relinquishment of institutional control, when we cannot claim total regulatory confidence about outcomes despite our use of current BAT and multiple lines of reasoning. Concerning the period beyond that time, it would be for policy makers and politicians to decide as a matter of policy, on behalf of current society, whether it is ethical or acceptable to leave a residual risk to future generations, e.g., in order to secure the benefits of nuclear power for the current and future generations.

The Córdoba Workshop

At Córdoba, the scene was set with descriptions of the regulatory process for waste disposal from the perspectives of both regulator and implementer. The actual situation at the time was described in some detail by reference to the current radiation protection context and to regulatory developments in Canada, the United Kingdom and the United States. The meeting then went on to examine various aspects of making a safety case for disposal and judging its compliance with relevant requirements.

In retrospect, this workshop represented an important milestone and appears to have stimulated significant progress in the regulatory areas that were identified as most needing practical development. These were:

- Radioactive waste disposal criteria.
- Performance assessment.
- Conduct of the regulatory process.

Radioactive Waste Disposal Criteria

In the context of *criteria*, it was recognised that there was a need for further guidance on the regulatory roles of dose and risk and on approaches to the setting of limits, indicators or targets for outcomes in the far future. It was also noted that the transparent interpretation of risk in the assessment and evaluation process needed its disaggregation into probabilities and consequences and that the whole process of making and judging a safety case needed to be reinforced with multiple lines of reasoning or multi-factor approaches. In addition, it was recognised that protection of the environment as such was becoming an important issue in some countries. These issues were exemplified by the new UK guidance on requirements for disposal of long-lived waste published only the previous year, in 1996. This guidance adopted risk (of fatal cancer or serious hereditary effect) as the fundamental criterion for long-term protection of the public, set a design target for level of protection as opposed to a limit, which was seen as un-enforceable for the far future, required transparent breakdown of the configuration of assessed risks, specified the need for multiple lines of reasoning and stipulated application of best practicable means (equivalent to BAT) in design, construction, operation and management of a disposal facility, as required in conventional hazardous waste disposal, all supported by a comprehensive quality assurance programme.

Performance Assessment

On *performance assessment,* the need was identified for clarification of its different purposes at different steps in the chain of system choice, design, site selection and licensing, with emphasis on the fact that such assessments cannot pretend to be predictions of the future but rather the most appropriate tool for judging or comparing potential long-term outcomes. This need for clarification extended to the issues of confidence building and the concept of reasonable assurance about the results of assessments. It was noted also, in this regard, that improvements were required in the explanation of assessment methods and results, particularly to political decision makers and the general public.

Regulatory Process

In regard to the *regulatory process* itself, the requirement identified was for development and publication of clear approaches to regulatory criteria and review (i.e. the "Rules of the Game") well in advance of licence applications. In particular, there was considered to be a need for guidance on stylised approaches to long-term scenarios including reference biospheres and human intrusion scenarios. It was also considered that a stepwise approach to the regulatory process needed to be developed, taking account of interim steps and decision points from both the regulator and implementer points of view, and that it should be seen in the context of the potential for well-structured dialogue between all stakeholders and the need for building confidence in the process.

It is against this background that we need to evaluate progress of the regulatory position over the past decade, since the Córdoba workshop, and to consider what challenges remain. It is appropriate, however, to review general international developments before reviewing progress in the three specific areas identified above. A detailed review has been prepared for the RWMC-RF and is summarised briefly below.

International Developments in Regulation

National regulations and guidelines addressing the long-term safety of deep disposal facilities have been developed or revised in various NEA member countries during the last decade or so. This must be seen as a good response to the need identified at Córdoba for timely publication of "Rules of the Game". The period has also seen these developments reflected in ICRP Recommendations, the Safety Standards of the IAEA and in the wide ranging publications of the NEA. The NEA has provided a forum for articulation of the practical experience of waste regulators in many discussions, questionnaires, workshops and summarising statements and has made a major contribution to harmonisation of regulatory approaches. Above all, it has developed the concept of the "safety case ", which was a feature of the workshop in Córdoba, and has established it as a key item for demonstration of the long-term safety of a repository. In parallel with this it has promoted the concept of stakeholder involvement and emphasised the associated need for criteria and processes employed by regulators to be comprehensible and acceptable by a wide range of intelligent but lay individuals. The key developments in the last decade or so may be summarised as follows.

ICRP Developments

The major developments in ICRP recommendations for waste disposal were ICRP 77 (1997), which recommended dose and risk constraints (0.3 mSv/year and 10^{-5} respectively) and recognised the need, identified at Córdoba, for a breakdown of information about the configuration of risks, and ICRP 81 (1998) which specifically addresses the post-closure safety of disposal of long-lived solid radioactive waste. The quantification of assessment criteria is made for different periods. Dose and risk bear a decreasing connection to health detriment in timescales from 1 000 to 10 000 years; beyond these timescales dose and risk are only reference values. The comparison with natural analogues is integrated into the assessment of long-term safety. Further characteristics of the ICRP approach for the assessment of the long-term safety of a repository include demands for constrained optimisation, technical and managerial principles, defence in depth, quality assurance, iterative safety assessment, a safety case, multiple lines of reasoning and a stepwise approach.

More recent recommendations confirm the recommendations of ICRP 81 with respect to final disposal but qualify some of them in the light of regulatory developments. As regards principles for the optimisation of final disposal, ICRP-101 (2007) recommends "a broader process reflecting the increasing role of individual equity, safety culture and stakeholder involvement into the decision-making process". ICRP-103 (2007) describes optimisation of protection as a forward-looking iterative process aimed at preventing or reducing future exposures. It expressly points out that "optimisation of protection is not minimisation of dose". Dose estimates beyond several hundreds of years "represent indicators of protection afforded by the disposal system". An approach for demonstration of protection of the environment is also formulated.

IAEA Developments

The responsibility of today's generation towards future generations is an essential driver in IAEA recommendations. This flows from the Safety Fundamentals, 111-F (1995), which set out requirements for protection of future generations, including avoidance of any undue burden on them, the need for intergenerational equity, and protection of the environment in addition to human protection. In the international Joint Convention of 1997 on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, which is administered by the IAEA, countries have specified these demands in provisions for effective protection of individuals, society and the environment, and avoidance of actions that impose reasonably predictable impacts on future generations greater than those permitted for the current generation, all of which is summarised under the heading of "sustainability". The most recent IAEA Safety Standard, WS-R-4(2006), also refers to responsibility for current and future generations as a central principle. Additionally, however, WS-R-4 considered the developments in regulation of geological disposal that have occurred both internationally and nationally in the meantime, especially with respect to the fulfilment of the protection goals and the demonstration of long-term safety in a safety case. The central demands of WS-R-4 include constrained optimisation as a judgemental process, with social and economic factors being taken into account. Regarding the long periods after closure, indicators of safety other than dose or individual risk are demanded. Further safety case requirements of WS-R-4 are reduction of the likelihood of events by suitable siting and design, stepwise decision making with adequate level of confidence, management system for quality assurance and multiple safety functions.

Revised Safety Fundamentals SF-1 (2006), which was published simultaneously with WS-R-4, put the Safety Fundamentals of 1995 in a broader context. Apart from the fundamental demand that people and the environment, present and future, must be protected against radiation risk, it points out that, above all, governments/regulators have to be provided with technical as well as managerial competence. The optimisation of protection is also promoted to become a central demand.

NEA Developments

The NEA Radioactive Waste Management Committee (RWMC) has continued over the past decade to be a major force in shaping and promoting the development of requirements for final disposal and its public acceptance. The importance of the "safety case" for a repository was recognised at the Córdoba workshop in 1997. Since then, the concept has been developed further and has resulted in various publications, the latest of which are the report on "*Regulating the Long-term Safety of Geological Disposal of Radioactive Waste: Towards a Common Understanding*" [NEA, 2007], the proceedings of a symposium in 2007 on "*Safety Cases for the Deep Disposal of Radioactive Waste: Where Do We Stand?*" [NEA, 2008d] and "*A Collective Statement by the NEA Radioactive Waste Management Committee (RWMC)*", published in 2008 [NEA, 2008e] on the latest status of final disposal. The net result seems to be that the safety case concept has been understood, accepted and adopted by radioactive waste management programmes worldwide.

The application of the safety case concept in practice, however, shows that details remain to be developed, and the NEA work during this period has encompassed a range of issues that has included criteria and standards, performance assessment and timescales for assessment, confidence-building and stakeholder involvement. It has even included an ethical element in considering what the basic, practically deliverable objective is by today's generation for the protection of future generations against the consequences of disposal of long-lived hazardous waste. It is arguable that perhaps the most significant developments have been in the context of the last point. The issues have arisen naturally in discussion of Long-term Safety Criteria (LTSC) together with those arising from both the FSC and IGSC and reflect closely those issues that were identified at Córdoba as most needing practical development.

Also, in the course of the NEA work, there has been a focus on the nature of regulation and regulators. This was an early element of the work of the RWMC-RF and resulted in publication in 2005 of "*The Regulatory Function and Radioactive Waste Management: An International Overview*". It describes the conventional regulatory cycle, with monitoring of outcomes and feedback to either the basic regulations or to the licensing process, and the opportunity to remediate if necessary, but notes that for disposal of long-lived waste there will be no effective feedback to current regulators and no opportunity for the current generation to effect any remediation. Importantly, however, it also shows how the regulatory process starts with policy planning and the setting of objectives for the activity being regulated, with licensing, compliance control and enforcement following establishment of legislation and regulations designed to meet policy objectives. It shows that, in the context of the whole regulatory process, there may be various players with, for example, politicians or policy makers deciding on behalf of society what should be the objectives for protecting future generations, and separate technical organisations responsible for securing compliance with these objectives. The question of how these roles are configured in different member countries is quite important in discussing how to set long-term safety criteria and how to explain them to the public.

Current Key Issues

Since the Córdoba workshop, more than a decade ago, an added piquancy has been given to our work by the closely linked matters of climate change and electricity supply. Although it may be entirely logical to observe that we already have a legacy of waste accumulated from past nuclear operations and that we must focus on that, it seems naïve to think that in the public mind this will be separated from the issues associated with new power nuclear plants, and some countries are already examining the waste implications of building a new generation of nuclear plants.

In this context, of course, we mean "nuclear waste", those wastes arising from the nuclear power industry, as opposed to radioactive wastes arising from conventional industry, medicine or research over whose management we have little difficulty. Illogical as it undoubtedly is, this distinction is significant because it has long been apparent that, in the public mind, anything "nuclear" is associated with mushroom clouds and devastation, and must be avoided. It is also a fact of life that the press and broadcast media may exacerbate this public dread with perhaps not fully investigated reports. For this reason we regulators, while carrying out our technical functions at a wholly professional level, must be able to explain to a lay public the regulatory objectives, criteria and decision-making processes associated with management of nuclear waste from whatever source.

Of course this requirement for engagement with the public, who are our employers in effect, has been long recognised and reflected in the work of the NEA Forum for Stakeholder Confidence (FSC) but it has been brought into sharper focus in the context of waste regulation by the NEA Regulators' Forum's (RWMC-RF) recent work on Long-term Safety Criteria [NEA, 2007]. The original intent of this work was to produce a Collective Opinion on the regulatory criteria for geological disposal of long-lived waste, but it soon became clear that the task was not as simple as first thought. There are quantitative differences between national criteria as well as differences in regulatory approach. We are confident that these differences have no significant consequences in terms of radiological impact, but to a lay audience this is not obvious. Additionally, it has emerged that we have no common basis for setting criteria as between different NEA member countries and that the process of setting criteria is not readily explicable to the general public. Furthermore we are required, for the purposes of the international Joint Convention on the Safe Management of Spent Fuel and Radioactive Waste, to protect, amongst other things, the ability of future generations to meet their needs and aspirations. There is no guidance or general agreement as to who these future generations are or what their needs and aspirations are likely to be, and international work to date seems to have created an expectation in the mind of the public and some organisations that it implies a need for nothing less than a guarantee, on the part of the regulator especially, of current levels of protection of both individuals and populations forever, in effect, regardless of the impracticality of "guaranteeing" today any particular outcome over a period in the order of many hundreds of thousands of years. *This expectation needs to be replaced with a carefully and clearly explained understanding of the choices involved in dealing with long-lived radioactive waste against a background of our responsibilities to both current and future generations and our practical capacity to deliver them.*

Within the framework of the NEA RWMC-RF programme, the LTSC group has studied most aspects of the regulation of nuclear waste management. The work started in 2004 and the first phase culminated in a workshop on the "Practical Issues and Challenges" in Paris in 2006 and in the subsequent publication in 2007 of a "*Towards Common Understanding of the Main Objectives and Bases of Safety Criteria*". This work involved much new thinking outside and beyond the confines of conventional radiation protection and has raised issues of a wider societal, ethical and practical nature. It was appropriate, therefore, to have a period for reflection and digestion of the new ideas and issues before returning to participants with a questionnaire on where we might usefully go from here. The interesting responses to that questionnaire have been analysed and synthesised, and are the basis for design of this workshop. [NEA, 2008b]

Synthesis of Responses to Questionnaire

The fifteen sections of the synthesis can be considered as falling into the following broad categories:

- *Policy-related* (Fundamentals, Undue Burden, Timescales).
- *Process-related* (Responsibilities, Stepwise approach, Management).
- *Radiological Standards-related* (Justification, Optimisation of dose and design, Health detriment, Human intrusion, Accidents).
- *Stakeholder-related* (Social values, Stepwise decision making).
- General Environmental Protection.

Process-related and General Environmental Protection Issues

Of the above five, broad categories, the *Process-related* and *General Environmental Protection* issues seem to require little immediate comment or attention here. For the most part, these are quite straightforward and are generally matters of national custom and culture or, in the case of environmental issues, may need further development before detailed discussion.

Radiological Standards

Some differences in thinking and approach to *Radiological Standards* are apparent, particularly in regard to the roles and interpretation of dose, risk, potential dose and optimisation. These matters will clearly be the subjects of further discussion, but two aspects appear to be particularly important.

- *The first is that debate about interpretation and use of these concepts seems to have no substantial foundation in terms of clear objective for what we are trying to achieve in the disposal of long-lived waste*. This is as true for conventional, long-lived chemotoxic waste as it is for "nuclear" radioactive waste but, because of the public dread of "nuclear" waste, we have to address this matter in much more detail. It touches on issues of ethics and policy and is addressed below.

- The second point is that the use *of language in this subject is not conducive to easy understanding by the public, certainly, and perhaps even by others. We need to consider how* *it might be made more accessible for the purpose of public involvement and regulatory dialogue*. For example, if we could agree that the objective of disposal was to minimise the risk of adverse effects to the public so far as is practicable, we might agree that "dose" is something we can estimate and that can be converted into something representing the chance of experiencing a defined adverse effect, and that "potential dose" incorporates the probability of a dose being delivered and, hence, represents an overall level of risk. We could then adopt the relatively simple concept of risk that is used in some countries, at least, as the basis for regulations designed to protect society from a wide variety of hazards. This might open the way to creating a readily comprehensible long-term objective for geological disposal that is consistent with the objectives for protecting society from the potential consequences of other activities with long-lived implications.

The time may now be ripe for progress on such discussion following the observation in the recent ICRP 103 that "*Considerable uncertainties surround exposures taking place in the far future. Thus dose estimates should not be regarded as measures of health detriment beyond times of around several hundred years into the future. Rather, they represent indicators of protection*…." This seems to acknowledge the point already made elsewhere that the concept of limits is inappropriate for regulation of activities with outcomes far into the future and long after the current regulatory and surveillance regimes have ceased to exist. This then raises a question about the role of "optimisation", originally seen in the ICRP context as applying narrowly to dose limitation.

Optimisation

One can recognise in recent literature an emerging view that optimisation, in any practice, ought to be more about procedures than outcome when it comes to the regulatory process and, indeed, this is now recognised in ICRP-103, which states that *"All aspects of optimisation cannot be codified; rather, there should be a commitment by all parties to the optimisation process. Where optimisation becomes a matter for the regulatory authority, the focus should not be on specific outcomes for a particular situation, but rather on processes, procedures and judgements. An open dialogue should be established between the authority and the operating management, and the success of the optimisation process will depend strongly on the quality of this dialogue."*

It may be helpful at this juncture to distinguish between "optimisation of long-term radiological protection" and "system optimisation". The two are not necessarily the same, and the former may be just one element of the latter. In the general context of environmental regulation, as in the case of conventional long-lived hazardous waste disposal under the EC IPPC Directive for example, this notion of optimisation is already applied to the disposal system as a whole and is described as BAT, which incorporates the ICRP concept of "*sound technical and managerial principles*". In practice this is probably closer to what we now need to be thinking about for making a readily comprehensible safety case for disposal of long-lived waste that is hazardous by way of radiotoxicity as opposed to chemotoxicity. In fact, as disposal programmes approach their industrial implementation, the concept of "optimisation" and related requirements are receiving increased attention. The guidance is, however, generic at this stage. Exchanges within NEA groups have shown that both regulators and implementers would benefit from a review of the relevant concepts and available guidance and experience, both at the national and international level, and there is already strong interest shown in this area by the NEA RWMC Regulators' Forum (RWMC-RF) and the Integration Group for the Safety Case (IGSC). This is described in a separate workshop paper [NEA, 2008c] designed to stimulate discussion of this topic and promote shared understanding on how optimisation concepts and related requirements may be interpreted and how regulatory requirements may be formulated so as to be transparent, understandable and deliverable during the many-decades-long, stepwise decision-making process that accompanies the development of any deep disposal project.

Policy Matters

Policy-related matters seem to be at the heart of the question about what our objective is in regard to disposing of long-lived waste, having due regard to protection of the needs and aspirations of future generations while also protecting the interests of the current generation. The issues of Fundamentals, Undue Burden and Timescales, together, would appear to be the issues that address this question and the related question of what it is that is practical and deliverable. Responses to the questionnaire, particularly in regard to questions about how we reflect changing timescales, justify cut-off times and handle the decreasing capability of control with the passage of time, indicate that these questions have been difficult to answer in any way that is internationally consistent. *This reinforces the impression that we still lack a convincing common commitment to a demonstrably deliverable objective for the long term.* We, too, may have become conditioned to the expectation of "guaranteeing" protection of all future generations to current standards, while knowing that such a guarantee by the regulator (as well as by others) is simply undeliverable in light of the irreducible uncertainties about repository and societal evolution over many thousands of years.

Some countries have attempted to deal with this by basing regulatory standards on "predicted" or "assessed" doses or risks, or setting design targets as opposed to limits. However, as suggested above, it seems likely that the issue of "guarantee" or certainty about the far future will have to be debated publicly in some countries at least. The UK Sustainable Development Commission, for example, has advised government that there is no justification for bringing forward a new nuclear power programme because, *amongst other things*, it would be impossible to guarantee safety over the long-term disposal of waste.[1] It is not clear that these are matters exclusively for us technical regulators, touching as they do on ethical questions and on the balance between the needs of the current generation and those of future generations.

We need to recall that the overall regulatory cycle involves *Policy Making and Legislation, Licensing and Enforcement* and *Assessment and Feedback.* [NEA, 2005] Our usual focus is on the second of these, which is the role of what is often called the "technical regulator". It is the role of policy makers and politicians, whose job is to reflect the will of society at large, to deal with the first of these regulatory steps. This raises the question of how, within the framework of the overall regulatory process, roles are configured in individual Member Countries and how we draw policy makers' attention to the need for consideration of what seems to be societal or ethical issues that affect our capability to provide convincing explanations of our technical regulatory activities to the public. *At its most basic, this question asks who makes policy on behalf of society, who formulates laws and regulations, who enforces them, are they separate roles and, if so, how do we bring them all together for the purpose of explanation to the public?*

Stakeholder Matters

The considerations associated with the *Stakeholder* issues would seem to flow naturally from the considerations immediately above. In particular, the synthesis of responses to the questionnaire indicated some difficulty in dealing with the question about handling of irreducible uncertainties about outcomes in the far future. It does seem that, until we have a definitive answer to that question, the public and others will question our credibility and ability to provide convincing assurance of compliance with long-term objectives and criteria. This is likely to arise in the context of whether or how to apply the "precautionary principle" or in the ethical context of balancing the needs of the current generation against the interest of future generations, or both.

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1. "…the timescales involved (many thousands of years) lead to uncertainties over the level to which safety can be assured", (UKSDC, 2006).

Remaining Challenges and the Way Ahead

The responses to the questionnaire show that, despite the substantial developments in regulating disposal of long-lived radioactive waste over the last decade, there are still matters to be resolved. Article 1 of the Joint Convention, the IAEA Safety Fundamentals and ICRP 81 all still refer to the principle that future generations, and even individuals in the case of ICRP, must be protected to the same level as the present generation. *It would seem that, with this principle in mind, respondents to the questionnaire have had most difficulty with the handling of uncertainties about long-term outcomes and, against that background, about how to define the requirements for protection in the far future, how to optimise the disposal system and how to explain it all to the public in a way that will elicit their approval.*

There is no doubt that there is a willingness to do the best we can to comply with this principle and we are broadly convinced that current concepts for geological disposal, supported by multiple lines of reasoning and application of BAT will meet that principle. However, we, as regulators, do not have the capacity to prove or guarantee this nor do we believe that it is possible practice. Also, we are advised that it is neither ethically nor morally necessary but we have to resolve the issue to the satisfaction of the majority of the intelligent lay public and to provide some form of "reasonable assurance". The specific challenges that would seem to flow from this, therefore, are as follows:

- To develop transparent, ethical objectives for disposal of long-lived radioactive waste, *recognising the possibility that these could be set for specific timeframes, having regard to our technical and institutional capacities*.
- To identify *comprehensible technical measures, effects or arguments by which these objectives may be defined*, disposal systems designed and safety cases judged for compliance.
- To develop the concept of "optimisation" for disposal systems, starting perhaps with a review of the relevant concepts and available guidance and experience, both at the national and international level.

Perhaps the very first step, however, is to review our *technical capability* to provide confident assurance about specific outcomes over specific timescales. This might allow us to build on the work of the IGSC by indicating the level of confidence we have in technical, geological and societal systems and in their regulatory assessment over specific periods. There will be a point in time, however, perhaps after about a thousand years from repository closure or relinquishment of institutional control, when we cannot claim total regulatory confidence about outcomes despite our use of current BAT and multiple lines of reasoning. *Concerning the period beyond that time, it would be for policy makers and politicians to decide as a matter of policy, on behalf of current society, whether it is ethical or acceptable to leave a residual risk to future generations, e.g. in order to secure the benefits of nuclear power for the current generation as future generations, as indicated in the first challenge above.*

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Session 2

Fundamental Concepts and Evolution of International Guidance

Chair: Marie-Pierre Comets, ASN Commissioner (France)
Rapporteur: Carmen Ruiz Lopez, CSN Branch Chief (Spain)

International Guidance, Evolution and Trends

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Introduction

International guidance plays an important role in the development of radioactive waste management and disposal, serving as a basis for national regulation development and as an element for stakeholder confidence. Clarity and transparency are important attributes of regulations, for they ensure some level of international consistency on fundamental safety and radiological protection objectives and issues, as addressed in previous work of the NEA Radioactive Waste Management Regulators´ Forum (RWMC-RF) [1].

There has been a significant development of international guidance in the last years, and there exists now an international framework for the development of geological disposal, integrated mainly by the Joint Convention, the generic and specific ICRP recommendations, and the IAEA safety standards, as well as the NEA advisory and position documents, as it has been recognised by the RWMC in Reference [2].

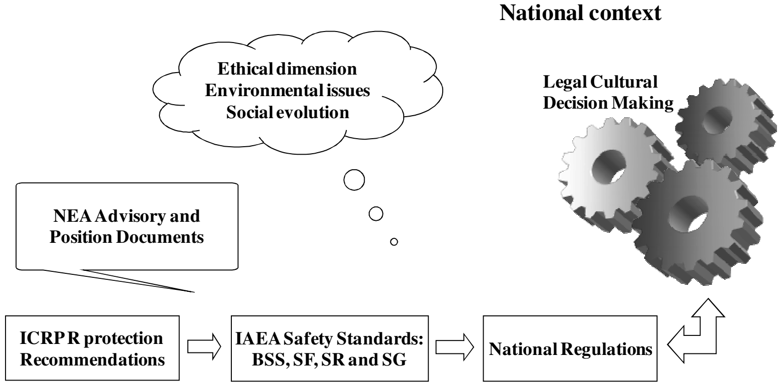
This international framework addresses the consensus on the prime fundamental objective of radioactive waste management and disposal expressed, in general terms, as *protection of humans and the environment now and in the future*, which is attained through safety and radiation-protection fundamental concepts, usually identified as principles, requirements and criteria.

Such fundamental concepts have evolved along with the progress in safety cases, the increasing importance of environmental issues, the evolution of the societal demands and the increasing role of the stakeholders in decision-making processes. Some of the fundamental concepts have been reformulated, and complementary approaches have emerged oriented towards a more practical demonstration of the long-term safety of geological disposal systems and compliance with numerical criteria [1-3].

Previous studies performed within the RWMC-RF have shown that this progressive shift of fundamental concepts in international guidance has not always been reflected in or incorporated into national regulations for various reasons: the relatively recent publication of the latest international recommendations and standards, the difficulties in the interpretation and implementation of some of the fundamental concepts and the specificity, to be expected, of each national context [1,4-5].

This paper tries to address the evolution of some of the fundamental concepts related to the objective of protecting future generation, with the intention of encouraging the discussion and to determine whether the recent international guidance implies any change in philosophy and approach regarding the practical interpretation and implementation of such fundamental concepts.

As a preliminary remark, it is important to have in mind a picture of the role and guidance of the different international organisations (ICRP, IAEA and NEA), their interconnections and the way they serve as a basis for national regulations. This perspective is illustrated, in a rather personal way, in the figure hereafter. The figure also shows that whatever the international guidance, national regulation is ultimately influenced by the national context, which is the main cause for the existing variation in final positions [1].



There is a close connection between the ICRP radiation protection recommendations and the International Basic Standards for Protection against Ionising Radiation and Safety of Radiation Sources (usually called BSS), which are cosponsored by the relevant international organisations within the UN group and issued by the IAEA. A similar relationship exists between radioactive waste ICRP specific recommendations and the IAEA safety standards (specific fundamentals requirement and guides). The NEA plays a key role as "think tank" in regards to issues related to the development and practical implementation of the disposal safety case and in the applicable criteria. In this regard, it provides independent input to the developing International ICRP recommendations and IAEA standards.

ICRP Guidance Evolution: General View and Major Changes

The ICRP system of radiological protection has evolved through periodic publications of "general recommendations", which have historically been followed by additional recommendations addressing specific issues. The recent ICRP publication 103 of 2007 [6] formally replaces the first general recommendation ICRP 60 (1991) [7]. Additionally, there is a set of successive specific ICRP recommendations with regard to waste management and disposal based on ICRP 60, the ICRP 81 of 1998 [8] being the most relevant to the geological disposal of long-lived waste. Another recent recommendation of interest regarding radioactive waste issues is the ICRP 101 of 2006 [9] on the optimisation process.

The most recent recommendations, published in 2006 and 2007 (ICRP 101 and ICRP 103), state that the ICRP 81 on long-lived disposal remains valid as the main ICRP reference for long-lived waste disposal:

- Thus, although the objective set up by ICRP 82 *"of protecting future generations to at least the same level as the current generations"* remains, ICRP 103 confirms the previous Commission's recognition regarding *potential exposures that can occur far in the future* by stating: *"doses and risks cannot be forecast with any certainty for periods beyond around several hundred years into the future... Instead, estimates of doses or risks for longer time periods can be made and compared with appropriate criteria… in a test to give an indication of whether the repository is acceptable, given current understanding of the disposal system. Such estimates must not be regarded as prediction of future health detriment."* (ICRP 81 par 41 and ICPR 103 par264).
- In this context, ICRP 81 recommends that *"technical and managerial principles for potential exposure situations should be applied during the disposal system development process to enhance confidence that radiation safety will be maintained throughout the post-closure period."* Key among these principles is the concept of defence in depth which provides for successive passive safety measures that, in turn, enhance confidence that the disposal system is robust and has an adequate margin of safety.

In this way, ICRP 81 set up the basis for *demonstration compliance but also for confidence in the safety of the disposal system.*

The major changes or reorientations of relevance introduced by ICRP 103 regarding the long-term issues of geological disposal are:

- Strengthening the importance of transparence in the decision-making process and in the demonstration of confidence in the scenario of increasing uncertainties with time: *"in the decision-making process, owing to the increasing uncertainties, giving less weight to very low doses and to doses received in the distant future could be considered. The Commission does not intend to give detailed guidance on such weighting, but rather stresses the importance of demonstrating in a transparent manner how any weighting has been carried out."*
- Reinforcing the principle of optimisation, confirming the nature and characteristics of the optimisation process, as well as the elements for its implementation, as they are described in ICRP 101, the latest ICRP recommendations state that the optimisation of protection is a forward-looking iterative process involving all parties and aimed at preventing and reducing future exposures.
- Furthermore, both ICRP documents point out that the effective implementation of optimisation requires the commitment of all relevant involved parties, in particular the regulator and the implementer, as well as the importance of having an open dialogue: "*Where optimisation becomes a matter of the regulatory authority, the focus should not be on specific outcomes for a particular situation, but rather on the process, and judgements. An open dialogue should be established between the authority and the operating management, and the quality of the optimisation process will depend strongly on the quality of this dialogue"* (ICRP 103, par 223 and ICRP 101, par 37).
- Reiterating that societal values usually influences the final decision on the level of radiological protection, and admitting that recommendations, based on scientific considerations, may serve as an input to the decision-making process, which may include other social concerns and political aspects, as well as consideration of transparency (ICRP 103, par 22), as it was recognised in previous ICRP publications (ICRP 82, and ICRP 101, par 18).
- Increasing the interest in the protection of the environment changes the previous commission position to a more proactive approach as derived from Chapter 8 of ICRP 103.

IAEA Safety Standards Evolution: General View and Some Major Changes

The evolution of internationally agreed safety fundamental objectives and principles can be observed in the changes from the IAEA's 1995 Waste Safety Fundamentals, Safety Series No. 111-F [10] to the new IAEA Fundamental Safety Principles SF-1, published in 2006 [11], which formally superseded the previous one. The 2006 Safety Fundamental SF-1, which is at the top tier level of the IAEA Safety Standards, was jointly sponsored by a number of international organisations, including the OCDE/NEA and EURATOM, representing in this way a high level of consensus.

In the mean time, the so called "Joint Convention" [12], issued in Vienna in 1997, was ratified in many countries and became, for these countries, the highest-level international instrument they are bound to apply.

In addition, the IAEA's current specific reference to geological disposal is the document WS-R-4, sponsored by the NEA and published in 2006, almost at the same time as the SF-1. This document, based on the ICRP 81, develops the safety requirements.

Thus, the current IAEA references for the development of geological disposal facilities are basically composed of the recent integrated Safety Fundamental SF-1 and the specific Safety Standard WS-R-4 [13]. A new guidance document, DS-354, is also in preparation.

However, since the Joint Convention takes the Radioactive Waste Fundamental 111- F as a basis, it may be understood that this former Safety Fundamental still remains in use, in spite of having been superseded by the SF-1. This situation is repeated in WS-R-4 and may contribute to the differences found in the bases used for national regulation development, as it has been reflected in Reference [5].

The major differences between the recently integrated Safety Fundamental SF-1(2006) and the former Waste Fundamental (1995) are detailed below.

New IAEA Fundamental Safety SF-1 vs. former Radioactive Waste Fundamental SS 111-F

General differences are inherent to the scope and content of each document. The 2006 Safety Fundamental SF-1 states the fundamental safety objective applicable to all circumstances that originate from radiation risk. Its ten safety principles apply, as relevant, throughout the entire lifetime of all nuclear facilities and activities. Radioactive waste management activities and facilities are only a subset of those. The 1995 Radioactive Waste Fundamental 111–F, however, is devoted specifically to radioactive waste management. Nine specific principles are indentified.

111 F. Radioactive Waste Principles (1995)	SF 1. Safety Principles (2006)
1. Protection of human health	1. Responsibility for safety
2. Protection of the environment	2. Role of government
3. Protection beyond national borders	3. Leadership and management for safety
4. Protection of future generations	4. Justification of facilities and activities
5. Burdens on future generations	5. Optimisation of protection
6. National legal framework	6. Limitation of risks to individuals
7. Control of radioactive waste generation	7. Protection of present and future generations
8. RW management interdependencies	8. Prevention of accidents
9. Safety of facilities	9. Emergency preparedness and response
	10. Protective actions to reduce existing or unregulated radiation risks

SF-1 addresses, among other matters, the radiation protection principles (justification, optimisation and limitation) as well as safety management issues (developing the "defence in depth" and "safety culture" concepts).

Several protection principles of 111-F are unified in only one SF-1 principle. Thus the SF-1 Principle 7 on "Protection of present and future generations" encompasses the SS 111 F Principles 2, 3, 4 and 5 on protection of the environment, protection beyond national borders, protection of future generations and burden on future generations.

Differences between both documents regarding the safety fundamental objectives and principles on protection of future generations and burden to future generations are detailed below.

Safety objective

The objective of radioactive waste management as stated in 1995 111-F is: *"to deal with radioactive waste in a manner that protects human health and the environment now and in the future without imposing undue burdens on future generations."*

The Fundamental Safety Objective as stated in SF-1 is: *"to protect people and the environment from harmful effects of ionizing radiation. This safety objective … has to be achieved without unduly limiting … the conduct of activities that give rise to radiation risks*". Further explanatory text addresses the measures *"to ensure that facilities are operated and activities conducted so as to achieve the highest standards of safety that can reasonably be achieved."*

The SF-1 fundamental safety objective is more general and less prescriptive than that of the 111-F. SF-1 and more explicit about recognising the need to achieve a "reasonable" level of protection and the necessity for a balance between protecting the future and not unduly limiting current activities, whereas the approach in 111-F seems more absolute and biased towards the protection of the future vs. the present. On the other hand, the reference to "undue burden on future generation" which appeared in the title of the Waste Management Objective is demoted in the SF-1 that includes it as just one aspect of one of the principles, as detailed below.

Protection of Future Generations

111-F Waste Principle 4 states that *"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."* (as expressed also by ICRP 81 and the Joint Convention safety requirements 4 and 11).

In an explanatory paragraph it is specified that *"while it is not possible to ensure total isolation of radioactive waste over extended time-scales, the intent is to achieve reasonable assurance that there will be no unacceptable impact on human health."*

SF-1 Principle 7, on the protection of present and future generations, states that *"Where effects could span generations, subsequent generations have to be adequately protected without any need for them to take significant protective action."*

Once again, the SF-1 fundamental safety principle is more general and less prescriptive than that of the 111-F. Although 111-F specifies in an explanatory paragraph that *"the intent is to achieve reasonable assurance that there will be no unacceptable impact on human health,"* 111-F seems more absolute and biased towards the protection of the future vs. the present.

Burdens on Future Generations

111-F Principle 5, dealing specifically with "Burden on future generations, states that *"Radioactive waste should be managed in such a way that it will not impose undue burden to future generation."*

In SF-1, this ethical obligation appears in paragraph 3.39. of Principle 7, as follows: *"Radioactive waste shall be managed in such a way as to avoid imposing undue burden on future generations; that is, the generations that produce the waste that have to seek and apply safe, practicable and environmentally acceptable solutions for its long-term management."*

As for the interpretation of this concept, explanatory paragraphs in 111-F focused on the responsibility of the present generation for developing technology, constructing and operating facilities, and providing a funding system, sufficient controls and plan for the management of radioactive waste.

In contrast, the interpretation in SF-1 seems to be more oriented towards providing effective and acceptable environmental solutions. The funding requirements for the management of radioactive waste are part of the SF-1 Principle 1 on Responsibility for Safety, which in paragraph 3.7 states *"Since radioactive waste management can span many human generations, consideration must be given to the fulfilment of the licensee's (and regulator's) responsibilities in relation to present and likely future operations. Provision must also be made for the continuity of responsibilities and the fulfilment of funding requirements in the long term."*

Finally, according to the WS-R-4 statement in Annex 1, *"Following the closure of a geological disposal facility, the long-term containment and isolation of the waste will be provided by passive means so that no further actions are required to maintain safety of the waste and to provide for protection of human health and the environment. Thus undue burdens of geological disposal are avoided, consistent with the principle 5,"* it should be interpreted that geological disposal is the option that places least burden on future generations

Focus on WS-R-4: Demonstration of Compliance vs. Confidence in the Safety

This recent safety standard, which takes as its basis the ICRP 81, starts by pointing out the aim of geological disposal to contain and isolate the waste and states the objective of the geological disposal facilities in the post closure phase as follows: *"Geological disposal facilities are to be sited, designed, constructed, operated and closed so that protection in the post-closure period is optimised,… and a reasonable assurance is provided that doses or risks … in the long term will not exceed the dose or risk level that was used as a design constraint."*

Although WS-R-4 takes the numerical criteria of ICRP 81 as compliance criteria, it states that *"Care needs to be exercised in using the criteria beyond the time where the uncertainties become so large that these criteria may no longer serve as a reasonable basis for decision making. For such long times after closure, indicators of safety other than dose or individual risk may be appropriate, and their use should be considered."*

Requirements for an adequate understanding of, and confidence in, the safety of disposal are established considering that *"the need for demonstrability requires that safety be provided for by robust features…..for which sufficient evidence has been presented on the feasibility and effectiveness before the construction activities commence."* Then, WS-R-4 establishes the requirements for safety functions, as well as requirements concerning containment and isolation.

Finally, WS-R-4 also defines the requirements for confidence in the safety case including, among other aspects, providing *"convincing estimates of the performance of the geological disposal system and reasonable level of assurance that the relevant safety requirements will be complied and radiation protection has been optimised."*

In this way, whereas *demonstration of compliance* is linked to dose and risk estimations, *confidence in the safety* is mainly linked to the features of the disposal system itself and the confidence in the safety case, which should be based, among others, on the use of sound technical and managerial principles, as well as on the use of multiple lines of reasoning and evidence.

According to the approach derived from WS-R-4, based on the confidence in safety of the disposal system, its components and safety functions, the trend would be to develop and use safety-oriented criteria, which may be even easier to understand by the stakeholder.

Conclusions

The results of the review of international guidance and its evolution confirms the conclusions of previous analysis carried out by the RWMC-RF, in particular those developed within the "Long-term Safety Criteria Initiative (LTSC)", referred to in the Workshop programme and included in the documentation previously distributed. Summing up:

- In the last years, there has been a significant development of international guidance. The current international framework applicable to the radioactive waste management activities and facilities is formed basically by the ICRP 81, ICRP 103 and ICRP 101, together with the IAEA safety Standards SF-1 and WS-R-4. In addition, the Joint Convention contributed to enhancing the level of harmonisation in policies, practices and regulation at the level required to ensure the safety of the spent fuel and radioactive management and disposal.
- This current international framework provides the basis for the development of national regulations and the development of geological disposal projects. However, there are still terms and concepts that need further clarification and interpretation for the practical implementation of some fundamental concepts. There is also a need for some more consistency among international guidance. Radiological protection and safety are two different concepts and, although connected, they should be better distinguished and defined.
- However, there are now well-defined terms related to the long-term safety (such as containment and isolation, safety functions, safety barriers) that provide a basis for the development of safety-oriented criteria.
- Recent ICRP recommendations reinforce the importance of transparency in the decision-making process and demonstration of compliance in a situation of increasing uncertainties with time, and recognise the influence of social values in the decision on the level of radiological protection, as well as the influence of social concerns and political aspects in the decision-making process.
- This kind of recognition also underlies the new IAEA Safety Fundamental, which states that the generations that produce the waste have to seek and apply safe, practicable and environmentally acceptable solutions for its long-term management.

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Dose Concepts and the Achievability of Protection for the Disposal of Long-Lived Solid Waste According to ICRP

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The main strength of ICRP is its set up of a unified protection system applicable to all types of exposure situations. However, in the case of radioactive waste disposal, the long timescale to deal with has led ICRP to publish dedicated recommendations (ICRP 81, published in 1999) in order to take such a challenge into account while still using the classical tools of ICRP system of radiological protection.

Since then, ICRP has issued new general recommendations, in 2007 (Publication 103), which formally replaced the previous recommendations of 1991 (Publication 60) on which ICRP 81 was based.

One of the major features of the new recommendations is the evolution "*from the previous process-based protection approach using practices and interventions by moving to a situation-based approach applying the fundamental principles…of protection to all controllable exposure situations*" in a similar way. The new recommendations also introduce a framework for the selection of source-related protection criteria to be applied according to the different exposure situations.

The present paper deals with the following issues raised by the radioactive waste management community, on the basis of ICRP 81 and of the new orientations provided by ICRP 103:

- Which are the units and the dosimetric concepts to be used in the specific case of waste disposal and notably the health detriment?
- How should the "basic principle, that the individuals and populations in the future should be afforded at least the same level of protection from actions taken today as in current generation" be understood? (ICRP 81 § 40)
- Does the meaning of the word protection change between the active and the passive phases of the management of the waste?
- What are the relevant documents to be considered as references of ICRP position in the area of radioactive waste?

ICRP units and dosimetric concepts and long-term validity

Question raised by NEA

Which are the units and the dosimetric concepts to be used in the specific case of waste disposal according to ICRP: Explain the effective dose, the potential effective dose (and the expression in risk). **In particular, explain their relation with the detriment (health detriment) and the related timescale**. If possible, what are the bases of ICRP positions?

ICRP Position

ICRP's dosimetric quantities consider the mean energy imparted to the whole organism (or specified organs or tissues) of an individual following his exposure to ionising radiation. Such quantities are in turn linked to the associated health effects (observed or extrapolated) at the corresponding level of exposure.

The ICRP system of radiological protection at low doses is based on the linear non-threshold model (LNT) which links the above mentioned dosimetric quantities to the health effects. This model assumes that a given increment in dose will produce a directly proportionate increment in the probability of incurring diseases (i.e. cancer and heritable effects) attributable to ionising radiation. The model is mainly – but not exclusively – based on the follow up of the survivors of the atomic bomb explosions in Japan in 1945. For this population, the level of exposure has been assessed with reasonable accuracy.

First Step: the Dosimetric Quantities

The fundamental physical quantity in radiation protection is the "**absorbed dose**", D, which corresponds to the mean energy imparted to the mass of a specified organ or tissue. The absorbed dose is a measurable quantity ($J.kg^{-1}$ and is expressed in gray). The average "absorbed dose", $D_{T,R}$., is the mean energy absorbed in the volume of a specified organ or tissue T due to radiation of type R

In order to take into account the ***biological effectiveness*** of the different types of radiation and the ***sensitivity of organs and tissues to these radiations*** weighted quantities are introduced ("e*quivalent*" and "e*ffective*" dose, $J\ kg^{-1}$ expressed in sievert). On the basis of the LNT model low doses (< 100 mSv) can be added linearly whatever the radiations and the organs involved in the exposure.

The "e*quivalent dose*", H_T to any specific organ or tissue, is then defined as:

$$H_T = \sum_R w_R D_{T,R}$$

where w_R is the unit-less radiation weighting factor for radiation-type R. The sum is performed over all types of radiation involved. The values of w_R are based on experimental data expressing the relative biological effectiveness of the various types of radiation and take into account the biological effectiveness of high-LET radiation compared to low-LET radiation, including biophysical considerations and judgements.

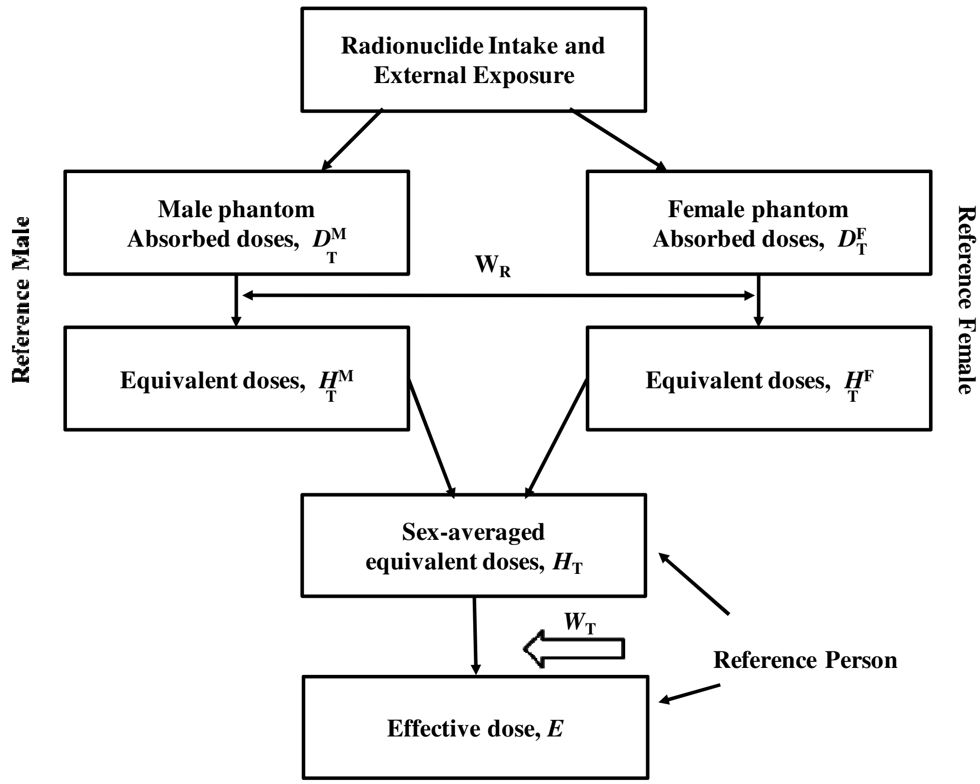
The "e*ffective dose*", E, to the whole organism, is defined by a weighted sum of tissue equivalent doses as:

$$E = \sum_T w_T H_T = \sum_T w_T \sum_R w_R D_{T,R}$$

where w_T is the unit-less weighting factor for tissue T and $\sum w_T = 1$. The sum is performed over all organs and tissues of the human body considered to be sensitive to the induction of stochastic effects. These w_T are determined in order to represent the contributions of individual organs and tissues to the overall detriment from stochastic effects due to radiation. These values are set up according to epidemiological studies on cancer induction and experimental data, and include judgements and simplifications for the purpose of application in radiation protection.

Equivalent and effective doses are not directly measurable quantities.[1] With reference to Figure 1 taken from ICRP Publication 103, §133.

Figure1**. Sex averaging to obtain the effective dose**



- The evaluation of equivalent doses is carried out through "idealised" individuals with specified characteristics, which are sex and age averaged, called "reference person" (male and female) based on anthropomorphic models (phantoms). Such computational representations are used to compute the mean absorbed dose, D_T, in an organ or a tissue T, from reference radiation fields external or internal to the body. These organ and tissue doses are weighted with the radiation weighting factor (w_R) to yield the corresponding equivalent doses in the organs and tissues for the reference male and female.

- As far as the effective dose is concerned, for the purpose of radiological protection, it is useful to apply a single w_T value for both sexes. The tissue weighting factors applied to sum up the equivalent doses to obtain the whole body effective dose are thus sex and age averaged values. *"This averaging implies that the application of this approach is restricted to the determination of effective dose in radiological protection and, in particular**, cannot be used for the assessment of individual risk**"* (ICRP, Publication 103, §132, underscore added). Thus the *effective dose is a risk-related quantity and should not be used in assessing the health risk to a specific individual*. Thus *"In its general application, effective dose does not provide an individual-specific dose but rather that for a Reference Person under a given exposure situation."* In practice, *"In practical radiological protection applications, effective dose is used for managing the risks of stochastic effects in workers and the public."* (both quotes from ICRP-103, Section 4.4.6, §154).

1. Effective dose is the reference concept for geological disposal as implemented in ICRP-81 and later.

Health Detriment

The second step of the approach is the definition of the health detriment to which the above mentioned quantities will be linked.

The radiation detriment is a rather complex construction based on scientific information (epidemiological studies complemented by experimental and biological studies) and on expert judgement. It is aimed at giving an estimate of the total harm to health experienced by an exposed group and its descendants as a result of exposure to radiation. It is expressed as ***nominal probability coefficients*** of stochastic effects (i.e. cancers and heritable effects) after exposure to radiation at low dose rate. The calculation is based on data on cancer incidence weighted by lethality and life impairment and weighted probability of severe heritable effects. The detriment is calculated for the whole population and for an adult population.

"*In the case of cancer, epidemiological and experimental studies provide evidence of radiation risk albeit with uncertainties at doses about 100 mSv or less. In the case of heritable diseases, even though there is no direct evidence of radiation risks to humans, experimental observations argue convincingly that such risks for future generations should be included in the system of protection."* (ICRP Publication 103, §62)

"Although there are recognised exceptions, for the purposes of radiological protection the Commission judges that the weight of evidence on fundamental cellular processes coupled with dose-response data supports the view that, in the low dose range, below about 100 mSv, it is scientifically plausible to assume that the incidence of cancer or heritable effects will rise in direct proportion to an increase in the equivalent dose in the relevant organs and tissues." (ICRP Publication 103, §64)

A dose and dose rate effectiveness factor (DDREF) has been used to project cancer risk determined at high doses and high dose rates to the risks that would apply at low doses and low dose rates. The DDREF value selected by ICRP is 2.

"*The calculation of sex-averaged nominal risk coefficients for cancer involves the estimation of nominal risks for different organs and tissues, adjustment of these risks for DDREF, lethality, and quality of life and, finally, the derivation of a set of site-specific values of relative detriment, which includes heritable effects from gonadal exposures. These relative detriments provide the basis of the Commission's system of tissue weighting…"* (ICRP Publication 103, §82)

On the above mentioned basis, the detriment recommended by ICRP is the following, **applied to effective dose**:

Table 1. **Detriment-adjusted nominal risk coefficients (10^{-2} Sv^{-1}) for stochastic effects after exposure to radiation at low dose rate *(ICRP 103)***

Exposed population	**Cancer**	**Heritable effects**	**Total**
Whole	5.5	0.2	5.7
Adult	4.1	0.1	4.2

Meaning of the Concepts on Long-term Timescale

The dosimetric quantities serve to assess the *robustness* of the radiological protection provided by the disposal. For exposures that may occur in the long term, one has to question the application of the ICRP dosimetric quantities.

The first issue to deal with is the appreciation of uncertainties associated with assessment of the dose to the exposed population (source term, transfer in the environment, habits of the representative person). Although the methodology of the assessment is well known, its implementation in the long term is a challenge.

Secondly, long term is a challenge for the concept of dose itself. We can expect an increase in knowledge concerning the stochastic effects allowing for a better estimate of the radiation detriment. This may induce an **evolution of the tissue weighting factors**, w_T and of the **radiation weighting factors**, w_R. As it was observed in the last decades (since ICRP publication 26, with the quantification of the radiation risk), this evolution of knowledge may lead to increase or decrease of the associated radiation risk.

Thirdly, the **general health status** of the population will evolve in the long term. We can expect improvements in medical treatments for cancers, and evolution of spontaneous incidence of cancers or heritable effects. Due to the multifactorial cause of some radiation-induced effects, the evolution of health status may have various influences on the radiation health detriment.

These three issues show that we can expect evolutions of the radiation risk assessment in the future, but it is not possible to define *a priori* how this risk will evolve. Some factors may increase the risk while others may contribute to its reduction.

Nevertheless, it would be a mistake to consider that the ICRP dosimetric quantities and the radiation detriment are not appropriate for long-term evaluation. *What is at stake is not to evaluate the level of health of a group of population in 10^6 years from now, but to estimate through a comparison (risk indicator associated with several options of protection at the design level of the repository) the level of protection achieved by a radioactive waste strategy.* Moreover, one should keep in mind the fact that such a system allows the summation of effects from different types of radiation and radionuclides.

The ICRP model has been in use for about 50 years and the evolution of the risk coefficient from Publication 26 to Publication 103 is limited to a factor 4 (evolution of the radiation detriment from $1.25\ 10^{-2}\ Sv^{-1}$ in 1976 to $5.7\ 10^{-2}\ Sv^{-1}$ in 2007).

In summary: the assessment of the *robustness* of the protection system provided by solid waste disposal in the long term does not need a precise knowledge of the evolution of the general health of the population in the far future. It seems more reasonable to assess the strategy selected for the disposal on the basis of the current radiological protection criteria, which gives an appreciation of the excess of risk resulting from the exposure of the involved population. In this perspective, ICRP has considered it was neither its responsibility nor a wise position to establish evolutionary scenarios for the health of future generations. ICRP has defined a radiation detriment, on the basis of current knowledge and with a cautious attitude that can be used for a prospective evaluation of the protection provided by the disposal.

Protection Strategies for Radioactive Waste Disposal and Level of Protection for Future Generation

Question raised by NEA

How should we understand in paragraph 40 the sentence "Nevertheless, the Commission acknowledges a basic principle that the individuals and populations in the future should be afforded at least the same level of protection from actions taken today as is in the current generation". What means concretely the expression "the same level of protection" if we cannot assess the detriment on health in the future? Could we accept today a release even limited in the biosphere? Thus is this principle more than a wish? And on what timescales?

Is there an evolution in the ICRP philosophy on this issue during the last 10 years as ICRP 103 in paragraph 222 states that:"The Commission is of the opinion that in the decision-making process, owing to the increasing uncertainties, giving less weight to very low doses and to doses received in the distant future could be considered."

ICRP Position

Planned Exposure Situations

ICRP 103 has introduced the concept of ***planned exposure situations*** referring to situations where radiological protection can be planned in advance. This is exactly the case of the waste disposal at the design stage. In general, in this kind of situations, the magnitude and the extent of the exposures can be reasonably predicted. However, ICRP has introduced the concept of potential exposures to take into account the fact that higher exposures than those reasonably expected to occur may arise following deviations from planned operating procedures, or from accidents. These higher exposures are referred to as ***potential exposures***, which of course are not planned to occur, ***although the situation is planned***. It is considered possible to foresee such deviations within these planned situations and to appreciate their probability of occurrence, although these potential exposures cannot be predicted in detail.

According to ICRP, long-lived waste disposal should be dealt with as a planned exposure situation and ***all resulting exposures should be considered as potential ones***. This is the relevant concept as the events leading to the exposure of future generations can be foreseen but not predicted with any precision. In such a situation, ICRP considers that *"the objective of protecting individuals from exposures associated with credible processes is best achieved by considering both the probability of occurrence and the magnitude of exposures"* (ICRP Publication 81, § 47).

This leads to setting up risk constraint to implement the optimisation principle, which implies the consideration of the dose and the associated probability of occurrence for each process or event corresponding to the scenario of exposure. In this context, ICRP has favoured a "disaggregated" approach to check the compliance with the risk constraint, i.e. separate consideration of each term of the risk (cf ICRP Publication 81) rather combining the two terms of the risk (cf. ICRP Publication 46).

Protection of Future Generations

One key principle regarding the protection of future generations is affording them a level of protection that is consistent with that provided to individuals today – i.e. maintaining the same level of protection. This principle is clearly stated in ICRP Publication 81.

(40) The principal objective of disposal of solid radioactive waste is the protection of current and future generations from the radiological consequences of waste produced by the current generation…Doses to individuals and populations over such long time-scales can only be estimated and the reliability of these estimates will decrease as the time period into the future increases. Nevertheless, the Commission acknowledges a basic principle that individuals and populations in the future should be afforded at least the same level of protection from actions taken today as is the current generation (ICRP Publication 81).

Therefore, the *approach* to protection is the same for current generation and for future generations. *Protection should be the best under the prevailing circumstances*. In other words, the risk resulting from the evolution of the disposal system should be as low as reasonably achievable below a selected risk-constraint.

Different categories of exposure scenarios of the disposal system are usually considered. Namely, gradual evolution ("reference" or normal evolution) and disruptive ones resulting either from natural events or from human intrusion. ICRP Publication 81 considered that gradual and disruptive natural events should both be considered as the result of "natural events" where the protection system plays its role, while human intrusion should be dealt with separately as the protection system is completely by-passed.

Natural Processes

In the case of long-lived solid radioactive waste disposal, one cannot assume that any monitoring will be carried out indefinitely in the future after the end of the institutional control period nor that an intervention will be possible. Thus, as mentioned above, the implementation of the system for the very long term should rely **only** on the demonstration of compliance with the radiological principle (constrained optimisation) **at the design step**. The demonstration should consist in:

1. Identifying the possible scenarios leading to the exposure of future populations.
2. Quantifying the probability of occurrence of such scenarios (or at least their likelihood).
3. Assessing the resultant dose to the hypothetical representative person in the future.
4. Comparing the two terms of the risk-the probability of the event and the associated dose – to the risk constraint either considering separately each term of the risk (ICRP's preferred disaggregated approach) or aggregating the two terms of the risk.

It is important once more to emphasise that in doing such calculations we are not attempting to estimate radiation detriment for future individuals. Rather we are testing the weakness and the robustness of the disposal system and comparing disposal options. We base our approach on stylised calculations assuming that future individuals will have the same characteristics (including radiation sensitivity) as individuals today which makes it possible to estimate the effective dose or its risk equivalent. We can then apply the same radiological criteria we would apply to calculate exposures occurring today. Thus, *as quoted in ICRP Publication 81, any calculated doses to future individuals should be regarded as indicators of safety only (by inference, not absolute measures of risk)*. The more stylised the calculations become in the far future the less predictive are the results.

In summary: in both cases (current discharges and natural processes), dosimetric criteria are set up at the design stage in order to select the best options under the prevailing circumstances for the different timescales. The implementation of the system relies on the ALARA approach in conjunction with quantified dose or risk constraint. The key difference being that the demonstration of compliance is achieved exclusively at the design step in the case of long-lived solid waste disposal, while for current discharges controls and actions can take place later on. Nevertheless, the approaches and the quantified criteria are the same.

Human Intrusion

Inadvertent human intrusion (HI) should be considered as a kind of accidental situation and, in principle, could be dealt with considering both the probability of occurrence of the event and the consequences, comparing the resultant risk with risk criteria.

However, there are some differences between the two situations that need to be taken into account in the assessment.

First difference: the system of protection has been ***completely by-passed,*** while the protection criteria assume that the barriers play their role in the protection.

Second difference: it is difficult to quantify the probability of occurrence of the event (lack of scientific basis), while in the case of current operating facilities we can to some extent assess the likelihood of an accident and include further preventative measures if the risk is judged to be too high.

The third difference concerns the accidental situation. Should the accident occur, the professionals would react while, in the case of events occurring in the far future, we do not know, if the future generations will understand what is happening.

Taking these differences into account, one has to consider how to reduce the possibility of such events, and in addition one should appreciate the acceptability of their associated consequences should they occur.

Publication 81, in paragraphs 61 and 62, emphasises the fact that:

"Protection from exposures associated with human intrusion is best accomplished by efforts to reduce the possibility of such events. Reasonable measures should be implemented to warn society of the existence of the disposal facility. These may include siting a disposal facility at depth or incorporating robust design features which make intrusion more difficult, or employing active institutional controls (such as restricting access or monitoring for potential releases) and passive institutional controls (such as records and markers).

Because the occurrence of human intrusion cannot be totally ruled out, the consequences of one or more typical plausible stylised intrusion scenarios should be considered by the decision maker to evaluate the resilience of the repository to potential intrusion…Since no scientific basis exists for predicting the nature or probability of future human actions, it is not appropriate to include the probabilities of such events in a quantitative performance assessment that is to be compared with dose or risk constraints."

We should focus our attention on the appreciation of the consequences of the accident – i.e. a contaminated land – and see if we would accept today such consequences. According to ICRP 103, land contaminated following inadvertent intrusion into a solid waste disposal facility should be an "existing exposure situation". Existing exposure situations are those that *"already exist when a decision on control has to be taken, including prolonged exposure situations after emergencies" (ICRP Publication 103, § 176).*

For such situations, the aim of the protection is to ensure that the resulting exposures should be at the maximum in the range of 1 to 20 mSv per year. The different scenarios can be assessed at the stage of the conception of the disposal in order to get reasonable confidence on the maximum range of exposure to be associated with an accidental situation (except for some intruders).

Long-term Uncertainty

In its Publication 103, ICRP introduced a discussion on the limitation concerning the use of collective dose. For long-term exposures associated with radioactive waste, ICRP rises the issue of uncertainty and proposes to introduce "weighting factors" to take it into account.

(222) In Publications 77 and 81 (ICRP, 1997d, 1998b), the Commission recognised that both the individual doses and the size of the exposed population become increasingly uncertain as time increases. The Commission is of the opinion that in the decision-making process, owing to the increasing uncertainties, giving less weight to very low doses and to doses received in the distant future could be considered (see also Section 4.4.7). The Commission does not intend to give detailed guidance on such weighting, but rather stresses the importance of demonstrating in a transparent manner how any weighting has been carried out (ICRP Publication 103).

This statement is not contradictory with the key principle to reach the same level of protection, but simply refers to the consideration of individual dose distribution in the ALARA approach.

Regarding the evaluation of the protection provided by the long-lived waste disposal, ICRP has emphasised the protection of individual, while the paragraph referred above is addressing the difficulties associated with the use of the concept of collective dose for long timescale. Therefore, the key issue for radioactive waste disposal is mainly to consider equity between generations which is not conflicting with the aim of reaching the same level of protection in terms of individual doses.

Active Management Phase versus Passive Phase

Question raised by NEA

Does the meaning of the word protection change between the active and the passive phase of the management of the waste? For instance, in the first case, there is a control by the authority, the operator can apply the ALARA principle, and the effective dose keeps a relation – even if it is a small one – with the health detriment. Does not all this change as soon as the controls are no longer applied, and that any exposure is potential and that the effective dose is only an indicator of the performance among others?

ICRP Position

The repository is designed such that if control and knowledge are lost post-closure, the repository is passively safe (using criteria derived from the principle of protecting future generations). *In reality society would try and maintain control over the repository by use of say land-use registries, essentially forever. Thus the passive safety phase is a fall-back position.*

Anyhow, the radioactive waste management community has to acknowledge that they cannot make true and detailed "predictions" about the future performance (even less in quantitative terms) of the repository, not only in what relates to the biosphere and human habits (directly related to the "dose") but also in the "geosphere", and even less about the decisions that future generations could or will take. The only thing we could reasonably and responsibly try is to do our best today, using approaches and criteria considered as "valid" today.

In its Publication 81, ICRP makes what it refers to as a "sound approach" the subject of "compliance" and ends by saying:

In the Commission´s view, provided that reasonable measures have been taken both to satisfy the constraint for natural processes and to reduce the probability or the consequences of inadvertent human intrusion, and technical and managerial principles have been followed, then radiological protection requirements can be considered to have been complied with (ICRP Publication 81, §88).

Therefore, for both phases (active or passive), the protection approach is the same: protection criteria have to be set up at the stage of the conception of the installation, considering that it will not always be possible to ensure the monitoring of the installation. In addition, different criteria will be considered according the exposure situations we referred to: those associated with natural processes and those induced by human intrusion.

ICRP References Applicable to Radioactive Waste

The following Table recalls the ICRP publications mentioned in the present paper. Still valid for dealing with radioactive waste are: ICRP 77, 81 and 82. However, some of their recommendations have to be updated taking into account the evolution introduced by Publication 103.

As far as ICRP 81 is concerned and as above mentioned, it is still in line with the new recommendations, the main modification being the criteria in case of intrusion (1-20 mSv instead of 10-100 mSv).

Table 2. **ICRP References Applicable to Radioactive Waste**

Publication	Title of publication	Comments
1985 – ICRP 46	Radiation protection principles for the disposal of solid radioactive waste	Distinction between normal exposure and potential exposure Introduction of upper-bound value
1991 – ICRP 60	1990 Recommendations of the International Commission on Radiological Protection	Introduction of potential exposures and risk constraint Assessment of the radiation detriment: $7.3\ .10^{-2}$ per Sv
1998 – ICRP 77	Radiological protection policy for the disposal of radioactive waste	Introduction of a public dose constraint for radioactive waste management at: 0.3 mSv/year Discussion of the limitation in the use of collective dose for public exposure Discussion on strategies: dilution (current exposure) / concentration (possible future exposure)
1999 – ICRP 81	Radiation protection recommendations as applied to the disposal of long-lived solid radioactive waste	Introduction of optimisation process with dose constraint at 0.3 mSv/year Same level of protection for current and future generations Distinction between natural processes and human intrusion Introduction of flexibility in the assessment associated with long term uncertainty No dose constraint for human intrusion but minimisation of occurrence
1999 – ICRP 82	Protection of the public in situations of prolonged radiation exposure	Reduction of dose constraint to 0.1 mSv per year for additive dose associated with prolonged exposure Introduction of a generic reference level for intervention: > 100 mSv: almost always justifiable < 10 mSv: not likely to be justifiable
2008 – ICRP 103	The 2007 Recommendations of the International Commission on Radiological Protection	Introduction of exposure situations: planned, emergency and existing ALARA: cornerstone of the protection system Optimisation with dose constraint or reference level)

Fundamental Concepts Used in National Regulation: Is the Terminology Sufficiently Clear?

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Introduction

In reviewing the responses to the questionnaire that was distributed in preparation for this workshop, it was observed that one of the notable features of the responses was that different responders interpreted the same terms in different ways.

For example, the term "undue burden", which appears in IAEA *Fundamental Safety Principles* [1] paragraph 3.29, was apparently interpreted by some responders to mean financial burden, and by others to mean the burden of potential radiological exposure.

In response to the question about the ultimate safety objectives applicable to the regulation of disposal, responses ranged from the specific: "compliance with regulatory dose or release limits" to the general: "safeguarding the interests of people and the environment, now and in the future."Among those responses that interpreted "ultimate safety objectives" to mean the fundamental goals underlying regulatory criteria for radiological exposures, these goals included: limiting future doses to a fraction of background radiation exposure levels, limiting future doses to be below currently acceptable exposure limits and limiting calculated future risks to levels of risk currently considered broadly acceptable.

Another question asked whether the terms "safety" and "protection" were explicitly defined in regulatory documents. The most common response was that these terms are not explicitly defined in regulation. This suggests that common dictionary definitions are assumed to suffice, and that if any additional clarification is needed, it will be found implicitly in the regulations, regulatory criteria and regulatory guidance. It may be instructive to investigate the usage and interpretation of these terms; are they, in fact, sufficiently clear and precise for the purpose?

Terminological Issues

Dictionary definitions of safety generally refer to safety as freedom from danger, risk or harm. In the technical domain, on the other hand, safety is often defined to be freedom from **unacceptable** risk of physical harm or damage. That is, the act of setting regulatory criteria recognises that as a technical concept safety is not an absolute, but must be measured relative to a criterion of acceptable risk or acceptable level of harm. For example, the USNRC's regulatory standard is the assurance of "adequate protection" [2]. Therefore the question posed by regulators is not "is it safe?", but rather "is it sufficiently safe?" These are two different questions, and this distinction is a common cause of miscommunication between technical and non-technical persons when talking about safety.

ISO/IEC guidance for persons involved in standards writing [3] suggests that the words "safety" and "safe" not be used as descriptive adjectives; thus, instead of "safety helmet", the term "protective helmet" is suggested. One reason for this recommendation is that use of the word "safety" may be taken by some persons to imply a guarantee of complete freedom from risk.

The IAEA *Safety Glossary* [4] distinguishes between safety and protection in the following way: safety is primarily concerned with maintaining control over sources, whereas protection is primarily concerned with controlling exposures to persons. Nevertheless, "protection systems" and "protective actions" are terms used in relation to sources rather than to recipients of exposure. In the IAEA *Fundamental Safety Principles*, on the other hand, "safety" is used to encompass both the protection of people and the environment against radiation risks and the safety of facilities and activities that give rise to radiation risks. That is, along this dimension safety may be used as a broader term that can be interpreted to include protection as a subset. Alternatively, we may consider protection of people and the environment to be the primary goal, and assuring the safety of sources of hazard to be just one of the means by which we achieve this goal.

The subtitle of the *Safety Glossary* includes the terms "nuclear safety" and "radiation protection". Nuclear safety is primarily concerned with the prevention and mitigation of accidents, i.e. rare events with large consequences. Radiation protection, on the other hand, is most often concerned with occupational exposures and with exposures to the public and the environment arising from normal activities, including authorised discharges, i.e. common events with minor consequences.

We may also see the term "safety" used together with "health", as in "occupational health and safety". In such contexts, safety is often taken to mean freedom from risk of immediate physical injury or damage, whereas health is more likely to be viewed as freedom from risk of chronic illness or disease. Detrimental health effects are often internal to the body, whereas a loss of safety is often considered to involve primarily external risks.

Another pairing is "safety" and "security", where security refers to protection against acts of evil-doing by persons, such as theft and terrorism, while safety is used in reference to protection against accidents [5].

Thus, there are several dimensions along which we might range various interpretations of the term "safety": absolute protection vs. levels of acceptability; control of the source of the hazard vs. protection of those subjected to the hazard; protection against high-probability low-consequence risks vs. protection against low-probability high-consequence risks; freedom from health hazards vs. freedom from risk of injury or damage; protection against human actions vs. protection against inanimate hazards. It might be an interesting exercise for the reader to consider where disposal of radioactive waste lies along these various dimensions.

Scope

The scope of the IAEA definitions is limited to protection against health hazards arising from exposures to radiation. This may fairly readily be extended to include other hazards (chemical hazards, mechanical hazards, electrical hazards, etc.), but when words such as "safety" are used as undefined terms, their scope may be felt to be even broader. In addition to freedom from risk of physical harm, injury or adverse health effects, the broader concepts of safety and protection may also include, for example, freedom from and protection against economic risk, and freedom from and protection against psychological damage (loss of well-being). These broader aspects are not normally considered to be part of safety regulation, but they can be significant components of societal decision making. Confidence and trust in the decision-making process depends in part on the process being seen as complete, i.e. as addressing all potential aspects; a process which excludes *a priori* certain aspects from consideration may be seen as untrustworthy by some stakeholders.

Connotational Issues

Perhaps an even more important aspect of the use of common-language terms, especially ones that have as much emotional importance as "safety" and "protection", is the aspect of connotational meanings [6]. Connotations vary from person to person and from group to group, and change with time more rapidly than dictionary meanings. They also often carry great emotional weight.

For example, the concept of safety often carries connotations of familiarity with the risk and of control over the risk. Familiarity is one aspect of the observation in a number of countries that inhabitants of a "nuclear community" are more likely to consider a repository concept to be safe than persons who have had little previous contact with the nuclear industry and nuclear issues. The connotation of familiarity also brings to bear concepts such as predictability, i.e. the presence of uncertainty reduces familiarity and lowers confidence in safety. A lack of familiarity with safety criteria may also contribute to a desire for an absolute level of safety as opposed to a level of safety based on a criterion of acceptability. Allowing time to build familiarity is often cited as one of the reasons for adopting a phased, staged or stepwise approach to repository development.

The aspect of control involves both personal control (i.e. involuntarily assumed risks are less acceptable than risks taken voluntarily) and also the comfort that comes from knowing that if anything goes wrong, there is someone who has been assigned the responsibility and has the capability to deal with the problem. Some stakeholders may not be prepared to agree that a repository that is no longer under active institutional control can be considered safe, because it is not subject to control. This connotational aspect of the concept of safety may well contribute in some countries to the use of terminology such as "long-term management" instead of "final disposal", and to requirements for reversibility and retrievability being imposed or considered in some countries.

These additional connotational aspects of the concepts of safety and protection are not constant or absolute. For example, while a staged or stepwise approach is sometimes considered a means to improve familiarity and therefore contribute to perceptions of safety, in some social contexts it may contribute to uncertainty and thus perhaps have a negative impact. Nevertheless, these connotational aspects play an important role in societal decision making. If a strict or narrow definition of safety is adopted that does not allow for them to be taken into account in an appropriate fashion during the decision making process, public confidence in the process may be affected.

The discussion of the meaning of terms is further complicated when translations between languages are involved. Some languages may not have separate words for the concepts of "protection", "safety", "security" and "safeguards", or when they do, the boundaries between the meanings of pairs of these terms may not coincide in different languages. In countries where English is not the national language, reference to international standards and guidance originally written in English may thus be further complicated by subtle differences introduced during translation.

Conclusions

Repository development is now recognised to be a process that takes several decades. As the separation in time and events grows between those persons who initially set a project in motion and those who carry it out and complete it, there is an increasing likelihood that meanings and connotations of terms will change along the way. Attention to terminology and definitions is therefore a component not only of communication between different communities today (e.g. technical vs. non-technical), but also of communication between the present and future generations.

Thus, the challenge for regulators is two-fold: to develop regulatory criteria that protect, to the extent that we are able, present and future generations from the hazards contained within a repository; and to develop criteria and processes that are likely to be understood by and acceptable to the generations immediately following us who must bear the burden of duty to complete the implementation of projects we start today. Clarity and transparency of terminology can play an important role in meeting this challenge.

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[2] Lyons, P.B. (2006),"The USNRC's Reactor Certification and Licensing Process – Meeting the Challenge?", presented at the15th Pacific Basin Nuclear Conference, Sydney, October 2006, *www.nrc.gov/reading-rm/doc-collections/commission/speeches/2006/s-06-033.html*.

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Ethical Issues and Societal Expectations

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From the time high-level radioactive waste was created, I believe it is fair to state, nuclear pioneers recognised that they had an ethical obligation to manage the material in unprecedented ways. And although technical solutions for the management of the waste would prove to be far more problematic and more costly to implement than ever imagined, this obligation has not only endured, but has become more explicit and multidimensional. So much so, that it is now subsumed under a more general rubric of "societal expectations".

The background document distributed in advance of this workshop contains five essays authored by Kjell Andersson, Andrew Blowers, Carl Reinhold Bråkenhielm, Francois Dermange, and Patricia Fleming that are relevant to the question of ethical issues and societal expectations, the topic of my to talk.[1] I commend each of the five papers to you.

Rather than trying to summarise them, I would like to take them as a starting point and to share some of my own thoughts and observations.

As a concept, "societal expectations" suffers from the same limitations as "public interest". It is hard to define and thus very hard to measure. Within a given pluralistic society, there are many, often contradictory, expectations. Consequently, acceptable conflict management mechanisms need to be developed and exercised. Finally, societal expectations may vary considerably from country to country. Given the "fuzziness" of the concept, gaining a historical perspective might be helpful in understanding whether we are dealing with transient and ephemeral ideas or objectives that are stable and enduring.

An Historical Perspective

To do that, I want to dust off a document written more than 30 years ago, *Proposed Goals for Radioactive Waste Management*.[2] The study was requested by the Commissioners of the U.S. Nuclear Regulatory Commission. A seven-person Task Group, made up mostly of outsiders, was composed of individuals with backgrounds in philosophy, social science, public policy, nuclear engineering, radiation effects, geology and law. The Task Group met over the course of more than one year, interviewed more than two dozen specialists and held two meetings with stakeholders. Comments were sought on the draft document; however, the Commission never adopted the proposed goals.

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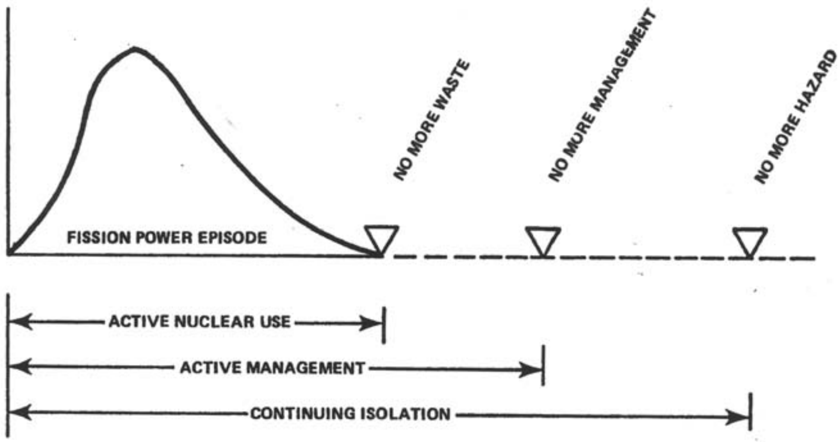
* The views presented here do not represent the views of the U.S. Nuclear Waste Technical Review Board, an independent federal agency charged with evaluating the technical and scientific validity of the U.S. Department of Energy's program to dispose of high-level radioactive waste and spent nuclear fuel.

1. *Regulating the Long-term Safety of Geological Disposal of Radioactive Waste: Practical Issues and Challenges*, Workshop Proceedings, Paris, France, 28-30 November 2006, NEA-6423.; web notice: *www.oecdbookshop.org/oecd/display.asp?k=5KZLC20PXCR5&lang=en*
2. W, P. Bishop *et al.*, *Proposed Goals for Radioactive Waste Management*, U.S. Nuclear Regulatory Commission, May, 1978, NUREG-0300.

The Task Group recognised from the start that different goals might be applicable for different time periods. For its purposes, three periods seemed especially appropriate:

- Period of active use of commercial or military nuclear power.
- Period of active management of nuclear facilities.
- Period of continuing isolation of radioactive wastes when active management ceases.

Figure 1 below depicts each period.



Expectations during the Active Use of Nuclear Power

Twenty-one objectives were advanced. Many of the goals were similar, if not identical, to what are widely viewed as societal expectations today. For example,

> There should be broadly based involvement of interested groups, jurisdictions and citizens in decisions and in the planning process.

Some goals are similar but have important, if nuanced, differences. For example,

> The existence of scientific, technological and *organisational* uncertainties…shall be made explicit along with the logic and procedures used to address those uncertainties.

A few goals seem novel. For example,

> Values not easily quantifiable shall be actively considered in the decision process.

Finally, several goals appear dated, that is, they seem to have faded from contemporary discussions of societal expectations. For example,

> The waste management system shall be designed in such a way that its operation does not depend on the existence of the commercial nuclear power system.

Expectations during the period of active management of nuclear facilities

The Task Group identified nine objectives. Most goals were similar, if not identical, to what are widely viewed as societal expectations today. For example,

> Adequate documentation of present activities and decisions shall be provided to allow future generations with a basis for action.

One goal seems to offer a somewhat nuanced formulation.

> If wastes are disposed on earth, their retrievability – assuming a technology as advanced as present – *shall not be precluded*.

One fairly novel goal was proposed.

> The organisational elements of the waste management system shall not be affected by or require changes in the political system.

Finally, one goal seems dated.

> The organisational elements of the waste management system shall not be self-perpetuating, nor shall they permit waste management activities to become ends in themselves, independent of the needs of society.

Expectations when Active Management Ceases

Four goals were proposed for this period. All of them are consistent with what are generally considered societal expectations today. For example,

> The waste management system shall not require long-term stability of social and governmental institutions for its secure and continued operation.

> The waste management system shall be capable of meeting all relevant radiation standards and criteria for both normal and accident situations throughout its operation.

Conclusions and Observations

For the most part, societal expectations in the United States appear to be quite stable over a period of more than 30 years. Relatively few goals proposed in the Nuclear Regulatory Commission document of 1978 now seem to be dated. Many of the ethical issues raised in recent years were anticipated in the document, although those ethical issues seem no closer to resolution today than they were 30 years ago.

In two areas, however, there are clear differences in emphasis between expectations articulated in the last few years and those proposed in 1978. Then the emphasis was on operational reliability of organisations and institutions. In particular, much care was taken to discuss the inherent limitations on *bureaucratic error-correction*. Nowadays, the focus is more on *bureaucratic behaviours* associated with carrying out decision-making processes. The current emphasis is on the importance of trust, transparency, and accountability.

Having begun my involvement in radioactive waste management policy making many, many years ago, the earlier concerns with the limitations on bureaucratic error-correction still resonate with me. Indeed, at the risk of sounding like a heretic, the Nuclear Regulatory Commission document seems to provide a healthy dose of scepticism about the reliability of a stepwise decision-making process. In fact, organisation theorists understand well the reasons why such a process may be more problematic than currently presumed. In the domain of radioactive waste management, error signals are notoriously unclear. Strong disagreements over objectives and value trade-offs often arise. Finally, the key prerequisite for reliable error-detection independence is often at odds with the key prerequisite for reliable error-rectification interdependence.

So where are we left? The good news is that societal expectations for post-closure and post-monitoring repository performance seem to be few. The less good news is that it is unclear just how far we have come in the last 30 years in meeting those expectations.

Session 3

Establishing Regulatory Criteria that Account for the Inherent Difficulties Associated with the Long-times Frames for Protection

Chair: Walter Blommaert, Head Waste Management Division (FANC)
Rapporteur: Esko Ruokola, Head Waste Management Division (STUK)

Planning for the Long Term: Perspectives of the Canadian Citizens

Atika Khan
Nuclear Waste Management Organization (NWMO), Canada

To determine the best approach for long-term used fuel waste management in Canada, NWMO conducted a dialogue with Canadian citizens over a three-year period (2002-2005) under the mandate given to it by the Nuclear Fuel Waste Act.

Canadian citizens were approached through a nation-wide telephone survey involving 2 600 Canadians, through focus groups, discussion sessions, dialogue workshops, on-line forum and open houses about their views on this subject. Over the course of the study, NWMO engaged 18 000 Canadians directly in its engagement activities.

The comments Canadians made during that dialogue included those concerning the long timeframes involved in high-level waste management and how these should be addressed in the development of a management approach for Canada.

In summary, Canadians want:

- Adaptability and/or flexibility.
- Phased implementation.
- An extended timeframe for implementation.
- The ability to monitor the waste.
- The ability to retrieve the waste.

Adaptability and/or Flexibility

As part of our nation-wide survey, 92 percent said it is important that the approach be "flexible enough to adapt to new learning, and new developments in science and technology," viewed as being a fundamental requirement.

While they want the plan to have a definitive outcome, they also want flexibility in the plan for future generations to make their own decisions

Adaptability was viewed as important in that it allows for anticipating and addressing changing conditions (e.g. the potential for climate change and future societal breakdown) the significance of which is unknown to us today.

Canadians want *Phased Implementation* because it:

- Provides opportunities for continuous learning from the experiences of other countries, leading to adjustments in design details.
- Provides opportunities for future generations to be proactively engaged in the management of the used nuclear fuel.
- Allows for the emergence of new technologies and approaches that might make geological containment and isolation unnecessary.

- Allows for decisions to move as quickly or as slowly as necessary.
- Provides time for capacity building and informed decision making among youth, potential host communities and others, and avoids predetermined outcomes that might undermine community support.
- Allows future generations to decide when to decommission the above and below-ground facilities, when to close them and the nature of post-closure monitoring.

Canadians want *an extended timeframe for Implementation*.

- This was seen as a signal that a cautious and considered approach to the management of used nuclear fuel is being taken, with sufficient time for new learning and technologies.
- It was considered as "pragmatic" in that it recognises the many issues that will need to be addressed, and the difficulty in pre-judging the time needed to achieve full confidence in the approach.
- It was preferred over an approach which does not embrace design features such as flexibility, continuous learning adaptability and implementation over an extended timeframe.
- And it was seen as providing opportunities for future generations to be proactively engaged in the management of the used nuclear fuel and influence implementation of the approach to suit their values and priorities.

This takes into account the recognition that building confidence takes time, and that implementation of the selected approach needs to keep pace with the comfort level of the people.

The long time frame of implementation presents an opportunity for new learning, to take stepwise decisions as we proceed taking into account developments in science and technology, experience, and an opportunity to retain flexibility to take decisions in the future that are in the best interest of society in light of their evolving priorities and expectations.

Canadians want *the ability to monitor* for themselves and future generations.

- This was viewed as essential to ensure the long-term protection of human and ecological health, and to allow for continuous learning and well-informed decision making.
- It provides assurance to the public that the facility continues to be safe.
- It allows future generations to measure and assess their stewardship over the used nuclear fuel.

The ability to monitor was looked upon as a precondition to future retrieval of the material, regardless of the intended purpose.

Canadians also want *the ability to retrieve the waste*:

- In case monitoring indicates that safety is compromised.

Also:

- Used fuel was viewed as a potential resource for future generations; decisions and actions taken now should not foreclose future opportunities – i.e. show respect for the future generations by ensuring that the used fuel is properly cared for but remains available for possible future use.
- And future technologies could emerge to better manage the used fuel.

What Do Implementers Need in Terms of Regulatory Safety Criteria for the Post-Closure Phase?

Bruno Cahen
Andra, on behalf of IGSC, France

Background and Scope

The national experience in siting and developing conceptual designs of geological disposal is growing rapidly. It implies increasing opportunities for interactions between implementers and regulators. Many regulators have already developed a regulatory framework. The implementers need practical, transparent and deliverable regulations. These regulations should draw on experiences gained from development of geological disposal projects.

There has been a large development of international guidance in recent years (ICRP-81, ICRP-103, WSR-4, NEA publications). The wish expressed by the members of the IGSC is that international guidance capitalise on the experience gained recently in the development of safety cases presented in the framework of international fora and simplify this guidance going back to core business.

The recent evolutions at the international level show that:

- There is a general awareness that doses and risks in the future are not a measure of health detriment but are good indicators of the performance of the repository.
- Yardsticks in the different timescales may be different depending on the national context, but all countries agree on the principle that the nature of the safety assessment may not be the same in the short/medium timescales as in the far future and that this may impact compliance measure and corresponding criteria.
- Key elements of the safety strategy have already been identified: the optimisation process (BAT/ALARA), R&D, the stakeholders' role in the project, the stepwise process. Exchange on experience would be fruitful.

Safety Criteria and Very Long-time Frames

Key questions identified by the IGSC

International guidance recognises the difficulties associated with safety assessment in long time frames, and NEA work in this domain has allowed some progress but still leaves many open questions. In its programme of work, the IGSC has identified five key questions that the RF may focus on:

1. Over what time framse are wastes deemed to present a hazard?
2. Over what time frames are regulatory criteria applied and do they change over time?
3. Over what time frames are safety assessments required to be conducted?
4. How do implementers have to address uncertainties in the long time frames?
5. What happens after cut-offs: are additional analyses needed? What types of arguments are to be used?

Need for Stable, Understandable and Practical Criteria

Stable and Understandable Criteria

Criteria will be stable if they are unchallenged which means that they need to be developed on a strong scientific and societal basis.

The determination of the level of hazard presented by the waste in the long time frames is very important in this respect. It was stated until recently that this potential hazard in the future would be comparable to hazards from uranium ore. This point of view has been called into question but there is not yet a common position on the subject.

Other related issues are 1) the basis for a cut-off for the safety assessment in the long time frames, 2) the trend to move from hard criteria to soft criteria when changing of timescales or 3) the need to use additional criteria than dose and risk because of increasing uncertainties the longer the time. National regulations are evolving on these subjects. Ethical issues are coming in and stakeholders should be involved early in the process in order to better understand what is at stake. A large range of points of views has to be dealt with.

Practical Criteria

Protection objectives and criteria should have a direct application to safety options and design or organisational requirements. Regulations have a tendency to be fairly general and sometimes difficult to interpret.

Of course, a relevant regulatory framework requires a project which is mature enough and for which constructive dialogue between the regulator and the implementer has taken place. In general, safety objectives will be set by the regulator and, on this basis the implementer will define safety options that will be reviewed by the regulator to give his approval. From safety objectives and a reference design, safety requirements will be defined.

There needs to be consistency of safety options and requirements for different types of waste. Going from VLLW to LLW, ILW and HLW there is a growing need for increased performances and redundancy. In the longer time frames the emphasis would be given to robust systems, passive safety and multiple safety functions. The criteria should fit the various phases of the project (siting, designing, operating, closure and post-closure).

Safety Priorities and Requirements for High-level Waste

Experience feedback from safety cases shows that safety priorities depend very much on time frames. In the short term (100 to 1 000 years) the radioactivity of waste is high, transient thermo-hydro-mechanical processes dominate. Protection is ensured mainly by engineered containment (waste package) and to some extent also by institutional control. In the range 1 000 to 10 000 years the protection of man and environment relies on the passive safety measures put in place and thus on the performance on the individual components of the repository system. It relies also on the measures taken to reduce the effect of natural phenomena and probability of human intrusion by the depth of the disposal and its location. After 10 000 years some migration of radioactive substances may occur. The role of the repository system is to insure that consequences will remain acceptable. The geology will play a large role in this respect. In the very long term, after "time cut-off", the inventory is limited to very long-lived radionuclides whose activity level is many orders of magnitude lower than in the initial inventory. The limitation of consequences will rely on the dispersion of the waste on large volumes (no "hot spots"), the depth of the repository and the limits set on erosion rates. No need for sophisticated modeling may be required.

It appears more and more important to carefully balance long-term safety and operational safety. Such issues as ventilation, radiation protection requirements during operation, timing for closure of disposal cavities may have consequences on long-term safety. The derived safety criteria for the individual components should lead to measurable, verifiable specifications.

Safety Analysis, Scenarios and Safety Criteria

The assessment of geological repository post-closure safety relies on a number of qualitative and quantitative arguments. One issue is to derive safety criteria in relation with these arguments. The assessment of the induced impact of the repository on man and the environment is one element in demonstrating safety. The corresponding criteria are usually dose or risk. An alternative criterion often proposed is the radionuclide molecular flow to the surface environment in order to alleviate uncertainties associated with the biosphere components.

Specific aspects are important in the safety assessment in order to increase the confidence in the safety case. The redundancy afforded by the existence of multiple safety functions enables the repository to be maintained in a safe condition even in degraded situations. The management of uncertainties contributes to the robustness of the repository despite known/suspected uncertainties in the knowledge and in the long-term evolution. Margins of safety are developed. The soundness of the scientific basis underpinning the initial state and evolution of waste and repository depends of the quality of data and adequate understanding of phenomena.

The safety assessment may rely either on deterministic or probabilistic approaches, each presenting advantages and drawbacks. They are actually complementary.

One fundamental element in the radiological impact assessment is the understanding of the behaviour of individual radionuclides. Different components and functions of the repository system will be brought forward depending on the type of radionuclide. At least three families may be distinguished:

- Short-lived and medium-lived elements, which decay before waste packaged are degraded. They will remain in the repository vaults in normal evolution conditions. They are controlled by containment in the waste packages.
- Long-lived elements that have a reduced mobility because of low solubility limits and/or high sorption properties. These may migrate in the geosphere because of their long decay time but their low mobility will delay their impact in the very long time frames and their low solubility limits will keep their molecular flow at a very low level. They are controlled by retention in the geosphere.
- Long-lived, highly soluble elements presenting low sorption properties. Their impact will be controlled by the concentration/molar flow reduced by diffusion/dispersion processes in the host rock. They are controlled by delay and dispersion in the geosphere.

The safety assessment should be based on the detailed understanding, description and modeling of the processes governing the migration of the different radionuclides. Scientific knowledge leads to reliable quantitative information on the repository evolution resulting in a transparent safety case. The detailed understanding of the system allows identifying intermediate safety indicators bringing confidence on the overall evolution of the system, the dose being the ultimate safety indicator. An optimisation process based on the assessment of the performance of a series of indicators linked with the properties of individual components of the repository system would certainly contribute to confidence and help uncertainty management.

Some examples of indicators associated with requirements may be the following:

- Requirement of data on the waste inventory as its chemical content and long-term evolution: the corresponding indicator is the soundness of the provided data.
- Minimum design performances required for the waste package, the EBS, the host rock for long-term safety. These minimum design performances should take also into account operational safety.
- Indicators of performance associated with each function associated with repository components and the level of redundancy corresponding to each time frame. Optimisation will be directed on these elements.
- Requirements on the safety assessment methods related to the definition of evolution scenarios, on sensitivity studies and on the hypothesis for the biosphere. The indicators will be the peak dose or the peak molecular flow of radionuclides to the geosphere, the percentage released activity per year or the time of occurrence of releases.

Scenarios Drive Criteria for Siting and Waste Characterisation (Optimisation Iterative Loop)

The confirmation of the favourable characteristics of the host rock, the location of the disposal facility with respect to site features depend very much on results from the analysis of the consequences from the normal evolution scenario and human intrusion scenarios. Many site properties come directly into play such as the favourable hydrological context, the low erosion rate, the geometry of the host rock which should be compatible with a disposal facility at a depth of at least 200 m and a thickness sufficient to delay and disperse long-lived, mobile and soluble radionuclides. The prevention from human intrusion and major disruptions is obtained by the absence, in the surroundings, of "profitable" natural resources and of natural risks connected to geodynamics.

Waste characterisation (content, chemical properties) should be driven toward radionuclides which dominate the radiological impact. It should also be driven by factors influencing THMCR processes or the interaction with repository components. Decisions on an overpack or canister to control the source term may be made on this basis.

In the framework of a stepwise approach an overall system optimisation comes into play and all the elements of the safety case should be adequately weighted. This includes balancing long-term and operational safety. In this context, operational safety also means risk analysis, evaluation of specific [dimensioning] accidental scenarios (fire, waste package falling…).

Conclusions

With respect to the main objectives for the RF-workshops, the possible further implication of IGSC may be both in long-term safety and operational safety. Long-term safety criteria, management of extremely long timescales and safety assessment methods are major topics of interest for the IGSC and inputs from RF workshops would be of the upmost importance. The IGSC feels that international developments, following experience feedback from implementation of ICRP-81 and ICRP-103 in national regulations, should deserve a particular attention. The IGSC has an interest in the technical implications of operational safety considerations on long-term repository performance and in terms of design constraints needed to balance operational safety and long-term safety requirements. A stepwise approach to explore this issue was initiated, beginning with an IGSC Topical Session in 2008 (IGSC-10) to define the issue and gather national experience and challenges. Workshops on this subject are planned for the period 2010-2012. Inputs from RF-workshops on implementing an optimisation process would be very valuable.

Consideration of Timescales in the Finnish Safety Regulations for Spent Fuel Disposal

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Introduction

The Finnish spent fuel disposal programme is progressing towards the construction-license stage. The preparations by the regulator (STUK) for the license application review include renewal of the safety regulations. These include the Government Decree[1] on the Safety of Nuclear Waste Disposal which entered into force on 1st December 2008. The Decree will be detailed by a STUK Guide which is currently being updated. These regulations distinguish three post-closure time periods for which different safety criteria are defined; these are discussed below.

Environmentally Predictable Future

The first time period, so-called environmentally predictable future, is defined to extend up to several thousands of years. During this period, the climate type is expected to remain similar to that nowadays in Northern Europe, predictable albeit considerable environmental changes will occur at the disposal site due to the ongoing land uplift: a sea bay will turn into a lake, then into wetland and might later on be used as farmland. The geosphere is expected to remain quite stable though slight, predictable changes will occur due to the land uplift and the heat generating waste.

In this timeframe, the engineered barriers are required to provide almost complete containment of the disposed waste because of its high radioactivity. Consequently, people might be exposed to the disposed radioactive substances only due to limited early failures of engineered barriers, due to e.g. fabrication defects.

Despite the environmental changes, conservative estimates of human exposure can be done for this time period and accordingly the safety criteria are based on dose constraints. The Government Decree includes the following radiation protection criteria:

Disposal shall be so designed that as a consequence of expected evolutions

- The annual dose to the most exposed members of the public shall remain below 0.1 mSv.
- The average annual doses to other members of the public shall remain insignificantly low.

These constraints are applied to assessment periods that are adequately predictable with respect to assessments of human exposure but that shall be extended to at least several thousands of years.

1. Government Decree on the Safety of Nuclear Waste Disposal (736/2008), Finland.

In the STUK guide,[2] the radiation protection criteria are clarified as follows:

The dose constraints apply to radiation exposure of members of the public as a consequence of expected evolution scenarios and which are reasonably predictable with regard to the changes in the environment. Humans are assumed to be exposed to radioactive substances released from the repository, transported to near-surface groundwater bodies and further to watercourses above ground. At least the following potential exposure pathways shall be considered:

- *Use of contaminated water as household water, as irrigation water and for animal watering.*
- *Use of contaminated natural or agricultural products originating from terrestrial and aquatic environments.*

Changes in the environment to be considered in applying the dose constraints include at least those arising from land uplift. The climate type as well as the human habits, nutritional needs and metabolism can be assumed to be similar to the current ones.

The constraint for the most exposed individuals, effective dose of 0.1 mSv per year, applies to a self-sustaining family or small village community living in the vicinity of the disposal site, where the highest radiation exposures arise through the pathways discussed above. In the environs of the community, a small lake and shallow water-well is assumed to exist.

In addition, the assessment of safety shall address the average effective annual doses to larger groups of people, who are living at a regional lake or at a coastal site and are exposed to the radioactive substances transported into these watercourses. The acceptability of these doses depend on the number of exposed people, but they shall not be more than one hundredth – one tenth of the constraint for the most exposed individuals.

Era of Extreme Climate Changes

Beyond about 10 000 years, great climatic changes, such as permafrost and glaciation, will occur. The range of potential environmental conditions will be very wide and assessments of potential human exposures arising in that time period would involve huge uncertainties. With conservative approach, the safety case should be based on extreme bio-scenarios and on overly pessimistic assumptions.

Though the climatic changes affect significantly also the conditions in the geosphere, their ranges are estimable. In this time period, substantial degradation of the engineered barriers cannot be ruled out, though they were planned to withstand the climate-induced disturbances in bedrock. Radionuclide release and transport in the repository and geosphere can be assessed with reasonable assurance and consequently, it is prudent to base the radiation protection criteria on constraints for release rates of radionuclides from geosphere to biosphere (geo-bio flux constraints).

The Government Decree includes the following the radiation protection criteria for the era of extreme climate changes:

Beyond the assessment period referred to above, the average quantities of radioactive substances over long time periods, released from the disposed waste and migrated to the environment, shall remain below the nuclide specific constraints defined by the Radiation and Nuclear Safety Authority. These constraints shall be defined so that:

- *At their maximum, the radiation impacts arising from disposal can be comparable to those arising from natural radioactive substances in the earth's crust.*

2. STUK (2001), *Long-term Safety of Disposal of Spent Nuclear Fuel*, STUK Guide YVL 8.4 (2001), STUK, Helsinki.

- *On a large scale, the radiation impacts remain insignificantly low.*

In the STUK guide, these criteria are specified as follows:

The nuclide specific constraints for the activity releases to the environment are:

- *0.03 GBq/a for the long-lived, alpha emitting radium, thorium, protactinium, plutonium, americium and curium isotopes.*
- *0.1 GBq/a for the nuclides ^{79}Se, ^{129}I and ^{237}Np.*
- *0.3 GBq/a for the nuclides ^{14}C, ^{36}Cl and ^{135}Cs and for the long-lived uranium isotopes.*
- *1 GBq/a for ^{94}Nb and ^{126}Sn.*
- *3 GBq/a for the nuclide ^{99}Tc.*
- *10 GBq/a for the nuclide ^{93}Zr.*
- *30 GBq/a for the nuclide ^{59}Ni.*
- *100 GBq/a for the nuclides ^{107}Pd and ^{151}Sm.*

These constraints apply to activity releases which arise from the expected evolution scenarios and which may enter the environment not until after several thousands of years. These activity releases can be averaged over 1 000 years at the most. The sum of the ratios between the nuclide specific activity releases and the respective constraints shall be less than one.

The selected approach means that the regulator has taken upon him the consideration of the impacts in biosphere from the releases of disposed radionuclides, and the implementer need not to consider the bio-scenarios when preparing its safety case for the time period discussed. The approach also means that more weight is put on the overall impact and less on peak impacts arising from the waste disposal. The given constraints are primarily derived on the basis of reference biosphere calculations. Besides that, some comparisons with fluxes of natural radionuclides in various scales were made in order to check the validity of the constraints and to have a more diverse standpoint on the issue.

The Farthest Future

In a time period of about 250 000 years, the activity in spent nuclear fuel becomes equal to that in the natural uranium from which the fuel was fabricated. In that time frame, the hazard posed by a spent fuel repository will be comparable to that of a medium sized natural uranium deposit and the repository might be regarded as being part of the nature. Also, the peak impact from disposal is expected to arise within the time period up to one million years, because in that time frame the containment provided by engineered barriers is assumed to be lost and there are no factors which would give rise to substantial increases in radiation exposure. Accordingly, beyond about one million years, the regulations do not require any rigorous quantitative safety assessments, but the judgement of safety can be based on more qualitative considerations, such as bounding analyses with simplified methods, comparisons with natural analogues and observations of the geological history of the site.

Session 4

Optimisation, BAT and Related Topics

Chair: Juhani Vira (Posiva)
Rapporteur: Ian Barraclough (EA)

Optimisation: an Overview of Concepts

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This presentation summarises and reviews the concepts relevant to the "optimisation" of geological disposal systems as they are outlined in national and international guidance as well as in the work of NEA groups. It leads to observations and key questions regarding the basic concepts relating to "optimisation" especially as it relates to the long term.

Background

In the technical field, we can relate the approach to "*optimisation*" to "finding the best way forward where many different considerations need to be balanced" (Draft GRA 6.3.44 from UK Environment Agency – May 2008). In the specific area of geological disposal of radioactive waste the objective is to find the "optimal" or "best" combination of characteristics in terms of balancing imperatives of current and future safety while respecting the interests of present and future generations.

Not everybody finds that the term optimisation needs to be used in the field of geological disposal for instance the Finnish regulator does not use this term, nor does the US regulator insofar as post closure safety is concerned. The term is, however, variously present in international and national guidance with different connotations, as follows. Overall, there is an attachment to willing to do our best which many may call optimisation but, because "doing our best" may mean different things to do in different contexts, "optimisation" may indeed mean different concepts to different groups of people. Hereafter are some of the viewpoints and associated issues. For more information the reader is also referred to the NEA report: "The Concept of Optimisation for Geological Disposal of Radioactive Waste: A Concise Review of National and International Guidance and Relevant Observations" (NEA/RWM/RF(2006)5/PROV).

The International Guidance

Most of the international guidance on optimisation of geological disposal is provided by ICRP (ICRP-81, ICRP-101[1] and ICRP-103), IAEA (WS-R-4) and the European Union IPPC (Integration Prevention Pollution and Control) Directive. Main features of the international guidance are described in Table 1 below. These organisations consider both post-closure and pre-closure safety, however the most detailed guidance (ICPR-81) only deals with post-closure safety. The main goal of optimisation as recommended by ICRP is to maximise radiological protection to man, however ICRP-103 states that, in an optimisation process, the chosen option is not necessarily the one associated with the lowest dose. IAEA requirements indicate that, for optimisation purposes, other factors than radiological protection may have to be dealt with such as availability of transport routes, public acceptability and cost. This leads to system optimisation. The IPPC directive goes beyond radiological protection, its main goal being to maximise the protection of the environment from all hazards by applying "Best available techniques not entailing excessive costs".

1. For all practical purposes, ICRP-101 is subsumed in ICRP-103, and only the latter is mentioned in this paper.

Table 1. **Main features of the International Guidance on Optimisation**

	ICRP-81	ICRP-103	WS-R-4	IPPC
Applicability pre- and/or post-closure?	Post-closure	All radiological exposure situations. For geological disposal, reference is made to ICRP-81 which is only applicable to post-closure	Both pre- and post-closure	Both pre- and post-closure
Main goal	Maximise radiological protection of man	Maximise radiological protection of man. However, ICRP-103 also says that "lowest radiological exposure" is not necessarily the optimum	Maximise radiological protection of man	Protection of the environment from all hazards
Tools	(a) Recurrent quantitative radiological analyses (b) "applying sound technical and managerial principles" (best practice)	(a) Recurrent quantitative radiological analyses (b) "applying sound technical and managerial principles" (best practice)	Idem Consider alternative options.	Use of "best available techniques"
Reference Yardstick	Dose or risk constraint	Dose or risk constraint.	Idem	No yardstick given
Non-technical elements considered	Social and economic factors are taken into account in ALARA.	Yes, to the extent that "lowest radiological exposure" is not necessarily the optimum.	Social and economic factors are taken into account	Yes; economical factors specially mentioned. Social factors may be factors as well in what is considered "best" and "available" technique
Transfer of responsibilities/ rights amongst generations	Not addressed explicitly; estimated doses or risks not measures of health detriment	Doses in the long term may be given less weight than in the short term; estimated doses or risks not measures of health detriment.	Reasonable insurance that doses in the long term will not exceed doses used for the design constraint.	Not addressed
Judgement	Based on meeting of dose/risk constraint for as long as the quantitative analysis is reliable and on having implemented sound technical and managerial principles	Goal is to stay as much as possible below dose/risk constraint but "lowest radiological exposure" is not necessarily the optimum	Doses do not exceed the appropriate constraint	
Process or outcome driven?	Outcome driven; based on progressive approach (stepwise decision making?)	Process driven; (based on stepwise decision making?)	Outcome driven (but stepwise decision making)	Process driven (based on stepwise decision making?)

The ICRP and the IAEA consider that optimisation is achieved by recurrent quantitative radiological analyses of different alternative options. A close connection is made between optimisation of radiological protection and "sound and technical managerial principles" ("best practice"). For the ICRP and the IAEA, the main yardsticks are doses and risks. Both ICRP-81 and ICRP-103 take the position that doses and risks, as measures of health detriment, are related to the degree of predictability of the repository system over time. Doses and risks can only be considered as health detriment for periods around several hundreds of years into the future.[2] Beyond this period and during the period of geological stability only estimates of doses can be made and such estimates should not be regarded as measures of health detriment. Beyond the period of geological stability other lines of arguments are more appropriate as "best practice" and "best available techniques". The IPPC directive directs toward the use of "best available techniques" which is more related to the design options and the safety functions of the system. No yardstick is given.

Non technical elements such as social and economic factors should be considered for the optimisation of the post-closure phase. However no indication is given on how to deal with them. The radiological optimisation process in the pre-closure phase is ALARA which considers social and economic factors and is standard practice for existing nuclear facilities.

Transfer of responsibilities and rights to future generations is to be considered in the optimisation process. International organisations consider that future generations should be afforded the same level of protection as the present generation. Nevertheless the ICRP-81 recognises that the yardsticks for optimisation change their meaning with time frames since doses and risks may no longer be considered as a measure of health detriment in the long-time frames and the ICRP-103 suggests that doses received in the long term may be given lower weight for decisions making.

On the question of judgement of compliance there seems to be an evolution from ICRP-81 where compliance is based on meeting dose/risk constraint for as long as the quantitative analysis is reliable and on having implemented sound technical and managerial principles vis-à-vis ICRP 103 where the goal is to stay as much as reasonably possible below dose/risk constraint but "lowest radiological exposure" is not necessarily the optimum.

Depending on the guidance, optimisation may be driven by the outcome, as in ICRP-81 and WS-R-4, or the process as in ICRP-103 and the IPPC directive.

Examples of National Regulatory Guidance

Countries have been preparing regulatory guidance on demonstrating long-term safety. Most countries believe that a stepwise approach should be followed which means that design options may evolve with time. In this sense, one may view that protection becomes optimised as the result of the process of repository development. The level of detail of the implementation of the optimisation concept varies depending on the country but it remains on a very general level. The meaning of these terms, the interpretation of international guidance and the degree of guidance provided varies significantly from country to country. Table 2 presents the main elements of optimisation in some countries' regulatory guidance.

From Table2, "optimisation of protection" in the long term is not a term that is utilised in Finland and the USA. Conversely, Sweden and the United Kingdom consider that optimisation and use of Best Available Techniques are important concepts. In Sweden, BAT becomes the predominant discriminating tool in the very long term when the risk analyses that underlie radiological optimisation become least reliable. The UK position observes that although reducing radiological risk is important, it should not be given a weight out of proportion to other considerations and that the best way forward is not necessarily the one that offers the lowest radiological risk.

2. ICRP-101 (par. 56) also says that "The Commission feels that our current state of knowledge and our ability to predict populations and exposure pathways can appropriately contribute to decision making for exposures to occur over a time period covering a few generations. Beyond such time frames, the Commission recommends that predicted doses should not play a major part in decision making".

Table 2. **The main elements of regulatory guidance in four countries in regard of optimisation for geologic disposal**

	Sweden	Finland	United Kingdom	United States
Stepwise approach	Licensing steps defined by law	Licensing steps defined by law	Stepwise approach allowed but not required.	Licensing steps defined by law
Level of guidance	Detailed guidance	General guidance	Detailed guidance	Detailed guidance
Formal requirement for optimisation	Optimisation procedure is formally required and is processed oriented	No formal optimisation procedure is required but the SAHARA (Safety as High as Reasonably Achievable) principle applies	Optimisation procedure is formally required and is process oriented.	ALARA required for pre-closure phase. No formal optimisation procedure is required for post-closure phase. Optimum then simply means meeting the regulatory criteria. Deep geologic disposal is, by its very nature, ALARA, and there are few technological alternatives in repository design (U.S. National Academy of Sciences).
Tools	(a) Recurrent quantitative radiological analyses as long as they are deemed reliable and (b) BAT analysis afterwards BAT takes precedence to radiological calculations in the long time frames	(a) Recurrent quantitative radiological analyses and (b) impact analysis based afterwards The planning shall take account of the utilisation of "best available technology" and scientific knowledge	(a) Recurrent quantitative radiological analyses and (b) best practice Requirements for best practical means and best practical environmental options. Similar to BAT	(a) Recurrent quantitative radiological analyses and (b) best practice
Reference Yardstick	Risk criteria for up to 100 000 years. No yardstick afterwards but comparison with alternatives	Dose/risk criteria up to about 10,000 years – Activity flux constraints for impact analysis through 1 M. years – No yardstick afterwards	Risk radiological criteria independent of timescales after period of authorisation. No yardstick on other hazards	Dose criteria. Reference values differ according to timescales.
Judgement of compliance	Based on meeting and possibly being below the dose/risk constraint for as long as the quantitative analysis is reliable and on having implemented sound technical and managerial principles	Compliance with post-closure dose constraints and activity flux constraints is sufficient.	Goal is to stay as much as possible below dose/risk constraint but reducing radiological exposures should not be given undue weight.	Compliance with post-closure radiological dose limits is sufficient on regulatory compliance period.
Non technical elements considered	Recognition that society is making decisions that may constrain the implementer's optimisation process along the way. This is also part of BAT		Fundamental objective : Safeguard interests of people and the environment now and the future to command public confidence and be cost-effective Optimisation requires good communication with local community	Recognition that the criteria for compliance are societal as well as technically driven.

Table 2. **The main elements of regulatory guidance in four countries in regard of optimisation for geologic disposal** (Cont'd)

	Sweden	Finland	United Kingdom	United States
Requirement for a documented process on optimisation	yes	no	yes	no
Tendency to privilege system optimisation	Yes, in the sense that it is recognised that society may be influencing the optimisation process.		Yes, in the sense that it is recognised that the best way forward is not necessarily the one that offers the lowest radiological risk.	

Towards Transparent, Proportionate and Deliverable Regulatory Framework

The variety of ways that optimisation is approached (see Table 1) and the variety of interpretations that seem to be placed on the terms used, as well perhaps as variation in the ultimate objectives that optimisation is supposed to help achieve, make for a very varied and confusing backdrop for formulating clear and deliverable regulations, especially concerning long-term repository performance.

A transparent regulatory framework should have clearly defined concepts. At present, clarification would be most useful in the area of explaining the relative weight of long- and short-term analyses and the yardsticks that would apply to the relevant timeframes. A clear position whether it is enough not to exceed the dose/risk constraint or if it is recommended to stay as much as possible below the constraint and on how and when the process of judging compliance may be brought to an end. It should also give indications on how to balance operational and long-term safety.

A proportionate regulatory framework relates to the choice made on the level of detail and stringency of the regulation. It may ask for general requirements such as the need of a stepwise approach and of recurrent safety analyses applying "sound technical and managerial principles" or may go further by requiring thorough historical records and a transparent approach for the selection of options. The regulations may also require a formal optimisation procedure where definition of constraints, associated indicators and relative weight given to individual constraints including BAT are specified. On the other hand, it may be observed that there are no examples of accepted and implemented procedures to document optimisation of a geologic disposal facility, which make the issue of deliverability of the regulation especially poignant.

A deliverable regulatory framework should lead to a manageable decision making process for implementing a geological disposal. In that context one may ask the question how do the regulators understand themselves that what they demand can be achieved and how they convey their confidence in this. There is indeed the risk of raising expectations in society beyond what is achievable. The regulator is called to strike a delicate balance to this effect, in that regulators are not immune from society's request and society may also prone for harder requests that the regulators may wish to make (e. g. very long duration retrievability period).

Conclusions

The principle of optimisation of the safety of the repository is closely linked to the decision making process. The latest ICRP recommendations state that the optimisation of protection is a forward-looking iterative process involving all parties and aimed at preventing and reducing future exposures. One could recognise in the recent literature an emerging view that optimisation, in any practice, ought to be more about process and procedures than outcome when it comes to regulatory attention. Strong support for this approach is provided by the recent ICRP-103, which states that "All aspects of optimisation cannot be codified; rather, there should be a commitment by all parties to the optimisation process. Where optimisation becomes a matter for the regulatory authority, the focus should not be on specific outcomes for a particular situation, but rather on processes, procedures and judgements. An open dialogue should be established between the authority and the operating management, and the success of the optimisation process will depend strongly on the quality of this dialogue."

International guidance on optimisation exists but it is varied and not always clear. Other factors than radiological protection after closure may have to be considered for optimisation. In particular there is no specific recommendation on methods to balance operational and post-closure safety.

We have seen that there is currently a trend to consider optimisation more as a process than an outcome and to strive towards system optimisation. It would seem, however, ineffectual to base optimisation on just one criterion – that related to radiological exposure – when in fact system optimisation is, by its nature, a multi-criterion endeavour. It is also difficult for regulation not to be non-normative, as people tend to expect hard criteria on which regulators can base their decisions.

Optimisation of Protection as Applicable to Geological Disposal: the ICRP View

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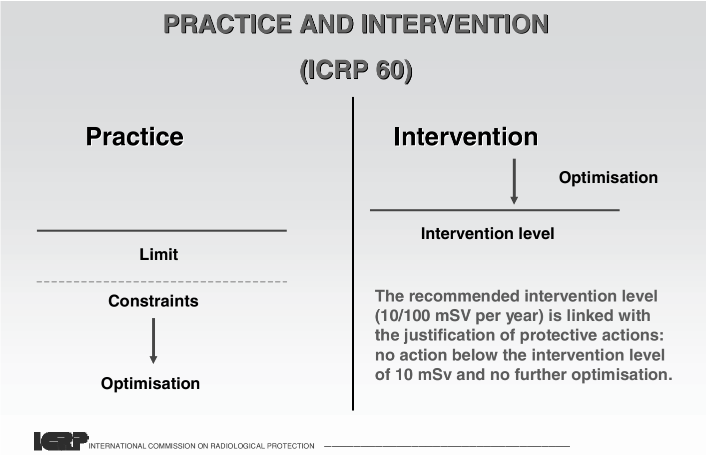
Introduction

During the past 40 years ICRP has published about 100 reports with recommendations to develop the system of radiological protection further. The majority of these reports focus on specific areas of radiological protection. Reports which describe the full system of radiological protection have been published by ICRP every ten to fifteen years. The three principles of radiological protection, i.e. justification, optimisation and dose limitation, have been the corner stones of the protections system for many decades; the practical application of the system of protection has been subject to modifications. The last publications in the series describing the full system of radiological protection are ICRP Publication 60, published in 1992, and ICRP Publication 103, published in 2007.

Review of ICRP-60

ICRP Publication 60 distinguishes between two types of situations: practices and interventions. The respective roles of optimisation are different in the two situations (see Figure 1). In a practice, optimisation is applied below a constraint to select the best protection options under the prevailing circumstances based on scientific considerations, societal concerns and ethical aspects as well as considerations of transparency. An important role of the concept of optimisation of protection is to foster a "safety culture" and thereby to engender a state of thinking in everyone responsible for control of radiation exposures, such that they are continually asking themselves the question, "Have I done all that I reasonably can to avoid or reduce these doses?" Clearly, the answer to this question is a matter of judgement and necessitates co-operation between all parties involved and, as a minimum, the operating management and the regulatory agencies (for details see ICRP Publication 101).

Figure 1. **The Role of Optimisation in Practices and in Interventions Situations Described in ICRP Publication 60 of 1992**



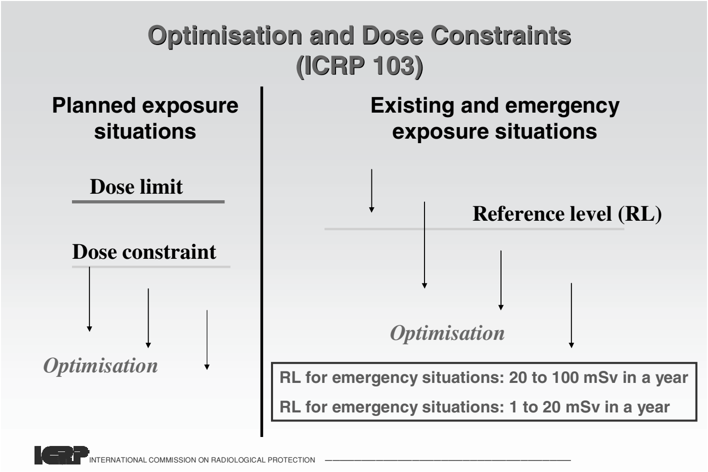
In an intervention situation (generic) optimisation is applied when intervention levels are selected. The intervention level is linked with the justification of protective actions following the identification of an intervention situation: below an intervention level no further optimisation is required according to ICRP Publication 60. In the specific situation of human intrusion which is one of the methodological options described in ICRP Publication 81 (see below) an existing annual dose[1] of around 10 mSv is recommended as a generic intervention level below which "intervention is not likely to be justifiable"; an existing annual dose of around 100 mSv may be used as a generic reference level "above which intervention should be considered almost always justifiable".

Review of ICRP-103

The ICRP Publication 103, which was published in 2007, provides recommendations for a new system of radiological protection. It replaces the Commission's previous ICRP-60 recommendations and updates, consolidates and develops additional guidance on the control of exposure from radiation sources issued since 1990.

According to ICRP 103 the three principles of radiological protection are reinforced; they should be applicable in a similar way in all types of exposure situations: planned, emergency and existing exposure situations (see Figure 2), with restrictions on individual doses and risks, namely dose and risk constraints for planned exposure situations and reference levels for emergency and existing exposure situations. The proposed system of radiological protection is based both on science (quantification of health risk) and on value judgement (what is an acceptable risk?), and optimisation is the recommended process to integrate both aspects. There has been an evolution from the previous to the new system: even if the dose/risk constraint is met, there still is the obligation to demonstrate that the protection is optimised. While for planned exposure situations (the former "practice") nothing changes, there are substantial changes in the application of optimisation in emergency and existing exposure situations, which used to be named – according to ICRP 60 terminology – "interventions". ICRP 103 recommends a framework for setting dose constraints and reference levels for these situations, i.e. 20 to 100 mSv in a year for emergency exposure situations and 1 to 20 mSv in a year for existing exposure situations.

Figure 2. **The Role of Constraints/Reference Levels and of Optimisation in the System of Radiological Protection Described in ICRP Publication 103**

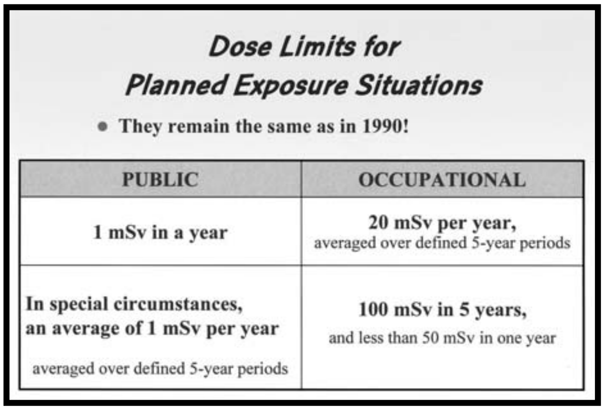


1. "Dose" is in fact "effective dose".

The Specific Issue of Geological Disposal

In the context of the questions related to the application of the new recommendations to geological disposal it is important to state that the following recommendations of ICRP Publication 60 have not been changed by ICRP publication 103: the dose limits (see Figure 3) and the generic constraints for workers ($2\ 10^{-4}$ per year) and for the public (10^{-5} per year).

Figure 3. **Dose Limits for the Public and at the Workplace in Planned Exposure Situations** (ICRP 103)



Dose Limits for Planned Exposure Situations

- They remain the same as in 1990!

PUBLIC	OCCUPATIONAL
1 mSv in a year	20 mSv per year, averaged over defined 5-year periods
In special circumstances, an average of 1 mSv per year averaged over defined 5-year periods	100 mSv in 5 years, and less than 50 mSv in one year

The ICRP view on the role of optimisation of protection as applicable to geological disposal was lastly provided in ICRP Publications 77 and 81. These publications are based on the concepts of the system of radiological protection described in ICRP Publication 60. In the context of human intrusion(s), the principle of intervention is introduced with a recommended generic intervention level of the existing annual dose around 10 mSv (ICRP Publication 81). At levels of the existing annual dose below 10 mSv an intervention is "not likely to be justifiable". According to ICRP Publication 103 the application of this approach is no longer recommended. In the new system this situation should be treated as an existing situation with the aim to ensure that the resulting exposures are in the range 1 to 20 mSv in a year.

Questions Raised by NEA

What kinds of checks and balances or factors that would be needed to be considered for an "optimal" system? Can indicators be identified?

Waste disposal projects are characterised by a long-lasting, stepwise approach which can be characterised by the following steps:

1. Site selection.
2. System design.
3. Construction.
4. Operation.
5. Closure.
6. Post-closure.

Stakeholders are involved in each step but the processes adopted are different for each step. The success of optimisation depends strongly on the dialogue between the regulator, the operational management and other stakeholders. Quantitative methods may provide input to this dialogue but they should never be the sole input. Parameters to select the best protection options are:

- Attributes of exposed population (e.g. Gender, age).

- Exposure characteristics of the dose distribution (e.g. number of people, dose).
- Distribution of individual exposures in space.
- Distribution of individual exposures in time.
- Social considerations and values.
- Environmental considerations.
- Technical and economic considerations.

Should a distinction be made between system optimisation (in the sense of taking account social and economic as well as all types of hazards) and optimisation of radiological protection? What could be criteria?

No, such a distinction should not be made.

The system of protection recommended by ICRP is based on both science (quantification of the health risk) and value judgement (what is an *acceptable* risk?). Optimisation is the recommended process to integrate both aspects.

How should factors like stakeholder acceptability (e.g. in selecting a site) taken into account in the concept of optimisation? And Does the process of stepwise decision making constitute a part of system optimisation? To what extent? Is this best practice?

The main types of stakeholders are:

- The decision maker.
- The operator.
- The radiological protection authority.
- The exposed individuals.
- Representatives of the society.

The requirement of the optimisation of protection is the responsibility of the operating management, subject to the requirements of the competent national authorities. Operating management, propose and implement optimisation, and then use experience to further improve it. Competent authorities require and promote optimisation and may verify that it has been effectively implemented. Regulatory authorities should encourage the operational managements to develop a "safety culture" within their organisations

How can "optimisation" or best practice aspects be made visible in the regulatory process?

ICRP recommends applying the approach of BATNEEC (best available technology not entailing excessive cost) rather than that of BAT. The principles of optimisation and BATNEEC complement each other. The control of residual doses (human health) is driven by optimisation, BATNEEC is applied as a means to control effluents in cases where humans are not directly affected.

Obligations of the operational management are to develop and provide internal policies, priorities, rules and procedures to ensure the existence of a vibrant safety culture at all levels of management and the workforce. Competent authorities are requested to establish clear policies and processes for decision making regarding the authorisation of proposed activities. Regulatory requirements should include the need for an active safety culture in both the authority itself and all regulated operating management.

Should the same weight be given to the distant future and to the near future with regards to optimisation and regulatory decision making? If not, how should this be reflected in regulation?

The key issue in radiological protection in the context of radioactive waste disposal is the equity between generations. ICRP recommends that beyond timeframes of a few generations predicted doses should not play a major part in decision making.

ICRP Publication 103 (para.222) states: "… in the decision-making process, owing to the increasing uncertainties, giving less weight to very low doses and to doses received in the distant future could be considered … ICRP does not give detailed guidance on such weighting but stresses the importance of demonstrating in a transparent way, how any weighting has been carried out. A variety of approaches could be taken as long as they are properly justified by the regulator."

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NRC Position on Optimisation for a Potential Geologic Repository

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This afternoon, I would like to focus on the regulatory framework that the US Nuclear Regulatory Commission (NRC) is using to review the U.S. Department of Energy's (DOE) license application for a geologic repository at Yucca Mountain, Nevada, US. NRC will evaluate this application using regulatory criteria that protect public health and safety, the environment and common defence and security. Regulations governing the potential repository at Yucca Mountain are contained in 10 CFR Part 63, which covers both the pre-closure operational period and the period of time following closure of the repository.

I must note that, in response to a successful legal challenge in 2005, the safety standards for Yucca Mountain must be extended from 10,000 yr to 1 000 000 yr following closure of the potential repository. The 10 000 year requirements that previously were established remain essentially unchanged. By law, the U.S. Environmental Protection Agency (EPA) establishes the safety standards for Yucca Mountain. The NRC, in turn, must make its regulations consistent with EPA standards. EPA issued revised standards for the 10 000 to 1 000 000 yr performance period in October, 2008 (40 CFR Part 197). Following a public comment period on the proposed revisions, NRC is currently updating its regulations to be consistent with the revised EPA standards for the 10 000 yr to 1 000 000 yr post-closure period. In this talk, when I need to refer to safety standards after 10 000 yr, I will necessarily speak to the revised EPA standards.

One of the requirements in Part 63 for the pre-closure operational period is to meet the applicable requirements in 10 CFR Part 20 for radiation protection. Part 20 contains requirements for a program to reduce radiation exposures to As Low As Reasonably Achievable (10 CFR 20.1101) during the operational phase of the potential repository. Having a good ALARA program isn't the only requirement for safety during the pre-closure phase of operations. DOE also must produce an appropriately detailed safety analysis, which considers event sequences that have likelihoods as low as 1 in 10 000 of occurring during the approximately 100 year pre-closure period (i.e., annual frequencies of occurrence $>10^{-6}$). For event sequences that have annual frequencies of $>= 10^{-2}$, DOE must show that these event sequences would produce a dose of no more than 50 mSv/yr [5 000 mrem/yr] to a radiation worker, no more than 1 mSv/yr [100 mrem/yr] to any on-site person who is not a radiation worker and no more than 0.15 mSv/yr [15 mrem/yr] to any real member of the public located on or beyond the facility boundaries. Any event sequence that has an annual frequency of 10^{-2} to 10^{-6} must be shown in the pre-closure safety analysis to give doses of <50 mSv/yr [<5 000 mrem/yr] to a person located on or beyond the boundaries of the facility.

For the period following permanent closure of the repository, NRC has numerous regulatory requirements to protect public health and safety, the environment and common defence and security. These requirements represent an optimised approach that ensures our regulations are appropriately protective and provide a transparent basis to judge the safety of the proposed repository far into the future.

The first post-closure requirement is that the repository system must be constructed so that there is a system of both natural and engineered barriers. The applicant must demonstrate an understanding of the capability of these barriers in the total-system performance assessment, which is an integral part of the safety analysis report. An understanding of barrier performance is important to gaining confidence that the safety standards will be met by the proposed repository system.

A total-system performance assessment also must be used to demonstrate compliance with safety standards. This assessment must include appropriate uncertainties in both models and data, and propagate these uncertainties through the performance assessment. Performance assessment must consider events with annual likelihoods of occurrence as low as 1 in 100 million, if such events would affect the timing or magnitude of radionuclide release significantly. At the Yucca Mountain site, such events include very infrequent earthquakes and the potential eruption of a small-volume basaltic volcano.

For Yucca Mountain, uncertainties about future changes in human society or key biosphere components, which cannot be constrained by current scientific understanding, have been addressed through rulemaking. In the performance assessment, expected doses are calculated for a stylised individual, called the "reasonably maximally exposed individual" (RMEI), who represents a small group of people that are most likely to receive a maximum dose. The RMEI lives above, and withdraws water from, the centre of the plume of contamination, and has the habits and lifestyles of individuals currently living in the accessible environment near Yucca Mountain. In addition to using water withdrawn from the plume of contamination for crop irrigation, the RMEI drinks 2 liters of this water each day. Thus, the RMEI approach for performance assessment avoids undue speculation about long-term changes in future societies or biosphere characteristics, while still allowing consideration of biosphere uncertainties in the performance assessment.

The numerical standard for the performance assessment is a probability-weighted expected annual dose to the RMEI. Thus, the likelihood of the RMEI receiving a dose from an event is factored into the conditional dose associated with the event. The performance assessment analyzes the uncertainties associated with data and models, and calculates a range of probability-weighted annual doses. The mean of those calculated doses to the RMEI is used to assess compliance with the post-closure dose standard.

For the post-closure period up to 10 000 years, expected annual doses to the RMEI cannot exceed 0.15 mSv/yr [15 mrem/yr]. EPA has recently specified that doses to the RMEI cannot exceed 1 mSv/yr [100 mrem/yr] from 10 000 yr to 1 000 000 yr post closure. NRC is in the process of updating its 10 CFR Part 63 regulations to conform to the EPA post-10 000 yr standard for individual protection.

In addition to the individual protection standard, for the first 10 000 yr following repository closure, a groundwater protection standard limits doses to the RMEI to less than 0.04 mSv/yr (4 mrem/yr) and sets some concentration limits for radium and some alpha emitters. The groundwater protection analysis, however, only needs to consider events that have a greater than 1 in 10 chance of occurring during the 10 000 yr period. Human intrusion is evaluated using a stylised scenario in which a driller penetrates a waste package and forms a pathway to the water table. This stylised event is evaluated for a future time when the waste package has degraded to the extent that a driller wouldn't recognise a drill bit has hit an engineered barrier. Doses to the RMEI that result from this stylised scenario cannot exceed 0.15 mSv/yr [15 mrem/yr] in the first 10 000 years, or 1 mSv/yr [100 mrem/yr] after 10 000 years.

Confidence that the geologic repository is optimised to protect public health and safety and the environment also is achieved through a performance confirmation program. If NRC grants DOE an authorisation to construct the repository, DOE must conduct a series of investigation to confirm that site characteristics encountered during construction are within the range of conditions considered in the license application. In addition, DOE must conduct additional investigations to confirm that barriers important to waste isolation are functioning as intended.

Repository oversight must continue following permanent closure. In order to close the repository permanently, DOE must have a program in place to continue monitoring the repository system, establish permanent land-use controls, construct permanent markers over the repository site, and preserve all applicable records of the repository and its contents.

NRC concludes that the regulatory requirements I've outlined provide a rigorous basis to determine if the proposed geologic repository at Yucca Mountain will be safe. Compliance with these requirements is sufficient, and appropriately optimised, to ensure public health and safety. The ALARA principle, while appropriate for pre-closure and decommissioning operations, does not apply to post-closure. If the repository system is shown to be safe, further design modifications incur additional costs with values that are difficult to judge against speculative changes in future societies and economies. As an additional consideration, deep geologic disposal, by its very nature, already is viewed as ALARA. There are few technological alternatives in repository design (10 CFR Part 63). Thus, NRC concludes that its post-closure regulatory requirements represent a sufficiently optimised approach to protecting safety.

In summary, safety of the potential geologic repository at Yucca Mountain will be evaluated by considerably more than compliance with a numerical dose standard. NRC concludes that the current US regulatory framework provides sufficient and optimised protection of public health and safety, the environment and common defence and security. The principle of optimised protection (i.e., ALARA) is being applied for pre-closure operations and decommissioning of the potential repository. However, long-term safety is optimised through compliance with the post-closure regulatory requirements.

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The Current Regulatory Requirements on Optimisation and BAT in Sweden in the Context of Geological Disposal

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Legal Framework

In Sweden a nuclear waste repository will be evaluated according to both to general environmental legislation (the Environmental Code, SFS 1998:808) and according to more specific requirements in the Act on Nuclear Activities (SFS 1984:3) and the Radiation Protection Act (SFS 1988:220). The evaluations according to these laws will be carried out according to two separate, but coordinated, legal review and decision making processes.

The environmental code defines general rules of consideration with requirements on both siting and use of best available technique (BAT). The siting rule states that a proposed site should be selected with the goal to give the least disturbance and negative impact on human health and the environment. This means that the proposed site should be compared to other plausible sites presented in the environmental impact statement, or otherwise available. Similarly, the requirement on BAT aims at preventing or counteracting damage to human health and the environment. Both BAT and the siting rule should be applied to the extent it cannot be considered unreasonable. In making this judgement the effectiveness of the protective and precautionary measures should be related to cost, as well as aspects of sustainable development.

Although the requirements on BAT and siting in the Environmental Code apply to radiological protection, they aim at a broader system optimisation. The more specific requirements on optimisation and BAT of radiological protection of geological disposal systems are given in the regulations associated with the radiation protection act. These regulations are the basis for the discussion in the remainder of this note.

Supplementary Requirements to Dose and Risk

The Swedish radiation protection regulations (SSM, 2009) comprise three cornerstones:

- A risk target: the repository should be designed so that the annual risk of harmful effects does not exceed 10^{-6} for a representative individual in the most exposed group.
- Environmental protection goals.
- The use of optimisation and BAT.

The risk target relating radionuclide releases to consequences for humans provides a yardstick by which the acceptability of the repository can be determined. Dose and risk calculations provide numbers for evaluating compliance with the target. However, risk analyses for geological repositories will always be associated with uncertainties, especially for distant time periods after closure and regarding climate, biosphere conditions and human society. Therefore there is a need for additional arguments in the safety case in support of decision making.

It is in this context that the requirements on optimisation and BAT should be seen as supplementary to the risk target, in providing evidence that the developer as far as reasonably possible has taken into consideration measures and options for reducing future doses and risks. Both principles focus on the proponent's work on developing the repository system and should be applied to the whole process of developing a disposal system, i.e. all steps from siting, design, construction, operation to closure of the repository. However, the application of these principles is subject to societal and economical boundary conditions as will be discussed later.

However, as mentioned above, risk and dose calculations will always be associated with uncertainties when looking far into the future. For these situations, and also for early stages of repository development when there is limited data from sites and the engineered barrier system (EBS), the concept of BAT is a more appropriate. BAT focuses on more robust measures of repository performance, aiming to hinder, reduce and delay releases of radioactive substances from both the engineered and the geological barriers, and is therefore less sensitive to speculative assumptions on climate and biosphere conditions in the distant future.

In case of a conflict between BAT and optimisation, measures satisfying BAT should be prioritised. For example, the risk analysis may suggest that a repository solution leading to early releases is acceptable if the radioactive substances are diluted in a large lake or the sea. In such a case a repository solution providing containment, according to the principle of BAT, should be prioritised.

Application of Optimisation and BAT on Different Timescales

The conditions for estimating risks from a geological repository are different for different timescales. Some elements of the risk analysis become speculative already after few hundred years after closure, for example human society and living habits. After a few thousand years the uncertainties regarding the human environment (the biosphere) will increase, which renders calculation of radiation doses and risk even more uncertain. In the time perspective of 100 000 years one could expect dramatic climatic changes with glaciations and large sea level fluctuations in the Scandinavian region. Other elements of the risk analysis, such as the evolution of the basement rock and the engineered barriers, can be expected to be more stable over long time periods. These are some of the considerations behind SSM's guidance on the reporting of risk analyses and other radiation protection arguments for different time periods, summarised in Figure 1.

Figure 1. **Summary of SSM's guidance on compliance demonstration for different time periods after closure of a geological repository**

<table>
<tr><th>Time after closure (yrs)</th><th>Safety case reporting</th><th>Compliance measure</th></tr>
<tr><td>0-1 000</td><td>• Risk analysis based on today's biosphere
• Special reporting on early barrier transients</td><td rowspan="2">• Calculated risk
• Description of environmental impact
• Application of optimisation and BAT</td></tr>
<tr><td>0-100 000</td><td>• Risk analysis based on illustrative scenarios for climate and biosphere
• Complementary safety indicators to support risk calculations</td></tr>
<tr><td>100 000-1 000 000</td><td>• Simplified risk analysis
• Analysis of long-term barrier performance and effects of major detrimental events
• Reasoning of protective capability based on risk and complementary safety indicators</td><td>• Application of BAT</td></tr>
<tr><td>> 1 000 000</td><td>• Description of radiological toxicity of the repository</td><td>• Basis for comparison with alternative waste management options</td></tr>
</table>

Three main compliance periods can be identified. The first is the period over which calculations of dose and risk has a meaning for compliance evaluation. The length of this time period may vary depending on country and setting of the repository site, but in Swedish guidance quantitative risk calculations are expected for the time period of one glaciation cycle or approximately 100 ka (for spent nuclear fuel repositories). For this time period the proponent should present quantitative risk and dose calculations for comparison with the risk standard. The calculated risk (and environmental impact) is the main compliance measure for this time period, but the application of optimisation and BAT are important supplementary arguments.

For the time period beyond 100 ka, after a glaciation, risk calculations become more speculative due to large uncertainties in climate and biosphere conditions, hence compliance demonstration based exclusively on a comparison of calculated risks with the risk target will not be meaningful. The compliance discussion for this second compliance period may instead be based on a combination of arguments including more robust measures of the repository's protective capability, such as different measures of barrier performance and activity fluxes. Indications of disturbances of the repository's protective capability should be reported together with a discussion on potential measures for improving the repository performance. Hence, for these long time periods SSM's evaluation of compliance will focus more on the application of BAT than on the uncertain results of a quantitative risk analysis.

At some point in the distant future, even analyses of more robust repository performance measures become speculative and meaningless. Further, it is hard to foresee any measures that could be taken in the design of the repository that would counteract the very long-term global geological processes, for example repeated glacial erosion that eventually may expose the waste to the human environment. Therefore SSM does not ask for a reporting of radiological consequences after 1 million years after closure of the repository. However, a simple analysis of the fate of the repository and the very long-term consequences of concentrating uranium in geological formations may provide an important basis for high-level comparison with alternative waste management options.

Future Human Intrusion

The potential for future human action (FHA), and the special case of human intrusion into the repository, is a direct consequence of geological disposal, and any attempt to estimate probabilities and consequences will be very speculative. Therefore Swedish guidance states that FHA scenarios should be reported separately and should not be included in the risk summation. Only inadvertent intrusion needs to be considered. FHA scenarios provide a basis for identifying measures to reduce the probability and consequences of the human disturbances, according to the principle of BAT, e.g. by increasing repository depth, avoiding mineral deposits and preservation of information. FHA scenarios may also serve to illustrate irreducible risks associated with geological disposal, and thus provide a basis for comparison with other waste management options.

Boundary Conditions for Application of Optimisation and BAT

There are of course limits for what can be expected in terms optimisation and BAT. The principle of voluntary participation in the Swedish Nuclear Fuel and Waste Management Co's (SKB) site investigations on part of the municipalities is one example of a government decided societal limitation on site selection. Cost considerations also set boundaries to SKB's optimisation process. In Sweden, it is the full responsibility of the waste producer (through SKB) to ensure that sufficient funds are available for the development of an acceptable geological disposal solution. However, society may provide feedback to SKB on optimisation and BAT considerations during the development process, through the recurrent regulatory reviews and subsequent government decisions on SKB's programme for research, development and demonstration (RD&D programme). Finally, technical constraints could be availability of technology and the effectiveness of various measures for enhancing the repositories protective capability.

Regulatory Review of Optimisation and BAT

Demonstrating compliance with Swedish radiation safety regulations involves demonstrating (1) that the risk and environmental protection targets are satisfied for at least the period of one glacial cycle, or approximately 100 000 years and (2) that optimisation and BAT have been applied as far reasonably possible during the process of developing the disposal system. It is the responsibility of SKB to motivate the balancing between radiological protection and societal and economical factors.

Because we cannot foresee exactly what issues that will appear in SKB safety case it is more or less impossible to, a priori, define a comprehensive set of acceptance criteria for BAT and optimisation. In this respect, SKB will not get the final answer to what is an appropriate level of optimisation and BAT until the licensing review. However, a stepwise process of developing a repository makes it possible to provide guidance along the way. As already mentioned, one example is the Swedish system with regulatory review and subsequent government decision on SKB RD&D programme every third year – where design choices and other important decisions in SKB programme are scrutinised. The government has also established a series of consultation meetings between SKB and the regulator with the aim of clarifying regulatory expectations on the license application. Recurrent regulatory reviews of SKB's preliminary safety assessments are another way of providing regulatory feedback to SKB, prior to the license application.

Nevertheless it is important that the safety case/license application contains a road map of the most important BAT considerations, i.e. the ones really affecting safety, throughout the development of the repository system so they can be reviewed and presented to the decision makers.

Summary

Optimisation and BAT are important regulatory (societal) tools for ensuring an attitude of doing as good as reasonably possible, i.e. important supplements to the quantitative yardsticks dose and risk. Critical BAT and optimisation considerations may become an important part of the decision basis and should consequently be presented in an understandable way to the decision makers. However, as the date for license application and review quickly is approaching there is a need for SSM to develop and communicate a strategy for how to evaluate these lines of argumentation. Examples of issues that may need further clarification include:

- How to best present optimisation and BAT considerations in a safety case/license application?
- How to value BAT and optimisation in relation to risk calculations for different time periods? This is particularly relevant for situations where the calculated risks and doses are close to the regulatory targets.
- Optimisation to or below the risk target? Recent ICRP recommendations (ICRP, 2007) are not very prescriptive in this respect.

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Session 5

Regulatory Research and Development Activities

Chair: Yutaka Kawakami (NSRA)
Rapporteur: Hans Wanner (ENSI)

Needs of Research for Regulatory Purposes

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Introduction

The question of active involvement of nuclear regulatory and supervisory bodies in research and development (R&D) projects has become a topic of increasing interest in recent years. The way in which research is included in regulatory activities varies from country to country. The range spans from countries with no regulatory R&D activities to countries with extensive activities which are often carried out by independent research organisations acting on behalf of the regulatory body. In few countries the regulator and implementer have their research carried out by the same research institutes.

In Switzerland R&D work carried out or supported by the regulator is called "regulatory safety research", which has the primary purpose to improve nuclear safety. With the sponsoring and coordination of such research, the Swiss Federal Nuclear Safety Inspectorate (ENSI) aims to establish and extend the current state of the art, and to make new results available for its own tasks as a regulator and supervisory authority. These activities are complemented by bilateral co-operation, in particular with the French and German regulators, and by collaboration of the regulator in committees and working groups of international organisations.

The intention of the present paper is to outline the potential merits of R&D work carried out by the regulator, and to address a number of questions that seem worthwhile to discuss at the international level.

Objectives of Research by the Regulator

It is the duty and responsibility of the implementer to design, construct, operate and close a repository for radioactive waste in such a way that safety is ensured during all pre- and post-closure phases. This includes the obligation to carry out the necessary R&D work which provides the scientific and technical basis for this purpose. The scope of work must be comprehensive in order to achieve the envisaged goal, and there should be no need for complementation by the regulatory body. Nevertheless, R&D work of the regulator has still several merits: It improves the regulator's competence, independence and confidence, and it can be essential for the regulator's scientific and technical ability.

- *Competence*: The stipulation of meaningful and practical standards and requirements for safe geological disposal of radioactive waste requires a high level of expertise and experience. The critical review of the safety case, which is usually the responsibility of the regulator or the supervisory body, requires the know-how and expertise of peers, i.e. of specialists being at the same level of expertise as the implementers. Research helps to acquire and maintain the necessary competence and provides access to the scientific community. Another issue the regulator needs to consider is the qualification of his workforce. In order to recruit talented scientists it is important for the regulator to offer attractive jobs and working conditions. Most young scientists will find it attractive to work for an employer who undertakes demanding research projects in which they can be actively involved.

- *Independence*: The regulator sets the standards and requirements for safe geological disposal, and he reviews the safety case. In fact, the regulator's review of the safety case may be regarded as a second opinion with respect to the implementer's view. Therefore, it is important that the regulator is entirely and truly independent of the implementer it is in fact key to credibility. The stakeholders must be convinced of the independence of the regulator. Certain stakeholders may acknowledge the R&D work performed or managed by the regulator as "independent research".

- *Confidence*: Confidence is of key importance when complex issues are at stake. Competence and independence are prerequisites for the stakeholders' confidence in the regulator, yet this may not be sufficient. Regular interactions of the regulator with all stakeholders, including appearances in public, are equally important. The stakeholders should be aware of the regulator's existence and perceive him as a competent and independent supervisor.

Further Issues

There may be further motivation of the regulator to carry out his own R&D projects, among which is the verification of key safety issues or the investigation of topics not addressed by the implementer, i.e. to fill scientific gaps. The question whether or not it is the duty of the regulator to carry out such complementary work is the subject of controversial discussions.

A further issue is the source of the budget from which research for regulatory purposes should be funded. Frequent sources of funding are the waste producers and the national budgets. National budgets are usually more restricted and less flexible than funds of the waste producers. In Switzerland, the expenses of specific R&D work that is in a strong context with Swiss nuclear installations or radioactive waste management are basically charged to the account of the waste producers while generic regulatory safety research with no direct link to such projects is funded through the national budget.

Conclusion

The question of how much regulatory research is needed is difficult to answer on a general basis. It appears obvious that the regulator must achieve the objectives of competence and independence. The research needed for this purpose is the least the regulator must undertake.

The verification of key safety issues and the investigation of issues not addressed by the implementer may be considered as optional.

IRSN Safety Research Carried out for Reviewing Safety Cases

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Introduction

IRSN (Radiation Protection and Nuclear Safety Institute) is the public body in charge of the scientific assessment of nuclear and radiation risks. Its mandate includes: advising the public authorities and contributing to public policies, delivering services to other organisations and developing the research activities necessary to support its scientific appraisal. The key fields of research relate to safety of nuclear installations and waste, to severe accidents in nuclear reactors and emergency preparedness, to radioactivity and ecosystems and to radiation protection.

In the field of radioactive waste safety, IRSN implements a pluri-annual research programme so as to develop IRSN staff skills and anticipate the needs for new knowledge necessary to perform comprehensive safety reviews of high quality. This research programme, launched initially to support the IRSN assessment of Andra's study of the "feasibility of reversible geological disposal in clay" issued in December 2005, is now related to the development of the high-level and long-lived intermediate-level waste repository project through 2015 and is structured along the main steps as identified in the French Planning Act of 28 June 2006 on the sustainable management of radioactive materials and waste. This act foresees a licence application to be submitted in 2015 for the creation of a deep geological repository. The IRSN research programme is annually updated and periodically reviewed by a scientific committee and is organised along 4 types of research activities devoted to addressing several "key safety issues", as explained below.

Taking into consideration the feedback and main conclusions drawn from the regulatory review of the "feasibility of reversible geological disposal in clay" in 2005, IRSN has identified a number of important issues, grouped hereafter in "key safety issues", on which research should be carried out with priority from 2006 to 2015. The issues presented hereafter relate only to the Meuse/Haute-Marne site and do not anticipate the possible emergence of other issues of importance for establishing the safety demonstration during further steps of project development. However, at this stage of the project, IRSN gives priority to examining:

- The confinement capabilities of the sedimentary host rock and the identification of possible fracturing in the host formation and the geological layers surrounding it.
- The perturbations due to excavation or due to the interactions between different components.
- The waste degradation.
- The uncertainties on corrosion rates of metallic components, due particularly to a lack of knowledge on transient environment conditions and their duration.
- The dimensioning hypotheses for the various repository components, with the aim at constructing containment barriers that are as effective as is reasonably possible.

- The construction/operational safety (accounting for reversibility) particularly with respect to the risk of explosion relevant to hydrogen produced by radiolysis in waste cells, the ability to remedy a situation caused by a package fall in cells and the possibility of retrieving waste.
- The sealing capabilities with the view to assessing the likely performance of a sealing engineered structure, taking into account the effects of potential disturbances over time or difficulties for emplacing seals at industrial scale.
- The long-term performance of the repository with emphasis on hydro geological modelling, integrated transfer of radionuclides and biosphere modelling. It is particularly important to be able to rule on whether or not localised preferential transfers exist and to assess their influence on the general flow patterns.

Definition of Safety Research Activities

The above-mentioned "key" scientific and technical topics should also be of prime concern for the implementer since they relate to "key" safety issues for demonstrating the overall safety of the repository, and the level of funding that the implementer should afford to research activities of concern for safety should be naturally much higher than those of the regulator and technical safety organisation (TSO). This is fully justified by the different respective roles played by both entities. On the other hand, it still is the assessor's duty to be able to cover all the safety case issues with care to make appropriate balance between topics that must be addressed by R&D programme or topics that do not require specific R&D development. In the latter case, the regulator or TSO should be able to explain why it is not necessary to develop its own research capabilities. In this respect, some aspects are not addressed by IRSN R&D programme because either they relate to conception/construction demonstration tests that are of implementer responsibility or because IRSN considers that the scientific knowledge is sufficiently shared by different stakeholders and well managed by the operator. Considering the elements that justify IRSN R&D programme, 4 categories of major questions are addressed: the adequacy between experimental methods and data foreseen, the knowledge of complex coupled phenomena, the identification and confidence in components performance and the ability of the components to practically meet *in situ* the level of performances required. Addressing these questions requires the research programme to be developed along the following lines:

- Test the adequacy of experimental methods for which feedback is not sufficient. The assessment of their validity allows addressing the consistency and degree of confidence of the data produced.
- Develop basic scientific knowledge in the fields where there is a need for better understanding of the complex phenomena and interactions occurring all along the life of the repository and their influence on nuclear safety, so as to preserve an independent evaluation capability in these matters.
- Develop and use numerical modelling tools to support studies on complex phenomena and interactions so as to allow IRSN assessing orders of magnitudes of components performance and physical-chemical perturbations, but independently from specified and estimated by implementers.
- Perform specific experimental tests aiming at assessing the key parameters that may warrant the performance of the different components of the repository. Such experiments are designed in particular to simulate the behaviour of components in altered conditions and allow IRSN delivering appraisal on the specifications of construction that are to be proposed by implementers.

These studies are carried out by means of experiments performed either at IRSN surface laboratories, or in the Tournemire Experimental Station (TES) operated by IRSN in the south-east of France. The TES is a former railway tunnel crossing a 150 m-thick Toarcian argillite formation and has been intensively used for some 20 years to perform *in situ* experiments devoted to better understanding:

- The diffusion mechanisms in stiff clay (origin of over-pressures and influence of pore size on water-rock interactions…). Many characterisation methods (devoted to characterise movement of natural tracers…) have been tested.
- The hydraulic role of faults/joints: survey methods (seismic survey analysis combined with others methods…) used to identify fractures in clay and their potential as water pathways have been tested.
- The differential fracturing phenomenon in clay and its high damping potential.
- The EDZ development: characterisation methods and modelling have been used and developed taking advantages of, on the one hand the 100 years passed since tunnel construction, and, on the other hand, the observation of new drifts recently drilled.
- The clayey materials evolution due to cement-clay/iron-clay interactions by characterisation and modelling of 10-year-old *in situ* experiments (using a coupled transport/chemistry code Hytec developed by École des Mines de Paris).
- The chemical conditions during transient processes and the specific effects of the presence of micro-organisms or of redox conditions (characterisation of processes upon Tournemire data) on the waste or engineered components degradation over time.
- The parameters that will have to be specified and controlled *in situ* to warrant the performance of seals and concrete liners. A dedicated *in situ* mock-up is under development and will be implemented in TES to study altered evolution of seals.

Besides the Tournemire Experimental Station, specific studies are in progress in complementary scientific fields with the view to:

- Better knowledge, on the one hand, of the physical and chemical properties of the concretes in their initial and altered state and, on the other hand, of the influence of industrial implementation conditions on their performance.
- Better understanding the transient phenomena and, in particular, the behaviour of hydrogen generated by corrosion and radiolysis and its influence on water flow – these studies are addressed by experimental, theoretical and modelling developments.
- Better knowledge of the waste performance.
- Better knowledge of the transfer properties of radionuclides and chemical elements under repository conditions (data base review).
- Modelling flow and transport of radionuclides by developing computer models simulating the underground flow patterns at various scales in the vicinity of the Bure site as well as radionuclide migration from the waste packages to the biosphere (3D computer code MELODIE).
- Modelling the biospheres of interest for the Bure site (existing and possible in future).

In addition, the safety research topics to be possibly undertaken related to operational safety and reversibility issues are in a preliminary phase devoted to the definition of targeted actions.

Organisational Aspects

Because of the complexity and the large scope of issues to be addressed, IRSN promotes a multi-disciplinary approach integrating experimentalists, modellers and experts in safety who work together on each of the topics of interest for safety. This synergy between research engineers and experts in safety assessment is a valuable tool to ensure consistency and quality of technical assessment. Scientific partnerships with research facilities and universities is the preferred strategy of IRSN in order to be able to take benefit of high-level scientific skills in different specialities and for a duration compatible with the planned time frames of the assessment process (several decades).

Part of IRSN research programme is integrated in the EURATOM Framework Programme related to radioactive waste management research. IRSN is involved in the 6^{th} and 7^{th} Framework Programmes which offer a valuable framework for achieving results and for sharing experience among countries involved in waste safety. IRSN supports also international research programmes such as the Mont Terri project as well as bilateral co-operation with homologous organisations in foreign countries.

The quality and independence of the research programme carried out by IRSN allow building and improving a set of scientific knowledge and technical skills that serves the public mission of delivering technical appraisal and advice. In particular, they contribute to improving the decisional process by making possible scientific dialogue with stakeholders independently from regulator or implementer.

Conclusion

Because of time constraints, it is of crucial importance to be able to anticipate the development of knowledge and resources required to assess risks posed by nuclear facilities in the future and, in particular, waste management safety. It is the reason why IRSN has identified very early in the French geological repository project development the scientific issues that had to be addressed in priority. This enabled IRSN to optimise the resources allocated to research. These resources are periodically assessed with respect to the progress made in studies, the new issues to be taken into account and duly planned, as well as the regulatory review agenda that requires swapping research and assessment activities.

The research activities carried out by IRSN are developed in consistency with conclusions drawn from the stepwise regulatory process that allows periodically addressing the remaining issues that must be dealt with to improve the safety demonstration. The expected outcomes of IRSN R&D programme are clearly identified with respect to the safety review approach, paying in particular specific attention to which phenomena must be studied by the TSO so as to ensure appropriate independent judgement of the level of safety that the repository may reach. It is also a duty for TSO to be able to deliver opinion on the consistency and degree of confidence of the data produced as well as on the ability of the implementer to realise, at an industrial scale, components that will perform “as designed”.

But the efficiency of the research carried out by the regulator or the TSO does not rely only on technical skills but also on its ability to promote synergy between experts in charge of assessment and researchers. This contributes highly in guiding research efforts that must be made for the purpose of maintaining the quality of the regulatory review. In addition, high scientific skills ensure efficient technical dialogue between the implementer and the evaluator which is also a necessary condition to achieve valuable assessments.

Regulatory Research and Development Activities in Japan

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A stepwise approach is applied to site selection process for geologic disposal in Japan, according to the 2000 Implementation Act, "Specified Radioactive Waste Final Disposal Act". Areas for candidate sites are narrowed down to finally identify the repository site through three steps: the literature-survey step to select preliminary investigation areas, the field-survey (surface and borehole survey) step to select detailed investigation areas, and the detailed-underground-investigations step to select a repository site.

The Nuclear Safety Committee of Japan has provided its guideline for the first step to select the preliminary investigation areas in 2002. The guideline for the preliminary investigation areas comprises exclusion requirements for geologic conditions that may cause destructive effects on the repository. Guidelines for the second and third steps will be given in accordance with the progress of the disposal programme.

The implementer, the Nuclear Waste Management Organization of Japan, will submit the license application for regulatory approval after the repository site is identified, and the Nuclear and Industrial Safety Agency (NISA) of the Ministry of Economy, Trade and Industry will judge the compliance with the applicable "Law for the Regulations of Nuclear Sources Material, Nuclear Fuel Material and Reactors."

The role of NISA is twofold:

1. To make a technical review on site selection, where the Agency reviews the investigation results to check the compatibility with the given guidelines.
2. To devise safety requirements and make technical judgements on safety assessment, where the Agency develops safety requirements and evaluates the safety assessment of the implementer to judge the compliance with regulatory requirements.

It is naturally expected that the Agency maintain and improve technical basis and competence. Accordingly, NISA needs to keep technical basis consistent with best available science and technology, and utilise research to both improve on technical basis and competence.

Research activities to support the aforementioned Agency's roles and regulatory-related measures are now under discussion within an ad-hoc expert committee within NISA. The planning of research activities is not yet completed. The views expressed hereafter are those of the support research organisations to the JAEA and the National Institute of Advanced Industrial Science and Technology.

There are two different scopes of research in response to the regulatory needs in the course of NISA involvement in the geologic disposal programme: one is to support the technical review of site selection, and the other to establish safety requirements and support technical judgements on safety assessment. As mentioned before, the Agency is also responsible for securing the research infrastructure and human resources as a research related activity.

The research to support technical review on site selection has the purpose of verifying that no significant geologic conditions exist that may cause adverse effects on operational and post-closure safety. It is therefore concentrated on geological and hydro-geological studies, which include:

- Uplift and erosion at a site, possibly placing the repository closer to the surface and impairing the natural barrier function.
- Fault activities, possibly increasing the hydro-geological paths.
- Volcanic activities, potentially accelerating geochemical weathering and subsequent physical destruction of repository.
- Geochemical evolution of groundwater.

In order to support technical judgements on safety assessment, we first need to select important scenarios that are associated with large uncertainty and, hence, may be critical from a safety view. The following topics of studies are envisioned:

- Long-term leaching characteristics of vitrified waste glass as the source term of safety assessment.
- Long-term alteration of engineered barriers, which may degrade their permeability.
- Resaturation of groundwater in buffer materials and gas transport, which may deteriorate the physical barrier function of the buffer material.
- Effects of geological evolution on hydrogeology.

These studies will provide the scientific and technical basis to judge the robustness of implementer's safety assessment methodology.

A safety assessment tool for use by the regulator is also needed. We have been developing a probabilistic safety assessment tool to check independently the implementer's assessment.

The above are ongoing and envisaged research areas and topics to support regulators' activities. The topics will be evolving to more design- and site-specific ones with the progress of site selection. Data quality and international co-operation are also part of the approach:

- Handling and Quality Check of Shared Data and Knowledge

  The regulatory agency, in establishing guidelines and safety requirements or in reviewing the license application, more or less depends on data acquired and knowledge managed by the implementer and/or implementer-funded technical supporting organisations. The data and knowledge provided by the implementer's side should be shared with the regulatory agency. Independent quality check of data such as expert panels is required for regulatory use, and transparency is essential to its process.

- International Co-operation of Regulatory Support Organisations

  The plan and the progress of geological disposal programs differ from country to country, and the regulator's involvement is accordingly different. Although regulator's views and concerns depend on the repository design and safety assessment methodology of the country, it is informative and helpful to share the critical safety issues, views and concerns between regulatory support organisations to solve technical problems.

Session 6

Human Actions

Chair: Daniel Schultheisz (EPA)
Rapporteur: Klaus Fischer-Appelt (GRS)

Assessing the Effects of Human Action on the Safety of Geologic Disposal: The U.S. Regulatory Experience

Dan Schultheisz
US Environmental Protection Agency, United States

There is general agreement that geologic disposal of long-lived radioactive waste provides the greatest degree of isolation from the biosphere, and hence the greatest protection for humans, over the extended time frames during which the waste presents a hazard. Geologic disposal has an additional advantage in that it does not rely on active institutional controls to maintain and protect the facility, but is instead intended to operate passively even if all knowledge of the facility is lost. Thus, geologic disposal does not rely on the questionable assumption that governmental or other responsible institutions can be maintained in perpetuity; this, however, also raises the possibility that some future human action could be taken that disrupts the repository and compromises its ability to isolate the radioactive material. It is clear, therefore, that some evaluation of this possibility must be included in the overall safety case for the facility. The nature and extent of the analysis, as well as the relative importance it is assigned within the safety case, is less clear.

The U.S. Environmental Protection Agency (EPA) has applied two very different approaches to the analysis of human intrusion scenarios at geologic disposal facilities. For the Waste Isolation Pilot Plant (WIPP) in New Mexico, which accepts transuranic radioactive waste from government defence activities, realistic drilling and mining scenarios are analyzed as part of the safety assessment addressing the natural (undisturbed) evolution of the repository. (40 CFR 194.32 and 194.33) For the proposed repository for spent nuclear fuel and high-level radioactive waste at Yucca Mountain, Nevada, however, a specified stylised drilling scenario is analyzed separately from the safety assessment for the undisturbed evolution of the disposal system. (40 CFR 197.25)

What is the basis for these different approaches? How can they both be “right”? The answer lies in the details of the two facilities, specifically in the:

- Characteristics of the site, including historical exploitation of mineral resources.
- Design of the disposal facility.
- Legislative framework.

WIPP

WIPP is located in a salt bed in south eastern New Mexico. Although the salt has not been extensively mined, the region has historically been widely subjected to drilling for oil and gas, as well as mined for potash. Potash mines can in fact be seen adjacent to the WIPP site. EPA therefore required that deep and shallow drilling scenarios be developed that are consistent with the historical rates and types of drilling performed in the area. EPA also required that mining scenarios consistent with historical mining operations be assessed for their effect on the hydraulic conductivity of the hydro geological units affecting the WIPP.

EPA also considered the design of the disposal system, specifically the waste package. Most of the waste being disposed of at WIPP can be contact-handled because of its low gamma content. This fact, coupled with the enveloping nature of the salt medium, means that it is not necessary for waste packages to be highly engineered for strength or shielding. In fact, the waste packages at WIPP are not considered an engineered barrier. EPA determined that the waste packages would provide little resistance to a drilling penetration, but such a penetration would represent the most likely scenario leading to releases of radionuclides to the accessible environment. As a result, the effects of drilling and mining are required to be incorporated into a probabilistic analysis along with the natural features, events and processes occurring at the site.

Yucca Mountain

By contrast, the Yucca Mountain site is in a desert location at which no mineral resources have been located. Yucca Mountain is at the top of a ridge composed of tuff, formed by volcanic activity roughly 10 to 12 million years ago. Significant ground-water resources do flow beneath Yucca Mountain; however, ground water is much closer to the surface and more accessible at distances of 18 km or more. Therefore, it is unlikely that a person would try to withdraw water from a point above the repository.

EPA was directed by the Energy Policy Act of 1992 (EnPA) to obtain advice from the National Academy of Sciences (NAS) regarding reasonable standards to protect public health and safety at Yucca Mountain. EPA's standards are to be "based upon and consistent with" the findings and recommendations of the NAS. The EnPA asked NAS two specific questions regarding the potential for human intrusion into the repository:

- Whether it is reasonable to assume that a system of post-closure oversight can be developed, based upon active institutional controls, that will prevent an unreasonable risk of breaching the repository's engineered or geologic barriers; and
- Whether it is possible to make scientifically supportable predictions of the probability that the repository's engineered or geologic barriers will be breached as a result of human intrusion.

NAS concluded that active institutional controls could not be maintained for a sufficiently long period to prevent an intrusion from occurring, nor would it be possible to make scientifically supportable predictions of the probability of such intrusions occurring, when they might occur, and for what purpose. NAS recommended, however, that a stylised intrusion scenario be evaluated to test the "resilience" of the repository. NAS suggested a scenario involving a single penetration through a waste package and into the aquifer, using water-well drilling technology employed today. NAS further recommended that this scenario be analyzed separately from the probabilistic analysis of the undisturbed (natural) evolution of the disposal system. EPA adopted these recommendations. EPA specified that the intrusion should be assumed to occur at the earliest time that a waste package would be sufficiently degraded so that such a penetration would go unnoticed by the driller. EPA included this provision because, unlike at WIPP, the waste packages for Yucca Mountain are highly engineered and robust to resist heat, physical impacts and corrosion. As designed, it is likely that they would provide significant resistance to drilling for several thousand years at least.

As these examples show, the appropriate analysis of human intrusion in the safety case for geologic disposal may be derived from situation-specific details regarding the site, the facility design and the legislative framework, as well as other aspects not addressed here. In this sense, a "one size fits all" approach to future human action may not actually fit the specific situation. The examples discussed above both incorporate the fundamental assumption that technologies used in a future intrusion will be the same as those employed today or historically. This assumption may not be universally accepted and should be considered along with assumptions regarding the predictability of future human lifestyles and locations, as well as potential advances in medical and other technologies.

IGSC Perspective on Human Intrusion

Hiroyuki Umeki
Japan Atomic Energy Agency (JAEA) on behalf of the IGSC, Japan

Background and Concept

The Integration Group for the Safety Case (IGSC) is the technical advisory body to the Radioactive Waste Management Committee (RWMC) of the Nuclear Energy Agency (NEA). The IGSC updated its Programme of Work in 2007 (NEA, 2007). The process raised a number of issues that IGSC recommended RWMC-RF to consider for further discussion. These include issues related to human intrusion**.**

The NEA previously addressed the issue of safety assessment of human intrusion during several projects in the 1980s and 1990s (NEA, 1989, 1993, 1995). This issue was also examined in more recent publications, including that from the INTESC (International Experiences in Safety Cases) Initiative (NEA, 2009a, 2009b). Since the start of these projects, there have been no significant developments in the methodologies to address human intrusion in safety cases.

As described in the next sections, these projects show that there is **agreement at a conceptual level** on the treatment of human intrusion in safety cases. However, no single approach to deal with human intrusion in a safety case is widely accepted (i.e. it is not possible to say that the issue is "closed"). The approach adopted in a given national programme is based mainly on policy considerations and does not depend heavily on scientific determinations or information (see e.g. NAS, 1995). The requirements and constraints for considering human intrusion, therefore, are **largely specified in regulations and in many national programmes**, relatively few, or no, aspects are left to the discretion of the implementer.

Furthermore, human intrusion is a sensitive issue for many programmes. It can be an issue of high interest to stakeholders, and decisions on approaches are normally undertaken with considerable consultation – those who have taken such decisions are generally satisfied with the approaches and would not support work that might undermine or re-open the issue. Thus, a detailed re-examination of safety assessment of human intrusion and of the conclusions that have been reached previously is not a priority. Nevertheless, there remain open questions and details to be addressed regarding the treatment of human intrusion in safety cases and the specification of key parameters. Depending on the extent to which human intrusion is addressed in regulations, the responsibility for addressing such questions may rest with either the regulatory agency or the implementer. These implementation issues are of interest to IGSC and could benefit from international discussion and information sharing.

Conceptual Agreement and Approaches for Safety Assessment

A geological repository is designed, in principle, to minimise the risk of human intrusion (i.e. the concept itself, which isolates waste far underground). The process of optimisation allows the application of measures to address human intrusion in terms of the probability or the consequences.

Examples of such processes include siting criteria to avoid natural resources, design features and institutional controls or markers. Nevertheless, the possibility of human intrusion can never be completely excluded: it is an unavoidable consequence of applying the "concentrate and confine" principle and must be considered.

In safety assessment, most regulators accept a treatment of future human action separate from the base case. Furthermore, regulators generally accept stylised approaches for assessing future human actions. Because the requirements and constraints for considering human intrusion are largely stylised, many aspects may be specified in regulations; in many national programmes, relatively few (or no) aspects are left to the discretion of the implementer.

However, the extent of stylisation varies, as does the degree to which the scenarios and parameters as well as consequence assessment and evaluation are specified in regulation. In terms of the scenarios, most national programmes exclude consideration of deliberate or "advertent" intrusion and focus on inadvertent intrusion.

Aspects Relevant to IGSC

Consensus on the conceptual approach to human intrusion has changed little over the succeeding decades since NEA examined the issue in detail, and there have been no significant changes or advances in the general methodologies to address or model human intrusion in safety cases. However, programmes continue to grapple with this issue in setting regulations for long-term safety of geological disposal. For programmes seeking to implement requirements, there remain open questions and details to be addressed regarding the treatment of human intrusion in safety cases and the specification of key parameters. Furthermore, there is ongoing discussion of what practical measures can be taken to reduce the chances or consequences of human intrusion, and how these are treated in safety assessment and in the broader safety case. The IGSC identified some key aspects of interest in this regard:

- Accounting for human intrusion aspects when designing the layout of the repository and other engineering and architectural aspects (which has some relation to the concepts of optimisation and "best available techniques" as applied in many programmes) :
  - What potential counter-measures may be considered (e.g. increased repository depth, more robust engineered barriers, intrusion shields, artificial underground markers (acoustic, magnetic, radioactive...), etc.)?
  - How are these seen to relate to the concepts of "optimisation" and "BAT (best available techniques)", as applied in many programmes?
  - An issue is "retrievable" concepts or post-closure monitoring measures that may introduce potential intrusion pathways.
- The design of long-term institutional controls and markers. This could include technological advances in materials that might be used in markers, as well as emerging ideas regarding memory/record preservation:
  - What technological advances have been made in materials that might be used in markers?
  - What are emerging ideas regarding memory/record preservation?
  - What credit should be given in safety assessment in terms of reducing or eliminating the chances of human intrusion, or changing the mechanisms of intrusion considered in safety assessments?
  - Could markers actually increase the risk of intrusion if knowledge preservation fails?
- How safety cases take account of institutional controls (if at all) in terms of reducing or eliminating the chances of human intrusion, or changing the mechanisms of intrusion considered in safety assessments.

- Factors considered in stylised scenarios:
  - What types or methods of intrusion are considered?
    - What methods and data are used to establish parameters to allow quantification of the intrusion scenario(s)?
    - To what degree are these specified in regulation or left to the implementer?
  - When is intrusion considered to be possible?
    - What factors are considered in this regard (i.e. institutional controls, package integrity, etc.)?

- Deliberate human intrusion:
  - Should not be addressed as scenarios in safety assessment, but possibly need for some discussion at general level.
  - Closely related to safeguards and retrievability for some wastes / repository concepts.

- Consideration of consequences:
  - What consequences are considered?
    - Are doses to the intruder considered?
    - Are doses to the public considered? From direct exposures of the intrusion, or from consequence of the intrusion process on containment capability?
    - Are there other aspects of performance considered?
  - What regulatory criteria are used to judge acceptability?
    - Any regulatory policy should be defended by philosophical and ethical arguments.

Summary

Human intrusion remains an issue of high interest in safety cases, especially in terms of implementation in safety assessment. The aspects noted above may benefit from international discussion. Some issues might deserve further attention in regulations and would benefit, in particular, from discussion among regulators (such as at the Regulators' Forum). Based on the IGSC observations and discussions, the following key questions can be raised to investigate whether there is still consensus on the areas of agreement and to understand how thinking has evolved:

- Should regulations require measures to reduce the likelihood or consequences of human intrusion? What "credit" can be taken for such measures? Is there new thinking or methods in terms of memory and markers?

- What types of stylised human intrusion should be considered in a safety case? What are the roles of the regulator and implementer in doing so?

- What consequences should be considered? What are the protection criteria against which to assess human intrusion scenarios?

- Are the answers to any of these questions site-, culture-, concept- or waste-specific?

Acknowledgements

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German Viewpoints on the Integration of Human Intrusion Scenarios in Safety Cases

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Introduction

There is a broad consensus that site selection, repository design, construction and closure should require measures aiming at a reduction of both the likelihood and consequences of human intrusion. Documentation of the repository position and its radiologic potential, the application of markers, the depth of the geological formation as well as keeping a distance to resources that could be of potential interest for future generations are typically regarded as appropriate measures. Because of the differing disposal concepts, site conditions and regulatory frameworks in several countries, safety requirements for dealing with human intrusion differ substantially across countries and internationally.

In Germany, two documents apply primarily concerning the treatment of human intrusion scenarios in a safety case:

- BMU Draft Guideline: "*Safety Requirements Governing the Final Disposal of Heat-Generating Radioactive Waste*" [1].
- Working Group on "Scenario Development":[1] "*Position of the Working Group on 'Scenario Development': Handling of human intrusion into a repository for radioactive waste in deep geological formations*," [2].

As to the first: The BMU presented this draft to the public in November 2008. It represents a proposed update of the regulatory "Safety Criteria" for the disposal of radioactive wastes in geological formations that were issued in 1983. At present, the draft is being revised by the German "Entsorgungskommmission" (Commission on Final Management), an advisory body of the BMU. In this draft regulation, the treatment of human intrusion is described in several chapters, particularly in connection with the fulfilment of safety goals within the framework of the safety case. The associated requirements are stated below.

As to the second: The Working Group on "Scenario Development" has elaborated a common position for the treatment of human intrusion which focuses on essential aspects of the topic and provides recommendations. This position paper deals with the question of how the possibility of human intrusion into a repository after its closure can be considered in a safety case.

The BMU Draft Guideline

Regarding human intrusion, the following three main requirements are addressed in the guideline.

Reduction of Likelihood of Human Intrusion

It is to be ensured that in the first 500 years after closure of the repository, information about its situation and existence should be maintained in a way that competent authorities are able to bring the

1. Members from BfS, BGR, GRS, DBE-TEC, FZK-INE and IELF TU Clausthal.

knowledge to attention. Thus all activities/measures are to be prevented for this period that could endanger the permanent isolation and containment of the radioactive wastes in the repository. Beyond that it is to be ensured that the knowledge about the presence of the repository remains permanently available, if possible.

It has to be demonstrated by the applicant to what extent possibilities of reducing the likelihood of unintentional human intrusion into the isolating rock zone has been taken into account during the site selection and the design, and development of the repository. These measures must not impair long-term safety.

- …"*The applicant shall also outline the extent to which the site designation and design of the final repository take advantage of all currently foreseeable opportunities for reducing the likelihood of unintentional human intrusion into the isolating rock zone of the final repository and the effects thereof, as well as confirming that this design does not impair the long-term safety of the repository system as long as it remains undisturbed by human intrusion*." [6.3]
- "*It has to be taken into account, that suspected use of the site as a raw material source or any form of use could increase the likelihood of human activity (drilling, driving, flooring of caverns).*" [Comments to 8.7]

Specification of reference scenarios

The draft guideline of the BMU requires that *reference scenarios*[2] for human intrusion and optimisation requirements to reduce the associated risk should be drawn.

- "*The radiological and other consequences of unintentional human intrusion should be analysed using reference scenarios based on current common human activities*." [8.7]

Radiation protection criteria

Specific protection criteria for human activities which unintentionally affect repository barriers are not prescribed in the draft guideline of the BMU, since neither the probability nor the type of impacts can be assessed with an adequate degree of reliability. In detail, the draft requires:

- "*High levels of radiation exposure >10 mSv/a that would effect a large number of people living in the vicinity [of the repository site] are to be avoided where possible*." [Comments to 8.7]
- "*No protection criterion is prescribed for people who come into direct contact e.g. by drilling into a waste container*." [Comments to 8.7]

Recommendation of the Working Group on Scenario Development

The Working Group defines human intrusion in the following way:

- "*Human intrusion (HI) is understood as any human activity after the closure of the repository mine that will directly damage the barriers within the backfilled and sealed mine workings and the isolating rock zone*."
- "*Human intrusion is considered as inadvertent if the awareness of the repository and the knowledge of the hazard potential of the waste emplaced have been lost. In the case of intentional intrusion, society is still aware of the repository and its hazard potential*."

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2. Reference scenarios = stylised scenarios.

- "*…it is exclusively inadvertent intrusion that the safety case has to deal with. Intentional intrusion can only be placed in the responsibility of the respective acting society*."

Regarding suitable and effective measures against unintended human intrusion, the Working Group comes to the following conclusions.

Effective Measures Against Unintentional Human Intrusion

The Working Group holds the view, that:

- "*…suitable and appropriate measures have to be taken upon the planning and construction of a licensed repository in the future that hinder or prevent inadvertent human intrusion and/or reduce the consequences. These measures must not impair the safety of the repository.*"
- "*…the most effective measures against inadvertent intrusion consist of establishing the repository in deep geological formations and providing knowledge maintenance in the long run. This limits the possibility of inadvertent human intrusion and the occurrence of the resulting consequences.*"
- "*…the knowledge of the repository site and the hazard potential originated by the repository can be maintained over a period of several hundreds of years and be brought to the attention of those acting in case of any activities at the repository site. Based on documentation from German mining archives that are still in use and preserved to this day, a time span of 500 years can be assumed in this respect.*"

Treatment of Human Intrusion in a Safety Case

The Working Group holds the view that the evolution, way of life, and behaviour of the society, including human intrusion, cannot be predicted over time frames that have to be considered for the isolation period of radioactive wastes. Therefore human intrusion into the repository system cannot be excluded. Based on this assumption, the Working Group proposes that

- "*…human intrusion has to be treated with due consideration in the safety case. It is exclusively inadvertent intrusion that the safety case has to deal with*."
- *"…inadvertent human intrusion should only be assumed to take place after at least 500 years*."
- "*A comprehensive study of human intrusion on the basis of a systematic scenario development would require a not feasible prediction of human actions as well as of the state of the art in science and technology of future generations. Therefore the issue of HI has to be treated apart from the systematic scenario development and thus has to be dealt with separately in the safety case*."

Specification of Scenarios

The Working Group holds the view that selected scenarios shall be used for the purpose of balancing measures aimed at reducing consequences. These HI scenarios have to be derived based on the specific repository plans and site conditions. The HI scenarios need not be encompassing or conservative. In particular, the Working Group recommends that

- "*The spectrum of HI scenarios should be appropriately limited, e.g. for the host rock "salt" to exploratory drilling, the construction of a mine, and solution mining of caverns.*"
- "*The boundary conditions for the derivation of such scenarios have to be determined on a regulatory basis e.g. in a guideline.*"

Radiological Consequences

The Working Group holds the view that

- "*With the decision for the concept of concentrating and isolating the radioactive waste in a repository, the possibility inevitably has to be accepted that radiation exposure limits may be exceeded in the event of intrusion into the repository.*"
- "*…it is not possible to quantify appropriately the consequences associated with human intrusion due to the lack of predictability of the boundary conditions and other parameters to be assumed.*"

Conclusions

Both documents coincide regarding the following recommendations:

- Only inadvertent human intrusion has to be treated in the safety case.
- The reduction of the likelihood of HI can be ensured by information maintenance, and intrinsically, by a strategy of deep disposal.
- There is no possibility for stipulating protection criteria since human behaviour in the distant future is absolutely speculative.
- A limited number of selected (stylised) scenarios based on current human activities and technical abilities have to be treated in the safety case. A Guideline with specifications of reference scenarios for human intrusion is regarded as helpful but is not yet available today.

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Means to Reduce Human Activities at the Site: Markers, Records…Where Do We Stand?

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Background

SKB has been assigned the task of managing and disposing the spent nuclear fuel (timescale – 100 000 years) and a draft action plan for long-term preservation of information about the repository will be presented in connection with the siting applications in 2010. The draft action plan should contain:

- Proposals on procedures for how the plan can be kept up to date.
- Suggestions for how the implementation of information preservation can be done.

The responsibility for implementing the action plan rests with the industry, SKB, until the closure of the disposal facilities. Thereafter, the responsibility for the repository, and its action plan for preservation of information, is expected to go to the State.

Aims of Information Preservation

The aims can be articulated depending on timeframes:

- In the longer term:
  - To avoid damage by accident.
  - To allow for our generation and future generations to make decisions based on knowledge (use of the site, withdrawal of spent fuel…).
- In the shorter term:
  - To manage today's knowledge and information so that the long-term goals can be reached.

What Information Is of Interest to Preserve?

Regarding facts and know-how, it would be important to preserve information:

- Vital to safety, environmental protection and licensing.
- Facilitating possible further development.
- Of great scientific or social interest.
- On location and site information.
- On design, structure and properties of the repository.
- On the properties and content of radioactive waste and other substance.
- On results from and data used in safety analysis.

Regarding the time horizons to be addressed, these are:

- Today and near future.
- At the time of decommissioning and closing of facilities.
- Far future.
- Very far future.

Attention to Potential Incidents

The action plan should address potential events or incidents that threaten the integrity and use of preserved information. A currently-identified set of events and corrective actions is reported in Table 1.

Table 1. **Potential Incidents and Corrective Measures Regarding Preservation of Information**

Incident	Consequence	Measure
War/sabotage (Political)	File or markers are destroyed or degraded.	Geographic redundancy of archives.
Society continuity breaks (Political)	Loss of authority facts.	Geographic redundancy of archives. Markers.
Information preservation poorly performed (Social)	Information is destroyed entirely or partly.	Long-term mandate with clear responsibilities.
Change of language and importance of markers (Social)	Misinterpretation can lead to wrong behaviour.	Regular update and revision of archives and markers.
Environmental changes (Environment)	File or markers damaged or lost.	Geographic redundancy of archives.
Degradation of the medium (Technical)	Misinterpretations.	Update medium. Several media, markers and archives.

Target Groups

The plan should address specific target groups of individuals or institutions, such as:

- Planners and developers of new facilities (e.g. Mines).
- Politicians, decision-makers.
- Waste management companies, energy companies.
- Scientists;
- Members of the public, nearby residents.

Strategies for Preservation

Two alternative tracks:

- From generation to generation.
- Directly to a distant future.

From Generation to Generation

- Media and projected lifetime.
- Paper, 200-1 000 years.
- Microfilm, 200-300 years.
- Video, cd, dvd, discs, approximately 10 years.
- Magnetic media, (data) approximately 10 years.

Examples of preserved archives:

- Vatican archives.
- Parish registers and population registers(Sweden).
- Runestones and petroglyphs.
- Cave paintings and pyramids.

About the Upcoming Draft Action Plan

A draft action plan for long-term preservation of information about the repository will be presented in connection with the applications 2010.

The draft action plan should contain:

- Proposals on procedures for how the plan can be kept up to date.
- Suggestions for how the implementation of information preservation can be done.

Included Parts to the Draft Action

What should be preserved? (Information with focus on the content of the canisters and location of the repository).

Where should it be preserved? (In established archives, in connection to the repository, as markers in the landscape, in the collective memory).

How should it be preserved? (Format, language and medium).

Key Actions to Handle in the Action Plan

- Clear responsibility for collection, updating and revision of information.
- The most serious consequences:
  - Information disappears physically (physical loss).
  - The information is available physically, but cannot be understood or interpreted (epistemic loss).
- Main measures
  - International co-operation.
  - Geographical redundancy of information (archives).
  - Markers.

Table 2. **An International Perspective**

Country	Organisation	Focus for information preservation
Finland	Posiva	Successive transfer (archives), following the international development (IAEA)
USA	DOE	Successive transfer (archives) and direct transfer (markers)
Great Britain	NDA	Successive transfer (archives – NNA in Scotland), Contextual Information Frameworks (CIF)
Switzerland	NAGRA	Successive transfer (archives)
Germany	BfS	Successive transfer (archives)
Japan	NUMO	Successive transfer (archives) and direct transfer (markers), medium (silicon carbide)
France	ANDRA	Successive transfer (archives) and direct transfer (markers)
	IAEA	Successive transfer (archives), Contextual Information Frameworks (CIF)
	NEA	Recent work in the area of cultural markers

International co-operation:

SKB is receptive to international co-operation, for example under the umbrella of IAEA or NEA

Examples of earlier co-operation:

- KAN-Nordic co-operation 1990-1993.
- Conferences and reports under the umbrella of IAEA.

Coming: International task group for co-operation?

Session 7

What Was Heard so Far: The View from Outside

Chair: Phil Metcalf, Unit Head (IAEA)

A View From Outside – Some Observations

Michael Sailer
Oeko-Institute, Germany

I want to thank the RWMC-RF for the invitation to present some observations, at the close of this workshop, from the viewpoint of an independent scientist.

The observations I will present are based on a twofold background:

- As a participant of this workshop.
- As chairman of the German "Entsorgungskommission (ESK)" (Waste management commission). ESK has the mandate to advise the German Regulator (BMU). ESK is actually involved in the discussion of the German safety guidelines for final disposal.

General Remarks

This RWMC-RF workshop was a very good and fruitful workshop with very open discussion, broad exchange of opinions, a lot of exchange of experience regarding rulemaking, application of rules, and interaction with stakeholders.

The feature of table discussions strongly supports the exchange, because more people can speak on their experience and because it enables a denser pattern of questions and answers. I suggest continuing with this format in future workshops.

Also, the questions for the table discussions were well prepared and contributed to a discussion in a focused and very productive manner.

International Guidelines

International guidelines have an important role for the national debate. They give strong support for implementing specific items or ideas in national regulations and national processes.

But taking into account the existing set of papers and guidelines from IAEA, NEA and ICRP causes in some sense problems. Comparing the papers one can identify differing views of things. No full coherency exists. Therefore my answer to the question "does a clear set of international guidelines exist?" is more "no" than "yes".

Of course, there is a history behind the interrelation of those papers and guidelines. The insiders are familiar with it. Some lectures and contributions within this workshop gave additional insights on the "production process" of specific papers. But the interaction between amendments and new guidelines and between different organisations (IAEA, NEA, ICRP) remains not very clear for "non-insiders".

Additionally, the knowledge of the history of those papers and guidelines does not help very much in the process of national adaption. That is because the authors of a national rule have to decide which ideas they have to implement in their national paper.

Interpretation of International Guidelines

Some doubts exist, whether basic definitions are clear enough. Examples are: "safety case" and its roles; "multiple lines of reasoning"; "optimisation". Therefore continuous discussion of their interpretation will be helpful.

Another problem is the transfer to other languages: An impressive lecture of this workshop dealt with the problems of the meaning of words within the same language – English.

But with the transfer to other languages the difficulties become bigger:

- Connotations may differ between languages.
- Connotations in the other language between its technical expert language, its law language and its general language additionally may differ.
- Differentiation between the meaning of words may be different (e.g. safety/security – German language has only one word "Sicherheit" for both terms; reversibility/retrievability – the German word "Rueckholbarkeit" has the connotation, that it must be possible within a very short time, days or months).

Transfer of International Guidelines

The transfer of international guidelines to national regulations has to respect the compatibility with national law (e.g. licensing procedures, rights of stakeholders, separation between nuclear law and other fields of law). The problem was mentioned by a lecturer in this workshop. It might lead to different "translations" into national regulations regarding different countries.

Another field is the compatibility with the national culture of decision making, which cannot be reflected in international guidelines. Examples are: different roles of numerical values in the decision making and in court cases; hard vs. soft in the decision-making processes.

Qualitative Factors

Regarding the qualitative factors in the guidelines I feel a need for more detailed discussion of some ideas.

Guidelines ask for different lines of argumentations ("multiple lines of reasoning"). I'm very much in favor of that because I have limited trust in model calculations. But the guidelines don't give clear ideas, how that issue shall be handled in a safety case (additive to the long-term safety calculations? with the same weight as quantitative results? with which types of argumentation?).

A clear need exists for a more detailed description of specific qualitative argumentation (e.g. what is sound engineering/sound geological judgement?; what are possible indicators for isolation?).

Without that, we just rely on numerical results and do not take into account the principal limitations of the modeling of scenarios.

"Stakeholders"

The term "stakeholder" has a very general meaning (and cannot be translated in a couple of languages, including German). The discussion on this workshop has shown that we have two classes of stakeholders:

- On one hand, the implementer (maybe including nuclear industry) and the regulator.
- On the other hand, all others – including the general public.

I fully agree that a distinction between those two groups is necessary.

But the guidelines and papers often do not distinguish between those two classes of stakeholders. They just speak of "stakeholders". The problem posed by this lack of distinction can be shown with the question: "What kind of process does ´stakeholder involvement´ in the ICRP papers really mean?"

A clearer view will be helpful for both, interaction in the licensing process and interaction in the general implementing process.

Processes and Roles

Regarding the description of processes within the papers and guidelines, it is not always clear whether a specific part is addressed to the implementer or to the regulator or to both of them.

In my view some clarification would be helpful, e.g.:

- For specific obligations: has the implementer to do that or the regulator (e.g. optimisation, decisions on BAT, stakeholder involvement)?
- What has to be checked by the regulator and in what degree of detail? What has to be confirmed by the regulator? (e.g. safety case).
- The balance between independence of regulator and co-operation with the implementer (e.g. stepwise approach – when and how do the implementer and the regulator interact?).

International papers and guidelines cannot go too much in details, but:

- It would be very helpful to have common pictures of processes behind the text of regulations.
- Pictures of processes and the respective roles played by implementer, regulator and other stakeholders are helpful to come to clearer advice in the text of guidelines.

This would help to clarify whether a specific discussion tackles the specific needs of regulators (or implementers) or just the general picture.

Feedback from Practical Experience

This workshop gave a broad range of feedback from practical experiences by both, the lectures and the table discussions. It seems to be very helpful to continue providing experiences regarding the implementation of rules and ideas from international guidelines and papers in the respective national context. Further feedback from practice is necessary (e.g. how to deal with the safety case; how to realise a stepwise approach; the implementation of optimisation/BAT).

Thank you.

On the Moral Standing of Future Persons and the Normative Basis of our Responsibility – Review of, and Reaction to, the Workshop's Previous Deliberations[1]

Carl Reinhold Bråkenhielm
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Introduction

Albeit I find it hard to conceive of myself as an "outsider" in the present context, I might temporarily accept the role and provide you with some philosophical and ethical perspectives on some of the considerations I heard during the workshop deliberations concerning our responsibilities towards future generations.

Ethical questions that were frequently voiced in different group reports are as follows: What is the normative basis of the responsibility we have towards future generations? And what is the scope of that responsibility when it comes to our management of nuclear waste?

These are questions on which I would like to elaborate in my review remarks about the workshop.

On the Moral Standing of Future Persons and the Normative Basis of our Responsibility

What is the normative basis of our responsibility towards future generations? The most straightforward answer to this question comes from a proponent of *utilitarian* ethics. We live under the obligation to enhance human well-being and – at least – to minimise human suffering. Such a form of *negative utilitarianism* was once formulated by Karl Popper. "It adds to clarity in the fields of ethics, if we formulate our demands negatively, i.e. if we demand the elimination of suffering rather than the promotion of happiness." (Karl R. Popper, *The Open Society and Its Enemies*, London 1945). More theoretically it could be formulated in the following way:

> An action is right if it – in comparison to all alternative possible actions – realises the least amount of evil or harm for all those affected by the action.

Negative utilitarianism is often combined with a *principle of egalitarianism*. When it comes to minimising suffering, all humans (or generations) should be treated equally – unless there are morally relevant reasons to treat them differently. All humans must cover all *future* humans as well. Kenneth Arrow makes the following dry remark: "…the fact that an individual will be alive at some future time instead of today, does not seem to be a morally relevant reason…" (See Arrow (1995), "Inter-generational Equity and the Rate of Discount in Long-term Social Investment", paper given at the IEA World Congress available at *www.econ.stanford.adu/faculty/workp/swp97005.htm*)

1. This paper is a further elaboration of the actual report provided at the workshop. The original workshop report focused on the moral standing of future human beings and less on the normative basis of our responsibilities. The "factual summary" of the workshop provided in these proceedings summarises only the original report.

So negative utilitarianism + egalitarianism gives us a fundamental justification for minimising human suffering now and in the future, and – among other things – to protect them from the threat of being exposed from the radiation of human waste. All human persons, and all human generations should be treated alike. If they live far away geographically or in time is not relevant. As long as they are affected by our actions today, we are morally responsible.

During this conference I have heard **three different arguments** against this kind of utilitarian justification for our responsibility for future persons.

The *first* argument against giving a moral standing to future persons has to do with one of the reports given during Session 3. Here it was argued that future generations may not be given equal weight in regulatory process "because they cannot sue us". *On the contrary they have to be given more weight!* They are unable to speak for and protect themselves; therefore we are obliged to give them a stronger moral standing than living persons who can stand up for themselves. This can be taken as *an argument for inequity in favour for persons in the distant future*.

Is this a sound argument? I´m not convinced about this. Persons in the distant future – or for that matter in the present – who cannot speak for themselves may require a stronger protection because they are more vulnerable. But from this we are not justified to question the basic principle of *the equity* of all human persons now and in the future.

Often enough quite a different conclusion is drawn. We can affect persons in the future, even in the very far future, but they cannot do anything for us. For example, they cannot punish us for our passivity. Nor can they reward us for our efforts to act in their interest. There is no symmetrical relationship of obligations. From this it is sometimes concluded that future generations should have a *weaker* – and not a *stronger* – position. Some, in the workshop did suggest that in regulatory decision-making *less* weight may be given to potential exposures to persons in the distant future than to actual exposures to persons in the present or near future. This, however, can be taken as *an argument for inequity in favour of persons in the present generation*.

But that is not a very strong argument either. Small children and elderly persons without the ability to take care of themselves cannot do anything for us. But we still have obligations for their wellbeing. ***Moral obligations do not require symmetrical relationships.***

A *second* argument has been voiced several times during this workshop. It goes like this; we only have an obligation for the actions for which we can foresee the consequences. With some stretch of imagination we have an obligation for generations a couple of hundred years in the future. But after that our ability to forsee the consequences of our action gradually diminish to zero. Our actions do matter, but we cannot explain how. And therefore, we cannot be blamed for the harm which our actions may cause future generations far off into the future. Maybe this is the reason behind ICRPs warning that doses or risks in the long term should not be interpreted as a direct measure of health detriment.

I am not convinced by this line of reasoning. First of all, as a general rule, one should be sceptical about persons or generations who claim that they really have no power and that they therefore cannot be blamed or be considered responsible. When it comes to nuclear waste management we do have the influence to health of future generation. It is more plausible that generations far off in the future – presuming that such persons are still around – are negatively affected by ill-designed canister, then by well-designed canisters. And if we bury them in zones where groundwater travels faster to the surface than in other zones, we equally put persons far in the future at a greater risk than if we bury them in a geological formation with more favourable hydrological conditions. Our Japanese colleagues reminded us of the distinction between *predictability* or *probability* on the one hand and *plausibility* on the other. Even if we cannot numerically and statistically calculate the risk beyond say a hundred years into the future, we can develop more informal arguments of plausibility. Such argument should – according to my opinion – be required by the regulators from the implementers.

Thirdly, a more devastating argument was levelled against the utilitarian position during the last session, session four, from Table 6. I heard the following argument: utilitarianism + egalitarianism puts intolerable burdens upon a given generation for the sake of futurity. *We would be obliged to sacrifice almost everything we have, and save it for future generations.* And our children, our grandchildren and so on, would similarly be obligated to save almost everything for the future. Let me once more quote Kenneth Arrow. He concludes that "the strong ethical requirement that all generations be treated alike, itself reasonable, contradicts a very strong intuition that is not morally acceptable to demand excessively high saving rates of any one generation, or even of every generation" (Arrow 1995, p. 16). Arrow arrives at an ethical position he calls *discounted utilitarianism*: each generation will maximise a weighted sum of its own utility and the sum of all future generations, with less weight on the latter. Really distant generations are treated all alike. In fact, discounted utilitarianism encompasses a non-utilitarian (deontological) element, namely a principle of self-regard: *living individuals and present generations are an end in itself and not merely a means to the welfare of other.* This could also be described as a principle of humanism. It goes against the principle of self-sacrifice. You should love your neighbour – even your future neighbour far off in the future, but not at the expense of loving yourself and your fellow human beings in the present living generation.

This argument in favour of the present generation is based on a *principle for the preference of the present generation* (PPP). One problem with this principle is that it might lead to a disregard of future generations. Excessive burdens might be put on future generations in name of PPP. This is as counterintuitive as is negative utlititarianism that obliges the present generations to save almost everything for the future. We need some restrictions on PPP to avoid such a partiality in favour of the present.

What Is an Excessive Burden on Future Generations?

Let me suggest some answers to this question.

Answer 1: A burden is excessive if it prevents future generations from having the same quantities and types of natural resources as the present generation.

Such an answer is based on static principle of justice. In the State of the Art Report 2004 of the Swedish National Council for Nuclear Waste (KASAM) this was called *a static principle of justice* (*www.karnavfallsradet.se/Uploads/Files/215.pdf*, p. 428). The following example served to illustrate why the static principle of justice should not be accepted. When we exploit a watercourse, we might develop a pumping system in order to use the water more efficiently. However, the watercourse is still there for others to use. Let us instead assume that we exploit the water-course by draining it in order to use the land for cultivation. Are we not jeopardising the possibility of future generations to use the watercourse to satisfy their needs? Of course we are. They can no longer use the watercourse because it no longer exists. However, the Brundtland Commission did not consider that we would be contravening our intergenerational obligations by acting in such a way:

> Every ecosystem everywhere cannot be preserved intact. A forest may be depleted in one part of a watershed and extended elsewhere, which is not a bad thing if the exploitation has been planned and the effects on soil erosion rates, water regimes, and genetic losses have been taken into account. In general, renewable resources like forests and fish stocks need not be depleted provided the rate of use is within the limits of regeneration and natural growth. (*Our Common Future*, 1987, p. 45).

Not only is the current generation considered to be entitled to consume natural products. They also have the right to change existing natural areas without neglecting their moral responsibility to future generations. Therefore, we do not need to live with a minimum impact on nature. Furthermore, we are entitled to consume non-renewable resources such as fossil fuels and minerals, even if we reduce the access of future generations to these products by doing so. However, the condition that must be met is that "the rate of depletion that the emphasis on recycling and economy of use should be calibrated to ensure that the [renewable resources do] not run out before acceptable substitutes are available … [So] few future options [should be foreclosed] as possible" (p. 46). Thus, intergenerational justice does not mean that the same type or quantity of natural resources should be distributed equitably among generations. In other words: we do not put an excessive burden on future generations if we prevent them from having from having the same quantities and types of natural resources as the present generation.

Answer 2: A burden is excessive if it jeopardises future generations' possibilities to life.

This answer could be based on *a minimal principle of justice* (see KASAM State-of-the-Art Report 2004, p. 429) – and it has clear consequences clear consequences for the nuclear waste issue. It would imply that we are obliged to use nuclear power today in a manner that does not harm future generations – even if these generations are very distant. We cannot escape from our obligations just because they have to do with very long-term consequences of our actions. We can make a comparison with objects that are located at a great distance from each other in space. Let us assume that people on the other side of the globe are affected by environmental toxins that, via air or water, could spread to New Zealand or Tierra del Fuego in a short period of time. The spatial distance is not a morally relevant circumstance and cannot excuse indifference for the consequences of our actions. In the same way, we cannot make an exception to the principle of an exception to the principle of non-maleficence just because the people concerned are at a large temporal distance from our own generation.

Answer 3: A burden is excessive if we use or consume natural resources in such a way that subsequent generations are prevented from achieving a quality of life equivalent to ours.

This answer is based on a very demanding principle which in KASAM State-of-the-Art Report 2004 is called *the strong principle of justice.* 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.

This is a demanding principle which would probably entail far-reaching changes in the present generation's consumption patterns and exploitation of nature. It should be distinguished from another principle involved in the following answer to the question about what constitutes an excessive burden to future generations:

Answer 4: A burden is excessive if we use or consume natural resources in such a way that subsequent generations are prevented from satisfying their basic needs.

This answer is dependent upon a *a weak principle of justice* which KASAM State-of-the-Art Report 2004 formulates as follows:

> *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 (i.e. needs for food and water, protection against weather and wind, and access to work, health care and education).*

Answer 3 puts future generations in a much stronger position than Answer 4, since Answer 3 not only assumes that future generations will have the same basic needs to be satisfied but will also be given the necessary conditions to achieve the same quality of life.

Conclusions

Let me conclude with a more general remark. Answer 1 is clearly not a valid answer to the question what constitutes an excessive burden for future generations. On the contrary, Answer 2 seems clearly valid; it is indeed an excessive burden if – for example – nuclear waste is stored in such way that it jeopardises future generations´ possibilities to life. At the same time, Answer 2 while necessary in defining what constitutes an excessive burden to the future seems insufficient. It needs to be complemented with something more like Answer 3 or Answer 4. We could say that we are *at least* obliged not to prevent future generations from satisfying their basic needs (Answer 3). One such basic need could be freedom of action. According to Answer 3 and the weak principle of justice, we are obliged to respect and protect future generations' rights to satisfy their basic needs. The need for freedom of action to decide for oneself whether one wants to use or not use the deposited spent nuclear fuel for some purpose is undeniably a basic need. Can we uphold the weak principle of justice and future generations' possibility to retrieve the nuclear waste from the repository at the same time that we also meet the requirements of the minimal principle of justice, namely that we protect distant generations and do what we can to ensure that their lives and health are not jeopardised by the hazardous waste?

Perhaps there is no clear answer to this question. In that case, one possible approach is the following: If we cannot meet the requirement for future generations' freedom of action at the same time that we also minimise the risk of human beings in the distant future being subjected to life-threatening harm from our spent nuclear fuel, the minimal principle of justice – namely our duty to not jeopardise future generations' possibilities for life (answer 2) – should be given preference. In other words: The principle of not running the risk of subjecting future generations to harm carries more weight than our obligation to take into account the possibility that a not too distant generation would wish to gain access to the deposited nuclear waste and use it for some purpose. In this sense, we can also question the first stage of the "KASAM principle", namely that the repository should be constructed so that the retrieval of the deposited waste is possible. If this means that we, in some respect have to lower long-term safety, it is our obligation to put "safety first".

Session 8

Stocktaking and Closure of the Meeting

In this session, the various each session rapporteur provided a short presentation of the main observations from his/her session, followed by a final presentation by the Chairman of the RWMC Regulators' Forum.

Closing Remarks

Uichiro Yoshimura
OECD Nuclear Energy Agency, France

Ladies and Gentlemen,

On behalf of the Nuclear Energy Agency of the OECD I would like to thank you all for your active participation in this workshop. Your input has been essential to its success.

Over the last two and a half days, we have had stimulating discussions on topics of current interest for policy makers, regulators and implementers of geological disposal. We have discussed a wide range of topics, including the needs for regulatory research in the present and how that will support the delivery of regulatory decisions that are both transparent and practical, the role of optimisation in safety cases and design, the responsibilities of succeeding generations that will complete the implementation of repository projects begun today, and regulatory criteria to be applied to safety cases for very long timescales, including the question of how to deal with human intrusion into a repository in the distant future.

There have been many thoughtful and fruitful ideas presented for the Regulators Forum to think about. The results of this workshop will be discussed at the next Regulators Forum meeting this March and will contribute importantly to the future work of the Forum in debating safety regulation for geological disposal.

This has been a successful first workshop for the Regulators Forum. It has demonstrated the usefulness of this format for stimulating discussions, for involving a wide range of viewpoints, and for including the voices not only of regulators but of many other interested parties. This first workshop will serve as a model for future workshops to be organised by the Regulators Forum.

I was especially glad to hear the many messages of appreciation of the quality and usefulness that the NEA RWMC and its regulators Forum are providing and will report back on this to my Agency in Paris.

Dear colleagues, I thank you for your active participation in this workshop, which has helped make it a success. It has demonstrated the commitment of your organisations and your countries to continuing dialogue on the management and disposal of long-lived radioactive waste. The future work of the RWMC and its Regulators Forum will benefit from your input during the last few days.

Finally, on behalf of the NEA I would like to thank once again our hosts, the Government of Japan through its Nuclear and Industrial Safety Agency (NISA), in co-operation with Japan Nuclear Energy Safety Organization (JNES), for arranging for us the excellent facilities that have helped make this event a success.

I wish you all a pleasant visit in Japan if you are taking the opportunity to visit, and a safe journey on your return home.

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Towards Transparent, Proportionate and Deliverable Regulation for Geological Disposal

As part of its activities, the Regulators' Forum of the NEA Radioactive Waste Management Committee has been examining the regulatory criteria for the long-term performance of geological disposal. In this context, it organised a workshop entitled "Towards Transparent, Proportionate and Deliverable Regulation for Geological Disposal", which served to verify current status and needs. Participants included regulators, implementers, policy makers, R&D specialists and academics. Themes addressed included duties to future generations, timescales for regulation, stepwise decision making, roles of optimisation and best available techniques (BAT), multiple lines of reasoning, safety and performance indicators, recognition of uncertainties and the importance of stakeholder interactions. The workshop highlighted the significant amount of work accomplished over the past decade, but also identified important differences between national regulations even if these are not in contradiction with international guidance. Also highlighted was the importance of R&D carried out on behalf of the regulator. In addition to the contributed papers, these proceedings trace the numerous discussions that formed an integral part of the workshop. They constitute an important and unique documentary basis for researchers and radioactive waste management specialists.

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